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Competitive Market Analysis For Laboratory Management Decision Makers

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Jondavid Klipp, Editor, labreporter@aol.com

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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

UNITED BEGINS LBM PROGRAM IN FLORIDA, BUT DELAYS CLAIMS ENFORCEMENT

UnitedHealthcare has started a lab benefit management program in Florida that requires physicians to use Beacon Laboratory Benefits Solutions Inc. to provide advance notification when ordering more than 80 frequently-performed tests, including most pathology services. Beacon is a wholly-owned subsidiary of Labcorp. The program, which went into effect October 1, also requires pathologists and labs to meet extensive second opinion and subspecialty certification requirements. However, UnitedHealthcare has delayed the enforcement of penalties that would impact claims payments until January 1, 2015.

Jonathan Myles, MD, Chair of CAP's Economics Affairs Committee, says the program is overreaching and takes medical decision making out of the hands of board-certified pathologists. "It's unclear what the problem is that United is trying to solve."

But Michael Snyder, President of Clinical Lab Business Solutions LLC (Flemington, NJ), believes the program is a first step toward full-blown lab benefit management that will eventually require preauthorization for most lab and pathology tests and the use of a small network of labs dominated by LabCorp.
Continued on page 6.

GROWING SKEPTICISM ON DIGITAL PATHOLOGY

"There is tremendous 'cool' factor, but 'cool' doesn't pay the bills." That's how one pathology lab executive sums up the current state of digital pathology in the United States. "Big hat, no cattle," is how a pathologist describes the hype that has surrounded digital pathology the past few years. These are some of the comments that *Laboratory Economics* received from respondents to its latest *Digital Pathology Trends Survey* conducted in mid-October. Survey results suggest that today's challenging reimbursement environment is forcing pathology labs to tighten their belts and cut out capital investments that don't demonstrably lower costs or add revenue. *Complete survey results, pages 3-4.*

FLOW CYTOMETRY IN CMS CROSSHAIRS

Independent pathology labs that provide flow cytometry services are bracing themselves. That's because CMS has identified flow cytometry code 88185 (technical component for each additional marker after the first) as "potentially misvalued" and its payment rate could be drastically cut when the Final Rule for the 2015 Physician Fee Schedule is released in early November.
Continued on page 2.

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FLOW CYTOMETRY IN CMS CROSSHAIRS (*cont'd from page 1*)

Flow cytometry testing is ordered on nearly all patients suspected of having blood cancers (leukemia, lymphoma and myeloma) to help pinpoint the exact type of cancer and determine the most appropriate treatment. All but the largest hospitals send the TC component of flow cytometry to independent pathology labs to be performed off-premises.

A potential cut to Medicare's PFS rate for CPT 88185 would follow the humongous reduction that has already occurred for hospital outpatients.

Effective January 1, 2014, CMS stopped providing separate payment for most add-on code services provided to hospital outpatients, including CPT 88185. Reimbursement for CPT 88185 is now bundled into the outpatient payment rate for CPT 88184 (TC for first flow cytometry marker). And the new bundled payment rate is woefully inadequate.

The standard flow cytometry work-up involves analyzing an average of 22 different markers, according to Part B claims data for 2009-2013. Prior to 2014, Medicare billing for flow cytometry TC services provided to hospital outpatients would include billing CPT 88184 for the first marker at the outpatient rate of $23.43. The next 21 markers would each be billed using CPT 88185 at the outpatient rate of $12.71 for a grand total of $290.34 for technical services per flow cytometry case.

This year, under the bundled payment, the same flow cytometry case is reimbursed by Medicare at an outpatient rate of only $36.53. That's a reduction of 87%—and that's not a typo.

Under the Proposed Hospital Outpatient Rule for 2015, the bundled payment rate for flow cytometry technical services is scheduled to increase to $181.66 per case, but that's still 37% below the $290.34 total in 2013 before bundling.

As mentioned previously, the reimbursement changes are hitting independent pathology labs that provide flow cytometry technical services to hospitals the hardest.

Medicare Rates for Average Hospital Outpatient Flow Cytometry Case (TC only)

	Actual	*Actual*	*Proposed*
CPT/APC	2013	2014	2015
88184/433	$23.43	$36.53	$181.66
88185	(21x) $12.71	Bundled	Bundled
Total	$290.34	$36.53	$181.66

Source: *Laboratory Economics* from CMS

The Top 10 Independent Flow Cytometry Labs by Billed Services to Part B Medicare

Laboratory Name	*88184*	*88185*	*Total*
Genoptix	12,620	286,135	298,755
Bio-Reference Labs	11,488	252,248	263,736
Clarient	6,825	146,881	153,706
LabCorp	4,799	114,233	119,032
Miraca	2,913	77,036	79,949
LabCorp	3,422	69,625	73,047
LabCorp	2,904	65,047	67,951
Cytometry Specialists	2,735	62,059	64,794
NeoGenomics	2,517	55,009	57,526
LabCorp	1,618	40,273	41,891

Source: CMS 2012 Medicare Part B Fee-For Service Provider Utilization & Payment Data

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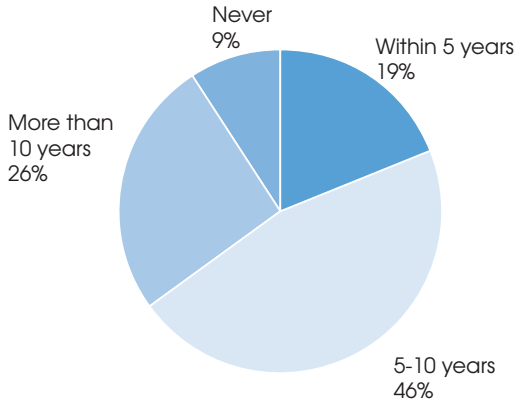
GROWING SKEPTICISM ON DIGITAL PATHOLOGY (*cont'd from page 1*)

About 10 years ago, the conventional wisdom was that digital pathology would play a big role in pathology in the near future. Major IVD companies made big bets on the technology. GE Healthcare invested tens of millions to create a new digital pathology company named Omnyx LLC in 2008; Roche's Ventana Medical Systems acquired BioImagene for $100 million in September 2010; and Leica Biosystems bought Aperio Technologies for nearly $200 million in July 2012. But despite the investments from these huge corporations, the digital pathology market is crawling instead of sprinting.

Our latest survey shows that lab executives and pathologists expect widespread adoption of digital pathology to occur slowly. Forty-six percent of survey respondents said it will take between 5-10 years before digital pathology becomes common practice for the primary diagnosis of cancer. And 9% believe it will never replace the traditional microscope.

How long before the majority of pathologists adopt digital pathology for primary diagnosis?



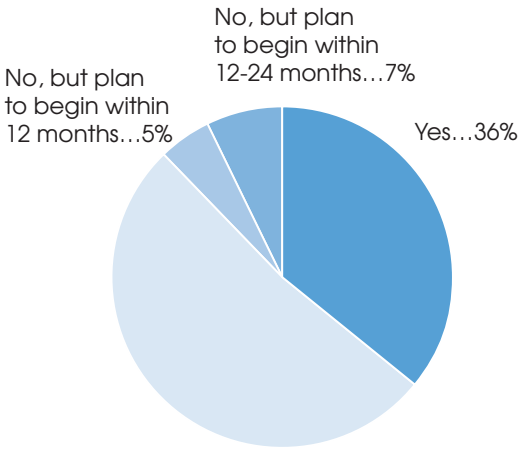
Source: *LE's Digital Pathology Trends Survey*, October 2014; n=206

"I have been hearing about the future of digital pathology for 20 years. Except in isolated situations, I do not see it in widespread use. Even brand new labs are not using digital pathology solutions," according to a survey respondent from New York.

Thirty-six percent of survey takers said their organization currently uses digital pathology, while 52% said they do not. Another 5% percent said they plan to begin using digital pathology within the next 12 months and 7% said within the next 12-24 months.

The perceived obstacles to adoption of digital pathology have increased since LE's last survey in July 2012. In our latest survey, 61% of pathologists and labs without digital pathology said "traditional pathology/microscope works fine," up from the 39% that cited this barrier in our July 2012 survey. Forty-six percent cited "too expensive," up from 40%. Twenty-eight percent said current digital pathology systems were "too slow" versus 19% from the previous survey. And the percentage of labs citing "reimbursement issues" doubled to 22%.

Does your lab use digital pathology to analyze patient slides?



Source: *LE's Digital Pathology Trends Survey*, October 2014; n=206

"I don't see the need for digital pathology with the widespread availability of inexpensive overnight package delivery. As far as second opinions go, the majority of those cases have multiple blocks and slides with special stains, all adding to the cost and difficulty of digital scanning," commented a pathologist from Kentucky.

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"It's still a niche market. It adds a step to the process of rendering a diagnosis, since a glass slide still needs to be prepared. Radiology digital images are different, since radiology was able to eliminate the films and directly capture digital images," noted a pathologist from Massachusetts.

Among surveyed pathologists and labs using digital pathology, 58% are using it for education and/or training. Fifty percent use it for quantitative immunohistochemistry for HER2 scoring, while 46% use it for second opinions and/or consultations. Other uses include ER/PR scoring (44%), archiving specimens (29%), primary clinical diagnosis (17%), contract research for clinical trials (15%) and photography for reports (13%).

If you do not use digital pathology: Why not?*

	2014	2012
Traditional pathology/microscope works fine	61%	39%
Too expensive	46%	40%
Too slow	28%	19%
Reimbursement issues	22%	11%
Integration concerns with LIS	17%	14%
Large data/image storage concerns	15%	26%
Limited clinical test menu	12%	5%
No time/patience to learn	4%	5%

*Survey respondents were able to select multiple answers

Source: *LE's Digital Pathology Trends Surveys*, October 2014 and July 2012

"One day it will become cheap enough and fast enough to be a routine automated step after cover-slipping. A minor increase in cost can be offset by reductions related to slide sorting, distribution, filing and couriers," commented a pathologist from South Carolina.

"As the technology matures I would have to believe that this will be the dominant method for screening. The benefits of having the information digitized and included in the medical record is powerful," concluded a survey respondent from Minnesota.

What do you use digital pathology for?*

Education and/or training	58%
HER2 scoring	50%
Second opinions and/or consultations	46%
ER/PR scoring	44%
Archiving specimens	29%
Primary clinical diagnosis	17%
Contract research for clinical trials	15%
Photomicrograph inside reports	13%

*Survey respondents were able to select multiple answers

Source: *LE's Digital Pathology Trends Survey*, October 2014; n=206

"Digital pathology is the future of slide diagnosis away from the central lab. Transporting specimens becomes a one-way instead of two-way trip, greatly reducing turnaround time. The FDA must get off the dime so pathologists and labs can serve patients with this technology," according to a pathology lab executive from Indiana.

Survey Demographics: The survey was e-mailed to approximately 5,000 pathology groups, independent labs and hospitals in early October 2014. A total of 206 responded for a response rate of 4.1%. Among the respondents, 85 were from hospital-based pathology groups, 67 from independent pathology groups and labs, 35 from academic medical centers, 10 from national pathology companies and 9 from in-office pathology labs

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PART B SPENDING ON DIGITAL IHC FALLS AGAIN

Medicare Part B carrier spending on CPT 88361 (digital pathology for quantitative IHC) fell by 20% to $11.7 million in 2013. This follows the 25% shrinkage of the digital pathology market in 2012. CPT 88361 is used to bill Medicare for the reading of digital HER2, ER and PR slides from a computer monitor.

The decline in 2013 was driven by two factors: 1) the number of submitted Part B claims for CPT 88361 fell by 9% to 173,724 claims; and 2) the percentage of denied claims for CPT 88361 increased to 18% (31,189 denied claims) in 2013 versus 12.5% (23,890 denied claims) in 2012.

Proponents of digital pathology point out that digital IHC represents only a portion of the market. They say the market is being driven more by non-reimbursed services, such as education and training, second opinions and archiving specimens.

Nonetheless, the digital pathology market is evolving much more slowly than experts had predicted a few years ago. Barriers to greater adoption include: cost, speed and limited FDA clearance.

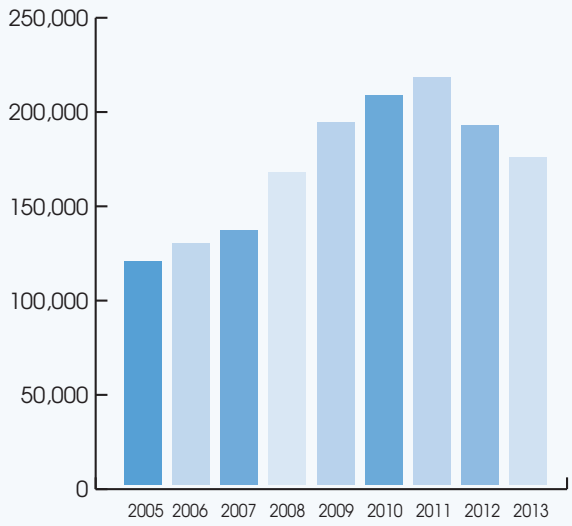
Under the proposed Physician Fee Schedule Rule for 2015, the Medicare Part B global payment for CPT 88361 will increase by 4.7% to $165.39, including an 7.9% increase in the technical component rate to $106.32 and a 0.7% decrease for the professional component rate to $59.07.

Strong Growth in Manual Quantitative IHC

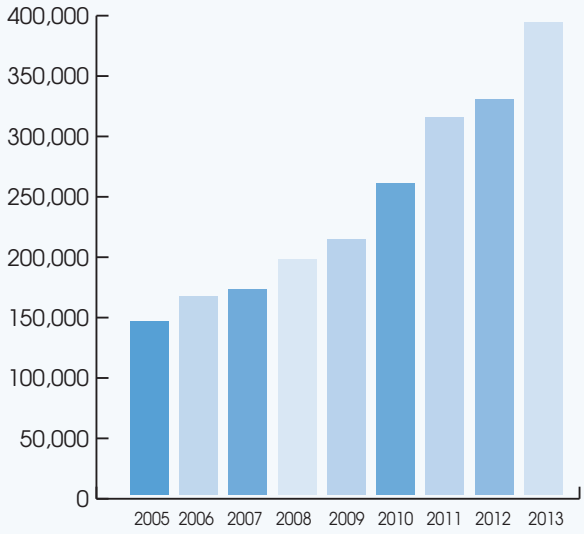
The digital pathology market is languishing; however, its manual counterpart (CPT 88360: quantitative IHC done manually) is showing strong growth. Part B carrier spending on CPT 88360 grew by 8% to reach $23.3 million in 2013. The volume of submitted claims for CPT 88360 increased by 19.5% to reach 391,375 claims in 2013.

Under the proposed Physician Fee Schedule Rule for 2015, the Medicare Part B global payment for CPT 88360 will increase by 2.7% to $133.53, including a 4.7% increase in the technical component rate to $78.75 and a 0.1% decrease for the professional component rate to $54.77.

Medicare Part B Submitted Claims for CPT 88361



Medicare Part B Submitted Claims for CPT 88360



Source: *Laboratory Economics* from CMS

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UNITED BEGINS LBM PROGRAM IN FLORIDA (*cont'd from page 1*)

UnitedHealthcare says BeaconLBS is a pilot program that applies only to its fully-insured commercial membership in Florida (excluding Neighborhood Health Plan), representing approximately 500,000 members. In a September 15 letter to Florida physicians, United said the program is designed to "improve the cost and quality of laboratory services" and "make sure that you get the right laboratory test, at the right time and at the right network laboratory." UnitedHealthcare has stated that lab testing represents only 2-3% of its healthcare spending, but is among its fastest growing expenses.

Prior Notification

The program requires physicians to notify United through BeaconLBS in advance of certain lab tests. It covers most high-priced and/or fast-growing tests, including allergy panels, cystic fibrosis screening, HCV and HIV genotyping, lipoprotein analysis, thyroid panels, Vitamin D testing, et al. Advanced notification is also required for the majority of biopsy tests, Pap tests, immunohistochemistry and special stains. United stresses that its advanced notification process does not involve a clinical coverage review that authorizes test orders. Prenotification allows United through BeaconLBS to verify member benefits and share evidence-based clinical guidelines with ordering physicians, according to United. The only test that requires prior authorization with the potential for a denied order is BRCA testing, and United has had this policy in effect nationwide since 2009. But the catch is that lab tests that have not had prenotification are subject to denial starting January 1, 2015.

Required Second Opinions for Maliginant Cases

Another component of United's pilot program is a requirement that essentially all malignant and pre-malignant diagnoses must have a second review in order for the claim to be paid, and in many instances it requires a sub-specialist to perform the second review. It's this requirement that has CAP and the Florida Society of Pathologists up in arms. "Board certified pathologists have the professional judgment to decide when a case needs a second opinion," notes CAP's Dr. Myles. He believes this policy is unnecessary, infringes on pathologist medical decision making and has the potential to delay patient care by increasing turnaround time. Dr. Myles says that CAP has voiced its concern during numerous conference calls with United and BeaconLBS over the past few months. "We're optimistic that our concerns will be addressed."

Laboratory of Choice

A third major component is the lab network that will serve the pilot program. United says that tests can be ordered from all of its existing network laboratories. However, BeaconLBS has also created a separate small network of labs to serve the program which have been given the designation: Laboratory of Choice. Included among these are all of LabCorp's labs and subsidiaries (Dianon, Integrated Genetics, Integrated Oncology and MedTox) as well as eight other lab companies and pathology groups, including Broward Health, Clarient, Dominion Diagnostics, Granite Diagnostics Labs, Gulf Coast Dermatopathology, Ketchum, Wood & Burgert Pathology, Millenium Laboratories and the Meditrend Group. Right now, there does not appear to be any incentive for physicians to direct their lab test orders to a Laboratory of Choice as opposed to a regular United network lab.

The First Step To Full-Blown Laboratory Management?

Clinical Lab Business Solutions' Michael Snyder says the United pilot is a lab benefit management on "training wheels." But there's no question in his mind that United intends to use this as a prototype to control lab expense as the healthcare market moves toward various capitated payment models of care. In addition, he thinks LabCorp will try to expand its BeaconLBS to other geographic markets and healthplans as well.

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LABCORP TO BUY LIPOSCIENCE FOR 1.5X REVENUE

LabCorp has agreed to buy LipoScience (Raleigh, NC) for $5.25 per share, indicating a total value of $85 million and an enterprise value of $63 million (after adjusting for an estimated $22 million of net cash that LipoScience will hold when the deal closes later this year). The deal values LipoScience at 1.5 times its annualized revenue of $42 million (i.e., $63M/$42M=1.5).

The $5.25 per share price represents a 65% premium to LipoScience's closing price of $3.19 prior to announcement of the transaction. However, it's 42% below LipoScience's IPO price of $9 per share in January 2013.

LipoScience markets a specialized cholesterol test under the brand name NMR LipoProfile test. The FDA-cleared test measures low-density lipoprotein (LDL), or bad cholesterol, a key risk factor in heart disease. LipoScience performs its NMR LipoProfile exclusively at its CLIA-certified lab in Raleigh, North Carolina. The test is reimbursed by Medicare (CPT 83704) at a national rate of $43.04.

LipoScience markets NMR LipoProfile through agreements with national and regional labs. Its biggest customer is LabCorp, which represented 30% of LipoScience's revenue in 2013.

Health Diagnostic Laboratory (Richmond, VA) had been LipoScience's biggest customer, accounting for 33% of revenue in 2013. However, in mid-March 2014, HDL began marketing its own non-FDA-cleared LDL Particle test in lieu of offering LipoScience's test. As a result, LipoScience's revenue declined by 22% to $21.1 million in the six months ended June 30, 2014.

In January 2014, LipoScience cut its workforce by approximately 24 positions and then laid off another 22 employees in May 2014. The company currently has a total of approximately 200 employees.

LabCorp expects its acquisition of LipoScience to add to its earnings in the first year, and to earn its cost of capital by year three.

LipoScience at a Glance ($ 000)

	First-half 2014	First-Half 2013	% Chg
Revenue	$21,053	$26,927	-21.8
Net loss	-5,238	-4,327	NA
Cash	42,789	54,246	-21.1
Total debt	15,848	15,760	-0.6
NMR LipoProfile tests	831,000	1,047,000	-20.7
Avg. revenue per test	24.37	24.72	-1.4

Source: LipoScience

HEALTH DIAGNOSTIC LABORATORY CEO RESIGNS

Health Diagnostic Laboratory's President and CEO Tonya Mallory has resigned from both positions amid a federal investigation into payments her company made to referring doctors (see *LE*, September 2014, p. 1). Dr. Joe McConnell, a co-founder of the company and its Chief Laboratory Officer, will succeed her. Mallory will remain on the HDL Board of Directors. An HDL spokesperson said Mallory's resignation was due to "personal family reasons" and only coincidentally came two weeks after a scathing WSJ article about the company's business practices was published.

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MEDICARE EXPENDITURES ON PATHOLOGY FELL 15% IN 2013

National Medicare Part B carrier payments for 12 high-volume pathology codes fell by 14.9% to $1.942 billion in 2013, according to data collected from CMS and the lab reimbursement consulting firm CodeMap LLC (Barrington, IL). During the five-year period (2008-2013), Part B carrier spending on these 12 key pathology codes increased by an average of just 0.3% per year.

Part B carrier spending on CPT 88305—the most frequently billed anatomic pathology procedure—decreased by 27% to $971.1 million in 2013, as a result of the 52% rate reduction for the technical component effective January 1, 2013.

Part B spending growth was strongest for FISH testing for bladder cancer. CPT 88121 increased 28.5% to $32.4 million, while CPT 88120 increased 23.4% to $53.1 million. Spending growth on these two codes was spurred by Medicare rate increases of 30+% effective January 1, 2013.

Part B spending growth was also strong for special stains. CPT 88313 increased by 8% to $63.8 million, while CPT 88312 was up 7.1% to $93.2 million. Spending growth for both codes was fueled equally by higher reimbursement (up 3-4%) and higher claims volume (also up 3-4%).

During the past five years (2008-2013), Part B spending has risen the fastest for CPT 88342 (immunohistochemistry), which increased by an average of 9.6% per year to reach $285 million in 2013. CMS eliminated CPT 88342 effective January 1, 2014, and replaced it with two new codes (G0461 & G0462) with significantly lower reimbursement rates.

Medicare Part B Carrier Spending on 12 Key Pathology Codes ($ millions)

Code (Description)	*2013*	*2012*	*1-Year*	*5-Year*
88305 (Level IV, tissue exam by pathologist)	$971.1	$1,331.4	-27.1%	-3.9%
88342 (Immunohistochemistry)	285.0	268.7	6.0%	9.6%
88185 (Flow cytometry, add on)	99.9	115.9	-13.8%	1.2%
88312 (Special stains)	93.2	87.1	7.1%	5.3%
88112 (cytopathology)	90.2	88.6	1.8%	5.8%
84153 (Total PSA)	86.7	91.0	-4.7%	-1.8%
88307 (Level V, tissue exam by pathologist)	81.7	80.7	1.3%	0.9%
88313 (Special stains)	63.8	59.1	8.0%	6.3%
88120 (FISH-manual for urine specimen)	53.1	43.0	23.4%	NA
88368 (FISH-manual)	46.2	53.5	-13.6%	-2.9%
88331 (Pathology consult during surgery)	38.4	37.1	3.6%	-1.2%
88121 (FISH-computer assist for urine specimen)	32.4	25.2	28.5%	NA
TOTALS	$1,941.7	$2,281.2	-14.9%	0.3%

*CAGR=compound annual growth rate

Note: Data is derived from analysis of the Physician Supplier Procedure Summary Master File (PSPSMF) which includes data from all Medicare Part B carriers. This data represents procedure-specific billing data for all physician/supplier services rendered to all Medicare beneficiaries during the calendar year named and processed by the carriers through the six months of the following year. Part B claims processed by fiscal intermediaries are not included.

Source: *Laboratory Economics* from CMS and CodeMap

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EXAGEN DIAGNOSTICS FILES FOR $69 MILLION IPO

Exagen Diagnostics (Vista, CA), which specializes in tests for autoimmune rheumatic diseases (ARDs), has filed with the SEC to raise up to $69 million from an initial public offering (IPO). The underwriters for this initial offering are Leerink Partners, William Blair and Baird. Exagen plans on using the proceeds for research and development as well as expanding its salesforce.

The company began marketing its tests under the brand name Avise SLE, in 2012. Avise SLE are laboratory-developed tests for patients with symptoms indicative of a wide variety of ARDs such as Lupus, Rheumatoid Arthritis, and other disorders that mimic ARDs such as fibromyalgia. Avise SLE allows physicians to more accurately rule-in or rule-out Lupus, and helps physicians make more informed decisions about the presence of other ARDs. Differential diagnosis of these diseases is important because earlier diagnosis has been shown to improve patient outcomes. Once diagnosed, physicians can tailor therapy to a patient's specific disease and avoid the "trial and error" approach that often takes place when a definitive diagnosis cannot be made.

Exagen markets its tests through a staff of 42 sales and marketing employees. Testing is performed at the company's CAP-accredited laboratory in Vista, California. The list price for the company's primary product, Avise SLE+CT, is $1,475.

Exagen's biggest competitors include Quest Diagnostis, LabCorp, ARUP Laboratories, Mayo Medical Labs and Rheumatology Diagnostics Lab (Los Angeles, CA).

Exagen reported a net loss of $8.4 million in the six months ended June 30, 2014, compared with a net loss of $5.8 million for the same period a year earlier; revenue increased to $3.8 million versus $1 million. The company processed 11,073 patient specimens in the first six months of 2014, up from 3,364 in the same period a year earlier.

Since being founded in 2002, Exagen has accumulated losses totaling $81.8 million.

Exagen's largest shareholders include New Mexico State Investment Council, 37% stake; Tullis-Dickerson Capital, 29%; and Hunt Holdings, 16%. The company's President and CEO, Fortunato Ron Rocca, has a 2.1% stake.

AURORA DIAGNOSTICS BUYS ARIZONA DERMATOPATHOLOGY

Aurora Diagnostics (Palm Beach Gardens, FL) has acquired Arizona Dermatopathology (Scottsdale, AZ) for an undisclosed amount. Arizona Dermatopathology, which has 30 employees, including three full-time dermatopathologists, was started in 2009 by its owner/president, Richard Bernert, MD.

Meanwhile, Aurora reports that it paid a combined total of $5.5 million in cash plus $560,000 of contingent consideration (payable over three years based on performance) for two separate acquisitions, Mid-Atlantic Pathology Services in Virginia and Hallmark Pathology in Massachusetts, completed on June 30, 2014. Together, these two acquired groups added four pathologists and annual revenue of $6 million to Aurora. This indicates that Aurora paid a multiple of 1x annual revenue for Mid-Atlantic Pathology Services and Hallmark.

In separate news, Aurora has hired Robert Pettit as Vice President of Revenue Cycle Management. Pettit was formerly Senior Director of the Revenue Services Project Office at Quest Diagnostics.

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MAYO SAYS FORMER CEO STOLE TRADE SECRETS

A judge has ordered Franklin Cockerill III, MD, not to continue working for his new employer, Quest Diagnostics, until the lawsuit against him moves forward. Cockerill had been the President and CEO of Mayo Medical Labs for eight years. Quest and Mayo compete nationwide for contracts to supply reference testing services to hospitals.

Mayo alleges in a suit filed October 14 that Cockerill secretly took a job with Quest Diagnostics and may have passed along trade secrets. He allegedly told Mayo in July that he was going to retire and move to Nebraska to help his 85-year-old mother run her fertilizer business. His final day of work was September 30. However, the next day, Mayo says that Cockerill went to New Jersey to work as Quest's Vice President and Chief Laboratory Officer.

According to Mayo, Cockerill had been communicating via email with Quest since February. He discussed business strategies with Quest CEO Steve Rusckowski through a series of emails in August, the lawsuit states. Cockerill took at least seven Mayo-owned USB memory drives with him when he left, according to the lawsuit.

On October 16, a judge issued a restraining order at Mayo's request against Cockerill to keep him from continuing to share sensitive information.

"Dr. Cockerill is hereby enjoined from working for Quest, from having any contact with Quest or soliciting Mayo or (Mayo Medical Laboratories) employees or customers for the benefit of Quest pending a hearing on the merits of this case," the order states. "The evidence demonstrates, at this stage, a pattern of deceptive behavior by Dr. Cockerill."

"Dr. Cockerill is disappointed that the Mayo Clinic has made such allegations and publicized its unproven claims in the media," according to a statement released by Cockerill's lawyer Nancy Brostrom Vollertsen with Lindquist & Vennum LLP (Minneapolis, MN). "He opted for early retirement at the Mayo Clinic's invitation and is not subject to any non-compete or other agreement that would limit his activities after leaving Mayo," she stated.

ENZO PAYS $3.5 MILLION TO RESOLVE FALSE CLAIMS SUIT

Enzo Clinical Laboratories (Farmingdale, NY), a subsidiary of Enzo Biochem Inc., has agreed to pay $3.5 million to settle allegations that it wrongfully inserted diagnosis codes into Medicare and Medicaid claims when a physician ordered tests from Enzo but did not submit a diagnosis code. According to U.S. Attorney Loretta E. Lynch of the Eastern District of New York, Enzo employees would insert codes which they believed would most likely lead to reimbursement from CMS. Enzo did not—as it was required to do—go back to the ordering physician to obtain the missing code, according to Lynch. The settlement covers the time period 2004-2013.

The settlement is the result of an investigation conducted by the U.S. Attorney's Office for the Eastern District of New York in conjunction with the OIG. While a number of potential issues were raised initially by the government, the investigation came to focus primarily on Enzo's alleged failure to collect diagnosis codes from physicians who ordered tests through Enzo Clinical Labs. The investigation was prompted by the filing of a whistleblower complaint by Realtor O and U 2011 Partnership LLP. The names of the individual whistleblowers were not released.

Enzo Clinical Labs operates a main laboratory in Long Island, New York, with 35 patient service centers in New York and New Jersey. Annual revenue is approximately $58 million, including 21% from Medicare.

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THE TOP 20 UROLOGISTS BILLING MEDICARE FOR CPT 88305

The top 20 urologists that bill for pathology charged the Medicare program for an average of 8.6 units of CPT 88305 per beneficiary served in 2012, according to Medicare Fee-for-Service Provider Utilization & Payment Data.

There was one significant outlier among the top 20 urologists. A urologist in Stockton, California, billed Medicare for an average of 21.7 CPT 88305's per Medicare beneficiary treated in 2012, according to the Public Use Data Files analyzed by Laboratory Economics.

For comparison, *Laboratory Economics* looked at the same data for seven independent pathology labs specializing in uropathology. These labs billed Medicare for an average of only 6.4 units of CPT 88305 per Medicare beneficiary.

We'll leave it up to our readers to draw their own conclusions.

TOP 20 UROLOGISTS BILLING MEDICARE FOR CPT 88305 IN 2012

PROVIDER	LOCATION	SPECIALTY	VOLUME	MEDICARE	SERVICES PER BENEFICIARY
BOCK	OVERLAND PARK	UROLOGY	4,845	429	11.3
WALTER	JAMESTOWN	UROLOGY	4,563	325	14.0
WORSHAM	SALINAS	UROLOGY	3,317	738	4.5
APAYDIN	SALINAS	UROLOGY	3,112	679	4.6
SETHI	STOCKTON	UROLOGY	2,129	98	21.7
GUREVITCH	NAPLES	UROLOGY	1,855	170	10.9
GAUTHIER	KALAMAZOO	UROLOGY	1,800	198	9.1
LUKE	NAPLES	UROLOGY	1,593	158	10.1
STERN	GLENDALE	UROLOGY	1,444	120	12.0
BIANCO	HIALEAH	UROLOGY	1,435	98	14.6
D'ANGELO	NAPLES	UROLOGY	1,339	134	10.0
GERANIOTIS	HYANNIS	UROLOGY	1,327	329	4.0
BROWN	DAYTONA BEACH	UROLOGY	1,307	170	7.7
VITKO	MCALLEN	UROLOGY	1,237	103	12.0
PATEL	GILBERT	UROLOGY	1,139	106	10.7
KAPLAN	HENDERSON	UROLOGY	1,118	92	12.2
RUTILA	FLINT	UROLOGY	1,030	87	11.8
KHAN	FREMONT	UROLOGY	990	105	9.4
HARRIS	FT. MYERS	UROLOGY	972	108	9.0
JAY	BONITA SPRINGS	UROLOGY	943	98	9.6
TOTAL 20 UROLOGISTS		UROLOGY	37,495	4,345	8.6
BOSTWICK LAB	UNIONDALE	LABORATORY	106,175	15,933	6.7
DIANON SYSTEMS	OKLAHOMA CITY	LABORATORY	49,109	5,210	9.4
BOSTWICK LAB	ORLANDO	LABORATORY	37,942	9,195	4.1
PROST DATA	BURLINGAME	LABORATORY	35,865	5,391	6.7
PROST DATA	NASHVILLE	LABORATORY	19,633	3,182	6.2
LABMD INC	ATLANTA	LABORATORY	7,030	871	8.1
BOSTWICK LAB	GLEN ALLEN	LABORATORY	4,906	674	7.3
TOTAL 7 LABS		LABORATORY	260,660	40,456	6.4

Source: 2012 Medicare Fee-for-Service Provider Utilization & Payment Data, Public Use File

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LAB STOCKS UP 1% YTD

Fifteen lab stocks increased an unweighted average of 1% year to date through October 14. In comparison, the S&P 500 Index is up 3%. The top-performing lab stock so far this year is Myriad Genetics, up 81%, followed by Enzo Biochem, up 62%, and NeoGenomics, up 30%. LabCorp is up 7% and Quest Diagnostics is up by 8%.

Company (ticker)	Stock Price 10/14/14	Stock Price 12/31/13	2014 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$28.18	$25.54	10%	$781	19.7	1.0	2.6
Cancer Genetics Inc. (CGIX)	6.49	13.78	-53%	63	NA	7.4	1.5
CombiMatrix	1.16	2.30	-50%	13	NA	0.8	1.2
Enzo	4.74	2.92	62%	211	NA	2.1	5.7
Foundation Medicine (FMI)	20.61	23.82	-13%	582	NA	5.7	5.3
Genomic Health (GHDX)	31.17	29.27	6%	983	NA	3.5	6.9
LabCorp (LH)	97.81	91.37	7%	8,304	15.9	1.5	3.1
LipoScience	5.19	4.25	22%	79	NA	1.7	1.9
Myriad Genetics (MYGN)	37.90	20.98	81%	2,743	16.5	3.7	3.9
NeoGenomics	4.70	3.62	30%	268	90.5	3.1	10.2
Psychemedics	14.11	14.69	-4%	76	21.4	2.7	5.8
Quest Diagnostics (DGX)	57.85	53.54	8%	8,354	14.6	1.2	2.0
Response Genetics (RGDX)	0.60	1.16	-48%	23	NA	1.3	4.6
Sonic Healthcare (SHL.AX)	17.18	16.58	4%	6,892	17.8	1.8	2.2
Veracyte	8.23	14.50	-43%	177	NA	1.2	3.9
Unweighted			1%		28.1	2.6	4.1

Source: Bloomberg and Zacks

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