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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

ACLA Seeks More PAMA Reporting Labs And Enforcement Action Against Labs Failing To Report

The American Clinical Laboratory Association (ACLA) is urging CMS to increase the number of labs that must report their private-payer payment data under PAMA. In its comments on the Proposed Physician Fee Schedule for 2019, ACLA said CMS should: 1) require hospital outreach labs to report; 2) make it easier and less costly for labs to submit their payment data; and 3) take appropriate enforcement action against labs that are required to report, but fail to do so. *Continued on page 10.*

SEC Charges OPKO Chairman With Stock Fraud

The Nasdaq Stock Market suspended trading in OPKO Health shares for one week (Sept. 7 to midday Sept. 14) after the Securities & Exchange Commission (SEC) filed a lawsuit charging that OPKO and its Chairman Philip Frost, MD, took part in classic "pump and dump schemes" that manipulated the prices of penny stock companies. News of the SEC lawsuit comes as OPKO struggles to turn around its largest subsidiary, BioReference Laboratories. *Continued on page 8.*

Guardant Health Seeks $100 Million From IPO

Guardant Health (Redwood City, CA) is seeking to raise $100 million through an initial public offering (IPO) that would have its shares listed on the Nasdaq. The company's primary product is Guardant360, a comprehensive liquid biopsy assay that analyzes 73 cancer-related genes to help match solid-tumor cancer patients with targeted therapies. The test is performed at Guardant's CLIA-certified laboratory in northern California and has a list price of $7,800. *Full details on page 6.*

Pfizer Reps To Help Sell Exact's Colorectal Cancer Test

Exact Sciences (Madison, WI) and the pharmaceutical giant Pfizer (New York City) have entered into an agreement to co-promote Exact's Cologuard stool-based DNA test for colorectal cancer in a partnership that will run through the end of 2021. Pfizer has agreed to have its primary care field reps (estimated 1,000+ reps) make a minimum of 625,000 Cologuard sales calls in each calendar year with 2018 adjusted for the partial year. The agreement with Pfizer represents an expensive "all-in" push to entrench Cologuard in the colorectal cancer screening market before competing liquid-biopsy methods reach the market in the next two to four years.
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Pfizer Reps To Help Sell Exact's Colorectal Cancer Test (*cont'd from page 1*)

Pfizer sales reps are scheduled to begin their training on the Cologuard test on October 1 and they will begin making detail visits to doctors before year's end. Cologuard sales calls for the Pfizer team will typically be in the second or third position relative to Pfizer's own products, which include the drugs Lyrica (for epilepsy and nerve pain), Eliquis (to prevent blood clots) and Chantix (smoking cessation).

Exact's own sales force of 350 field reps will continue to market the Cologuard test as well.

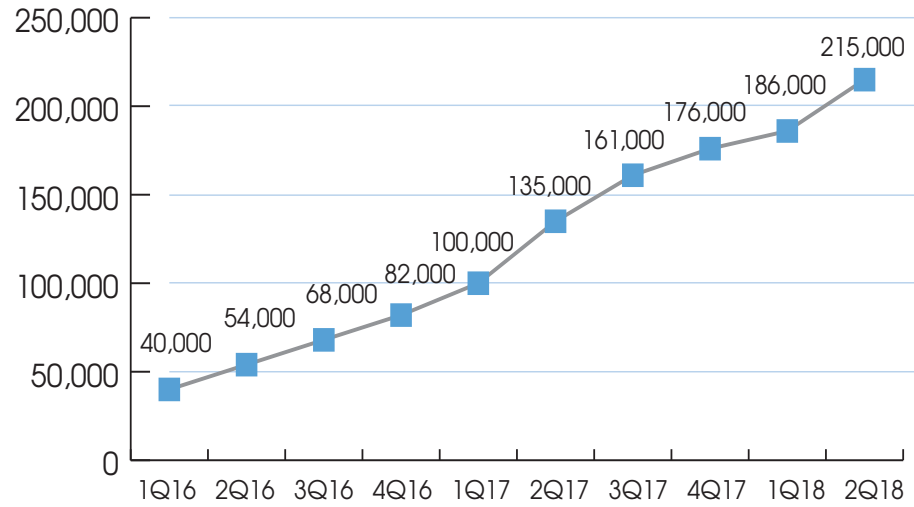
In addition, the two companies have agreed to share equally in spending about $45 million per year on advertising promotions (e.g., TV ads, internet marketing, social media, et al.) through the end of 2021. The additional spending for advertising will come on top of a baseline of $80 million per year that Exact Sciences already spends on marketing for its Cologuard test.

"This partnership enables us, we believe, to permanently alter the trajectory of Cologuard," Kevin Conroy, Chairman and CEO of Exact Sciences, said in a conference call with Wall Street analysts on August 22.

The agreement includes a promotion fee to be paid by Exact to Pfizer equal to 50% of the gross profit on Cologuard sales, above an agreed-upon revenue baseline. The baseline revenue thresholds that must be met before Pfizer begins earning its share of the gross profit are $441 million in 2018, $622 million in 2019, $861 million in 2020 and $1.191 billion in 2021.

Exact's average collected revenue per Cologuard test is currently approximately $475 and its gross profit margin is about 70%. So Pfizer will earn an estimated $166 per test (50% of $475 x 70%) for the incremental volume it brings to Exact.

Quarterly Volume of Colorguard Tests Completed



Source: Exact Sciences

In addition, after the agreement expiration at the end of 2021, Exact will pay up to a 3% royalty on cumulative incremental Cologuard revenue achieved during the partnership to Pfizer for up to three years (2022-2024).

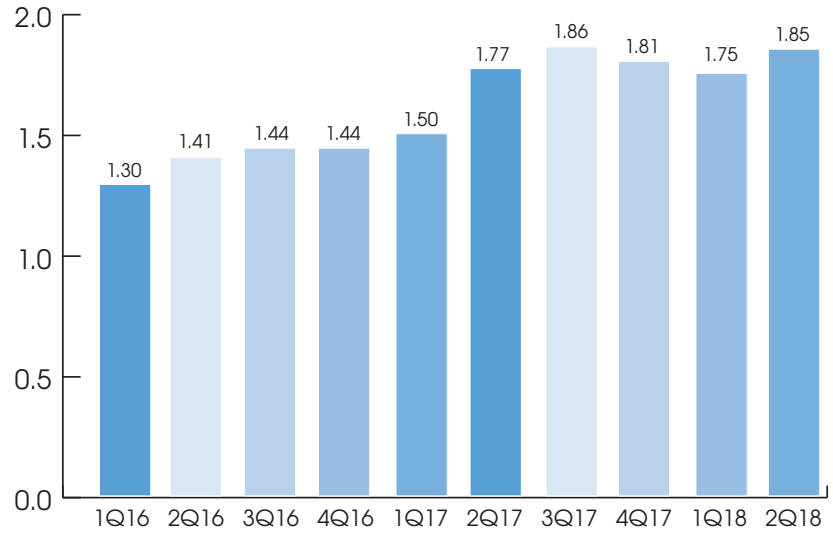
The contract includes an escape clause that says that 18 months after the effective date (August 21, 2018), either Exact or Pfizer may terminate the agreement without cause after giving six months' notice.

Prescriptions Per Physician

Exact's Cologuard test volume grew by 134% to 571,000 tests in 2017 and is expected to grow to 910,000 tests in 2018. Cologuard test volume growth has been strong but it masks an underlying weakness: physician utilization of the test is low.

For example, Exact says that approximately 10,000 healthcare providers (physicians, nurse practitioners and physician assistants) ordered their initial Cologuard test during the second quarter (ended June 30, 2018), and that nearly 121,000 providers have ordered since the test was launched in late 2014. Completed Cologuard test volume in the second quarter was 215,000 tests, which means that Exact is averaging less than two completed Cologuard tests per quarter per ordering provider. In other words, Exact's provider clients are each ordering an average of less than one Cologuard test per month.

Average Completed Colorguard Tests Per Existing Ordering Doctor



Source: *Laboratory Economics'* estimates

"Frequency matters. Our data shows that there is a direct relationship between the frequency of calls on a healthcare provider and the frequency with which they order Cologuard," according to Exact's Conroy. Exact is hoping that the extra 625,000+ per year sales calls by Pfizer reps will boost provider prescriptions of Cologuard.

Longer term, Cologuard May Come Under PAMA Pricing Pressure

The first PAMA private-payer pricing data collection period covered January 1, 2016 through June 30, 2016, and the new Medicare rates based on this data became effective with Medicare's CLFS on January 1, 2018. The new PAMA rates trimmed Medicare reimbursement for Cologuard (CPT 81528) by only 3%—from $512 in 2017 to $509 in 2018. Cologuard's Medicare reimbursement rate of $509 will remain unchanged for three years, 2018-2020.

Laboratory Economics believes that Exact was able to maintain its Medicare rate for Cologuard during the initial PAMA survey cycle as a result of several quirks:

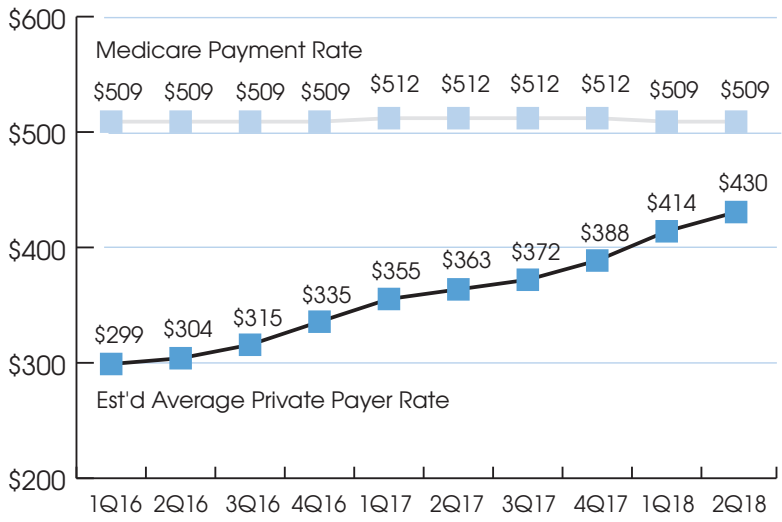
1) Exact only completed 94,000 Cologuard tests between January 1, 2016 and June 30, 2016, and roughly 50% of these tests were for Medicare Part B patients and therefore not reportable under PAMA.
2) Exact may have had a large number of Cologuard test claims under review by or appeal before commercial insurance payers that were not deemed final and therefore not reportable under PAMA rules. The exclusion of disputed lower-reimbursed claims would have helped to boost the pricing data that Exact did report to CMS.

However, a new PAMA survey takes place every three years. The next Medicare rate adjustments will become effective January 1, 2021, based on a new private-payer pricing survey covering data

collected from January 1, 2019 through June 30, 2019. This second survey has the potential to reduce Medicare reimbursement for Cologuard by a maximum of 15% in 2021, followed by additional max cuts of up to 15% per year in 2022 and 2023.

Exact has gained in-network status with numerous commercial insurance plans over the past two years. The company says that Cologuard is now in-network with insurance plans covering about 95% of its potential patient population. This is nearly double the in-network coverage that Cologuard had back in early 2016 during the initial PAMA survey period.

Payment Rates for Cologuard



Source: CMS and *Laboratory Economics'* estimates

Major commercial insurance companies like Aetna, Anthem BCBS, Cigna, Humana and UnitedHealth generally reimburse contracted in-network labs at a steep discount below Medicare CLFS rates. At a minimum, *Laboratory Economics* thinks these insurers may be reimbursing Cologuard at 10% to 20% below the current Medicare CLFS rate of $509. This could put pressure on Cologuard's Medicare reimbursement rate during the second PAMA survey cycle.

Blood Tests for Colorectal Cancer Are On The Horizon

Exact has about three years or so to entrench Cologuard in the colorectal cancer (CRC) screening market before serious competition from liquid biopsy blood tests start hitting the market. For example, **Freenome Inc.** (South San Francisco, CA) recently announced plans for a clinical validation study for its blood-based CRC screening test. The study aims to collect samples from up to 3,000 patients and is being conducted in partnership with Health Decisions Inc. (Research Triangle Park, NC), the same contract research organization that managed the FDA pre-market approval study for Exact's Cologuard test.

In addition, **CellMax Life** (Sunnyvale, CA) is in the process of raising $50 million from private equity investors so that it can begin a 5,000+ patient U.S. clinical study for its CRC blood test. Patient specimen testing is expected to begin in the fourth quarter and will be performed at the company's CLIA-certified and CAP-accredited laboratory in northern California (see *LE* articles, May and June 2018).

Clinical Genomics (Bridgewater, NJ) markets a circulating tumor DNA blood test designed to monitor residual disease and recurrence in patients being treated for colorectal cancer. The test is sold as a laboratory-developed test under the brand name "Colvera" and is performed at the company's CLIA-certified lab in northern New Jersey. Ultimately, the company plans to develop Colvera into a CRC screening test.

Other blood-based CRC tests include **Epigenomics' Epi ProColon, Quest Diagnostics' ColoVantage** and **VolitionRx's Nu.Q Screening Test**.

Aurora Diagnostics Seeking Buyer

Aurora Diagnostics (Palm Beach Gardens, FL) has hired the investment bank Moelis & Company (New York City) to help locate a potential buyer of the pathology practice management company, several sources tell *Laboratory Economics*.

Aurora's largest shareholders include Summit Partners (51% stake) and KRG Capital (35% stake) and former Chairman and CEO James New (5% stake).

Since being founded in 2006 by James New and other former executives from AmeriPath, Aurora has acquired 32 pathology practices with more than 220 pathologists and annual revenue of roughly $300 million.

However, Aurora borrowed heavily to make these acquisitions. The company owes more than $220 million to Cerberus Business Finance (New York City) that is secured by essentially all of Aurora's assets and acquired subsidiaries. This debt comes due on July 14, 2019.

In addition, Aurora has another $200 million of unsecured debt that comes due January 15, 2020.

Aurora's total debt of $420+ million requires interest payments of more than $40 million per year and limits the company's options.

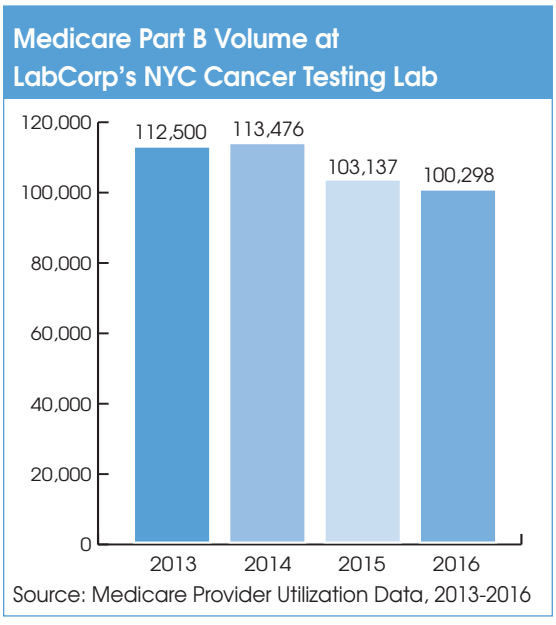
Ideally, any potential sale of Aurora would also include a debt refinancing, notes *Laboratory Economics*.

LabCorp Closing Big Cancer Testing Lab In NYC

LabCorp plans to shut down a major cancer testing laboratory in New York City by year's end, according to a worker adjustment and retraining notification (WARN) filed with the New York State Department of Labor on August 8. The 80,000-square-foot laboratory located at 521 West 57th Street in Manhattan has a total of 173 employees, including 12 pathologists.

The NYC laboratory is the former headquarters and main lab of IMPATH Inc., which was acquired by Genzyme Genetics in 2004. LabCorp took over the lab when it purchased Genzyme Genetics for $925 million in late 2010.

LabCorp plans to consolidate the NYC lab into its Dianon Pathology laboratory in Shelton, Connecticut (located about 1 hour north of NYC). About 129 employees are expected to lose their jobs, according to the WARN notice.



The NYC laboratory specializes in hematopathology and has suffered from substantial Medicare rate reductions for flow cytometry testing. For example, Medicare reimbursement for the key flow cytometry procedure (CPT 88185) was reduced by 19% in 2017 and then by another 19% in 2018. And CMS has proposed cutting CPT 88185 by yet another 19% in 2019.

In addition, the latest available utilization data from Medicare shows that the volume of Part B services provided by the NYC lab declined from 112,500 paid procedures in 2013 to 100,298 paid procedures in 2016.

Guardant Health Seeks $100 Million From IPO (*cont'd from page 1*)

Guardant360 (G360) came to market as a laboratory-developed test in 2014. The company plans to seek FDA clearance for the test to improve coverage and reimbursement.

In July, Palmetto GBA's influential MolDx assessment program finalized a limited local coverage determination for G360 for fee-for-service Medicare patients in the United States with metastatic non-small cell lung cancer who are ineligible for traditional tissue-based genomic testing. The coverage followed recent publication of a validation study of G360 in *Clinical Cancer Research* that demonstrated low false positive rates at the gene variant level for G360 vs. tissue testing, with positive predictive values (PPVs) for key biomarkers ranging from 92% to 100% compared to tissue-based genotyping in 543 patients.

Noridian Healthcare Solutions, the MAC responsible for adjudicating claims in California, where Guardant's laboratory is located, is a participant in Palmetto's MolDx program, but has not yet finalized its LCD for G360.

Guardant employs 30 sales reps that sell G360 primarily to oncologists and cancer centers. As previously mentioned, the current list price for G360 is $7,800 for U.S. clinical patients, although actual average collected revenue per test performed is estimated to be approximately $3,000.

According to Guardant, approximately 5,000 oncologists have together ordered more than 70,000 G360 tests since it was introduced in the U.S. in 2014.

The company sold 13,969 tests to clinical customers in the six months ended June 30, 2018, an increase from 12,080 tests in the six months ended June 30, 2017. In addition, Guardant sold 6,141 tests sold to biopharmaceutical customers in the six months ended June 30, 2018, an increase from 2,154 in the six months ended June 30, 2017.

For the first six months of 2018, Guardant recorded a net loss of $35.5 million versus $39.6 million for the same period in 2017; overall revenue increased by 93% to $36.1 million. As of June 30, 2018, Guardant has accumulated losses totaling $231.2 million since being formed in 2011.

JP Morgan and BofA Merrill Lynch are the lead underwriters for Guardant's IPO, and Cowen, Leerink Partners and William Blair are acting as co-managers.

Guardant's biggest shareholders include SoftBank Group, 39% stake; Sequoia Capital, 11% stake, and Khosla Ventures, 10% stake. The company's co-founder and CEO, Helmy Eltoukhy, PhD, has an 8% stake.

Guardant says it will use proceeds from the IPO for general corporate purposes, including working capital, sales and marketing, administrative matters and capital expenditures.

Guardant Health Financial Summary ($000)

	First-Half 2018	First-Half 2017	% Chg
Clinical oncology testing revenue	$32,013	$17,674	81%
Biopharma development service revenue	4,061	1,034	293%
Total revenue	36,074	18,708	93%
Net loss	-35,483	-39,571	NA
Clinical oncology testing volume	13,969	12,080	16%
Biopharma development testing volume	4,832	2,154	124%

Source: Guardant Health

Spotlight Interview with Metropath's Matthew Moore


Matthew Moore

Metropolitan Pathologists (Metropath) is the oldest private pathology laboratory in Colorado. Founded in 1913, Metropath was based in Denver before moving to nearby Lakewood, Colorado. The lab has about 100 employees, seven of whom are pathologists. *Laboratory Economics* recently spoke with Metropath's Director of Business Development Matthew Moore.

Which areas do you serve and who are your clients?
We serve the state of Colorado, and we have a few pockets of business in Wyoming and Minnesota. We serve hospitals, clinics, private practices and surgery centers. We provide medical directorships to six hospitals in Colorado, mainly in the Denver market. In total, we process an average of approximately 750 accessions a day. Our histology department does about 300 blocks a day.

Is Metropath growing? If so, by how much and what is driving growth?
We are on a growth curve. Our business development team has done a really good job of mining new business, as well as upselling existing clients. Our big area of growth is in molecular pathology. We are seeing double-digit growth in that area. We did take a pretty drastic hit a few years ago when guidelines on Pap smears changed from once every year to once every three years. But we are seeing an uptick in Paps. Overall, we are growing.

Are you involved in any joint ventures or partnerships?
We have a co-marketing agreement with Roche to market their Harmony NIPT [non-invasive prenatal testing] line. Our volumes are picking up. It's been a great learning experience.

Did the PAMA rate cuts impact your lab in terms of Pap and HPV testing and other CLFS tests?
It has to an extent, but our sales growth in recent years has helped minimize that.

Have you enacted any strategies to combat this decline?
We are always looking at potential opportunities. We are one of the strange industries where we're told what we're going to get paid. Metropath is a conservative organization. We look at new opportunities for a very long time before we would move on them.

Are specialty groups such as urologists, GIs and dermatologists still insourcing pathology lab work?
I'm sure it still goes on, but I think it has slowed down and we have not experienced a loss of business because of it. We do offer histology services to the local dermatologists, and we have seen growth there.

Your thoughts on the outlook for digital pathology? Do you use digital pathology today?
Not currently. The healthcare system (Centura Health) we work with is talking about it. I personally am excited about it because it shrinks our world by linking us to remote locations. But it's expensive, the workflows aren't yet perfected, and adoption has been slow. If we get there, it will be through our hospitals.

What do you see as your biggest challenge?
Hospitals are buying up practices, which makes it difficult for smaller groups like us to retain clients despite our high quality of service. Also, connectivity is difficult. Hospitals will often include that in the practices they purchase. We are interfaced to a significant portion of our clients, but not all. In some cases, there just isn't enough volume to justify it.

What are your greatest opportunities?
We hope to gain some more hospitals. We have to make the decision whether we want to bring in additional testing and whether we want to expand geographically. We have a small sales team—we are pushing them to venture out to get some of the more remote parts of their territories.

SEC Charges OPKO Chairman With Stock Fraud (*cont'd from page 1*)

The SEC alleges that Frost, Opko and others made more than $27 million in stock sales proceeds between 2013 and 2018 by organizing large stock buys and promoting the stocks—including through misleading articles and manipulative trading—while failing to properly disclose their stakes. The scheme left public investors "holding virtually worthless stock," according to the SEC complaint. In response, OPKO says that it is confident that once a proper investigation is completed and the facts of the case have been fully disclosed, the matter will be resolved favorably for the company.

OPKO's BioReference Labs Hurt By PAMA Rate Cuts

Separately, OPKO reports that its BioReference Laboratories (Elmwood Park, NJ) posted an operating loss of $6.5 million for the six months ended June 30, 2018 versus an operating loss of $8 million during the same period in 2017; revenue decreased by 7.6% to $427.4 million.

OPKO attributed declining revenue at BioReference primarily to lower overall reimbursement rates, including the effect of PAMA cuts to the Medicare's Clinical Laboratory Fee Schedule. Overall, BioReference's test volume was down slightly (<1%).

During the first half of 2018, BioReference's revenue from government payers (Medicare, Medicaid, TRICARE, et al.) was down 11%, while its revenue from private healthcare insurers was also down 11%. This suggests that private healthcare insurance payers are mimicking the across-the-board 10% cuts made by Medicare at the start of the year, observes *Laboratory Economics*.

BioReference Revenue by Payer ($000)

	First-Half 2018	First-Half 2017	% Chg
Healthcare insurers	$192,986	$217,062	-11.1%
Government payers	139,595	157,090	-11.1%
Client payers	83,357	76,900	8.4%
Self-paying patients	11,431	11,404	0.2%
Total revenue	$427,369	$462,456	-7.6%

Source: OPKO Health

On an August 7 conference call with analysts and investors, which took place prior to the SEC lawsuit, OPKO's Frost said that the new General Manager of BioReference, Geoff Monk, is now in full control at BioReference and is making operational changes and new hires to improve results.

Monk was previously Managing Director of the New York and New Jersey unit of Quest Diagnostics. And he recently hired Cindy Jacke as BioReference's new Senior Vice President of Sales. She was formerly Vice President of Sales at Pathline Emerge Pathology Services, a full-service pathology lab located in Ramsey, New Jersey. Prior to that, Jacke spent 25 years at Quest Diagnostics, most recently as Sales Director for the East region.

Frost noted that a bright spot at BioReference has been its GeneDx laboratory in Gaithersburg, MD. GeneDx, which specializes in testing for rare genetic disorders, accounts for roughly 18% (or ~$150 million per year) of BioReference's overall revenue. Frost said that GeneDx has recorded double-digit volume growth throughout this year and last year.

Meanwhile, BioReference reported no updates regarding allegations by the U.S. Attorney's Office in Manhattan that the company violated the False Claims Act by improperly billing Medicare and TRICARE for lab tests provided to hospital inpatient beneficiaries at certain hospitals since 2006. BioReference says it continues to review the allegations, and, at this point, has not determined whether there is any merit to the claims nor can it determine the extent of any potential liability.

Publicly-Traded Labs GROW 3.6% In First-Half 2018

On a combined basis, 17 publicly-traded labs saw their revenue increase by 3.6% to $9.4 billion during the first six months of 2018 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Excluding Quest Diagnostics and LabCorp, 15 publicly-traded labs grew by 10% in first-half 2018 (after adjusting for acquisitions).

Pro forma revenue growth was fastest at Invitae Corp., up 116%, Exact Sciences, up 82%, and Foundation Medicine, up 79%. Other fast-growing lab companies included Interpace Diagnostics, up 41%; CareDx, up 35%; and Natera and Veracyte (each up 23%).

Acquisition-adjusted revenue for Quest Diagnostics increased by 0.3% in first-half 2018, while LabCorp's revenue was up 3.1%. The third largest U.S. lab company, Sonic Healthcare USA, grew by 2%.

Revenue Growth at 17 Publicly-Traded Lab Companies ($000)

Company	First-Half 2018	First-Half 2017	Reported Change	Pro Forma Change*
Quest Diagnostics (lab testing only)	$3,638,000	$3,506,000	3.7%	0.3%
LabCorp (lab testing only)	3,584,200	3,360,800	6.6%	3.1%
Sonic Healthcare USA[1]	453,750	428,300	5.9%	2.0%
Opko/Bio-Reference Labs	427,369	462,456	-7.6%	-7.6%
Myriad Genetics	382,200	394,300	-3.1%	-3.1%
Exact Sciences	193,190	106,009	82.2%	82.2%
Genomic Health	188,244	169,467	11.1%	11.1%
NeoGenomics	131,169	119,693	9.6%	9.6%
Natera	125,409	101,665	23.4%	23.4%
Foundation Medicine	109,846	61,332	79.1%	79.1%
Invitae Corp.	64,977	24,674	163.3%	116.0%
Veracyte	42,792	34,838	22.8%	22.8%
Enzo Clinical Labs (lab testing only)[2]	37,667	38,421	-2.0%	-2.0%
CareDx	31,876	23,630	34.9%	34.9%
Psychemedics	21,722	19,893	9.2%	9.2%
Cancer Genetics Inc.	14,703	13,570	8.3%	8.3%
Interpace Diagnostics	10,310	7,325	40.8%	40.8%
Total, 17 companies	$9,432,411	$8,851,478	6.6%	3.6%
Total, 15 companies (excluding Quest and LabCorp)	$2,235,224	$2,005,573	11.5%	10.0%

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

[1]Sonic Healthcare USA revenue for the six months ended June 30, 2018 at constant exchange rate of 1 Australian Dollar equal to 0.75 U.S. Dollar.

[2]Enzo's revenue is for lab services only for six months ended April 30, 2018.

Source: *Laboratory Economics* from company reports

ACLA Seeks More PAMA Reporting Labs (*cont'd from page 1*)
In its comments to CMS, ACLA noted that CMS collected data from less than 1% of labs paid through the Medicare Clinical Laboratory Fee Schedule (CLFS)—1,942 out of 261,524 labs—in the first PAMA data reporting period in early 2017. Consequently, pricing data from Quest Diagnostics and LabCorp dominated the data and is resulting in three straight years (2018-2020) of 10% rate cuts for most high-volume tests on the CLFS.

The next PAMA rate-setting cycle will cover private-payer pricing data for the period January 1, 2019 to June 30,2019, reported by labs to CMS in early 2020, with new rates effective January 1, 2021.

ACLA's suggestions for increasing the number of reporting labs include:

1) Broadening the definition of applicable reporting labs to include hospitals with significant laboratory outreach programs.
2) Reducing the burden on reporting laboratories by excluding the requirement to report private-payer payment data from manual (hard-copy) remittances for which test-level payment information is not captured in the lab's electronic billing system.
3) Urging CMS to implement aggressive education efforts directed at independent labs, POLs and hospital outreach labs about how to determine if they are required to report. "And CMS must investigate applicable laboratories that are required to report applicable information but fail to do so, and take appropriate enforcement action against them," according to ACLA's comments. The PAMA statute authorizes CMS to impose civil monetary penalties of up to $10,000 per day to labs for each failure to report or misrepresentation.

Of course, it is far from certain that CMS will make any of ACLA's desired changes to the PAMA rules when it issues its Final Medicare Physician Fee Schedule Rule for 2019 this fall.

Meanwhile, ACLA is still waiting for U.S. District Judge Amy Berman Jackson to schedule oral arguments for its PAMA lawsuit against CMS. Judge Jackson might be waiting to see if the Final MPFS for 2019 includes changes that effectively resolve the lawsuit, notes *Laboratory Economics*.

Quest To Buy Workplace Wellness Company For $27 Million

Summit Health Inc., a subsidiary of Quest Diagnostics, has agreed to purchase the assets of Hooper Holmes Inc. (dba Provant Health) for $27 million. Based in Olathe, Kansas, Provant Health provides on-site screening services and flu shots, laboratory testing, health risk assessment, and sample collection services to employers and health plans.

The acquisition agreement coincides with Provant's Chapter 11 bankruptcy filing on August 29. The deal is expected to be completed by October 10. Provant plans to use the proceeds from the sale to Quest to pay off its debts.

In the six months ended June 30, 2018, Provant reported a net loss of $10.3 million on revenue of $21.6 million. Provant currently has approximately 200 direct clients representing nearly 3,000 employers representing over 3,000,000 individual employees. Provant currently contracts for lab testing services with the privately-held Clinical Reference Laboratory (Lenexa, KS).

Quest made a major expansion into the employer on-site prevention and wellness program business when it acquired Summit Health (Novi, MI) for $151 million in 2014. Quest is expected to operate the combined Summit Health and Provant businesses under its Quest Diagnostics Health & Wellness division.

Lab Groups Renew Call for Narrowing of Self-Referral Loophole

The American Clinical Laboratory Association (ACLA), the College of American Pathologists (CAP) and other members of the Alliance for Integrity in Medicare (AIM) are renewing their call for CMS to narrow the in-office ancillary services (IOAS) exception to the Stark Law.

In comments submitted in response to an August 22 request for information (RFI), the groups argued that the Medicare program could save at least $3.3 billion over the next decade by narrowing a loophole in the physician self-referral law that they say drives questionable utilization patterns for certain health services. Specifically, they are calling for CMS to remove anatomic pathology from the list of services that physicians are allowed to self-refer and perform in their own offices.

Clare Krusing, an ACLA spokesperson, says the organization believes the time may be ripe for CMS to actually consider narrowing the IOAS exception. "We think the RFI, in addition to the recent House hearing on modernizing the Stark Law, demonstrate a willingness in both the Administration and Congress to consider reform," she tells *Laboratory Economics*.

While CMS's request largely centered on how the Stark law might impede value-based healthcare models, ACLA and the CAP highlighted what it considers abuse of the IOAS exception to the Stark law. The argument is nothing new. Research published in *Health Affairs* in 2012 found that urologists who self-referred submitted more specimens per prostate biopsy than those sent by urologists to an independent pathology lab. Other studies have reached similar conclusions including one by the Government Accountability Office that found additional self-referrals for AP services cost the Medicare program about $69 million in 2010.

In comments submitted August 24, ACLA argued that pathology services are not truly "ancillary" to other services furnished by non-pathologists. "Although the physician may bill for the pathology services by taking advantage of the Stark Law's IOAS exception, the pathology service is not truly 'ancillary' to the primary services and has not in any way had an impact on the physician's treatment of the patient while he or she is in the physician's office," unlike simple clinical laboratory tests or X-rays that can be done while a patient waits and can be used to guide treatment during an office visit.

ACLA said it supports "the establishment of narrowly-tailored exceptions to the Stark Law to accommodate value-based care arrangements and alternative payment models that promote coordinated care, where such arrangements eliminate inappropriate financial incentives for self-referral."

Theranos Is Finally Shutting Down

Over the past four months, Theranos reached out to more than 80 potential buyers to raise cash, but none were interested. In a September 4 letter to shareholders, the company's lawyer and replacement CEO, David Taylor, said "Unfortunately, none of those leads has materialized into a transaction. We are now out of time."

Theranos is dissolving and plans to turn over its assets and intellectual property to secured creditor Fortress Investment Group. The company's remaining $5 million of cash will go toward paying part of the $60 million it owes unsecured creditors.

Theranos shareholders will get nothing except a copy of the certificate of dissolution, for use for tax loss purposes, Taylor's letter says.

Taylor became CEO in June after previous CEO and founder Elizabeth Holmes was indicted for fraud by federal prosecutors. Holmes is facing criminal charges and potentially 20 years in prison.

Lab Stocks Jump 53% Year To Date

Prices for 17 publicly-traded lab stocks are up 53% on an unweighted average basis through September 14. In comparison, the S&P 500 Index is up 9.9% year to date. The top-performing lab stocks so far this year are CareDx, up 256%; Natera, up 172%; and Genomic Health, up121%. At the two largest public labs, LabCorp is up 8% and Quest Diagnostics is up 10%.

Company (ticker)	Stock Price 9/14/18	Stock Price 12/29/17	2018 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$1.04	$1.85	-44%	$29	NA	1.0	1.7
CareDx (CDNA)	26.16	7.34	256%	950	NA	16.8	32.5
Enzo Biochem (ENZ)	4.82	8.15	-41%	227	NA	2.1	2.6
Exact Sciences (EXAS)	76.27	52.54	45%	9,360	NA	26.5	12.6
Foundation Medicine (FMI)*	137.00	68.20	101%	5,090	NA	28.4	267.6
Genomic Health (GHDX)	65.05	29.39	121%	2,330	77.4	6.5	10.4
Interpace Diagnostics (IDXG)	1.45	1.02	42%	41	NA	2.2	1.1
Invitae (NVTA)	15.58	9.08	72%	1,080	NA	9.9	7.8
LabCorp (LH)	172.98	159.51	8%	17,630	13.7	1.6	2.5
Myriad Genetics (MYGN)	47.56	34.35	38%	3,370	26.1	4.4	3.5
Natera (NTRA)	24.42	8.99	172%	1,490	NA	6.3	NA
NeoGenomics (NEO)	13.89	8.57	62%	1,270	NA	4.7	6.9
Opko Health (OPK)	3.90	4.90	-20%	2,183	NA	2.1	1.2
Psychemedics (PMD)	19.25	20.56	-6%	106	17.5	2.6	5.8
Quest Diagnostics (DGX)	108.19	98.49	10%	14,790	18.6	1.9	2.8
Sonic Healthcare (SHL.AX)	25.12	21.40	17%	10,690	22.4	1.9	2.6
Veracyte (VCYT)	11.16	6.53	71%	440	NA	5.5	14.9
Unweighted Averages			53%	$71,076	29.3	7.3	23.5

*Foundation Medicine was acquired by Roche for $137 per share on July 31.
Source: Capital IQ

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