Jondavid Klipp, Editor, labreporter@aol.com

Volume 12, No. 8 August 2017

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

CMS OFFICIALS SAY THEY ARE ON SCHEDULE WITH MEDICARE LAB TEST REPRICING

Officials with the Centers for Medicare and Medicaid Services (CMS) say they are on track to publish preliminary payment rates for laboratory tests that will be paid under a new market-based Clinical Laboratory Fee Schedule (CLFS) scheduled to take effect January 1, 2018. Valerie Miller, director of the Division of Ambulatory Services, said the agency intends to publish the preliminary rates in September. Miller spoke during the CLFS annual laboratory public meeting held July 31-August 1 in Baltimore. *Continued on page 3.*

QUEST LIKELY TO REGAIN UNITED HEALTHCARE CONTRACT IN 2018

Quest Diagnostics' long-term strategy for regaining in-network provider status with United Healthcare has likely paid off. Informed sources tell *Laboratory Economics* that Quest will once again become a contracted provider with United effective as early as March 1, 2018. LabCorp is expected to remain in-network with United, but will lose its exclusivity as United's sole national lab provider. *More details on page 4.*

IN-OFFICE PATHOLOGY TARGETS FLOW CYTOMETRY

The owners of In-Office Pathology Inc. (Lake Forest, IL), Joe Plandowski and Bernie Ness, have formed a new company aimed at setting up in-office flow cytometry labs at Ear, Nose and Throat (ENT) specialty groups. Plandowski says the new company, In-Office Cytometry Inc. (Woodstock, GA), will offer a turn-key solution to in-sourcing flow cytometry testing for physicians treating chronic rhinosinusitis (CRS) patients.

Plandowski says that patients that continually fail antibiotic and/or surgery have new treatment options once properly diagnosed. Flow cytometry can be used to enumerate bacteria and virus-like particles in sinus flush samples of CRS patients. The relevance of enumeration is that with increasing antimicrobial resistance, antibiotics are becoming less effective at treating bacterial infections of the sinuses, so alternative therapies are needed. "This is a relatively new testing market that has been ignored and undervalued by the laboratory industry," according to Plandowski. *Continued on page 2.*

Contents

IN-OFFICE PATHOLOGY TARGETS FLOW CYTOMETRY (*cont'd from page 1*)

Plandowski says that he and his partner Ness are already in negotiations with four ENT groups. The ideal candidate groups have six or more physicians. There are roughly 500 ENT groups with 6+ doctors in the United States. An in-office flow cytometry lab requires about 150-200 square feet of space, a $150,000 investment for a flow cytometer and other equipment, and the hiring of a medical technologist. Professional services and laboratory back-up will be provided by Oral Alpan, MD and his specialty laboratory Amerimmune, LLC (Fairfax, VA).

Plandowski estimates that flow cytometry testing on chronic sinusitis patients generates an average of $1,000 in collected revenue per patient. An in-office flow cytometry lab at a six-doctor ENT group should produce annual revenue of about $1.5 million and a profit of $1 million (or about $165,000 per physician).

Meanwhile, Plandowski says his original company, In-Office Pathology Inc. (IOP), has opened in-office histology labs at a total of 76 specialty groups, including 50 gastroenterology groups, over the past 12 years. He says IOP is on track to open histology labs at about five specialty groups this year, including two new gastroenterology-based labs opening this month for a group in California with seven doctors and another in Georgia with five doctors. IOP is also scheduled to open a histology lab at a two-doctor dermatology group in Indiana later this year.

Separately, an analysis of Medicare Part B paid claims for key flow cytometry codes shows that Genoptix (Carlsbad, CA) and Bio-Reference Labs (Elmwood Park, NJ) are by far the largest flow cytometry labs in the nation.

Genoptix, which was recently acquired by the private investment firm Ampersand Capital Partners, was paid for a total of 236,350 Part B claims for five key flow cytometry codes (88184, 88185, 88187, 88188 and 88189) in 2015.

Bio-Reference Labs, which is owned by Opko Health, was paid for a total of 187,400 Part B claims for the five key flow cytometry codes in 2015.

Top 20 Flow Cytometry Labs by Volume of Medicare Part B Services, 2015

Name	Location	88184	88185	88187	88188	88189	Total
Genoptix	Carlsbad, CA	9,311	214,984	389	106	11,560	236,350
Bio-Reference Labs	Elmwood Park, NJ	7,693	168,869	926	648	9,264	187,400
LabCorp/Accupath Diagnostics	Brentwood, TN	2,862	70,058	276	0	4,967	78,163
Miraca Life Sciences	Irving, TX	2,260	53,895	125	0	5,611	61,891
LabCorp	Research Triangle Park, NC	1,872	44,801	0	0	2,005	48,678
LabCorp/Genzyme Genetics	New York, NY	1,691	38,902	0	102	1,680	42,375
LabCorp/Esoterix	New York, NY	1,753	36,456	224	185	3,672	42,290
Pathologists Biomedical Labs	Lewisville, TX	1,421	32,721	102	57	4,258	38,559
Hematogenix Laboratory Services	Tinley Park, IL	1,168	34,659	58	0	1,221	37,106
Quest Nichols Institute	San Juan Capistrano, CA	2,190	32,268	30	194	1,518	36,200
NeoGenomics/Clarient	Aliso Viejo, CA	1,270	29,388	65	67	3,473	34,263
Dr. Abuel-Haija/Florida Cancer Specs	Fort Myers, FL	1,250	26,950	108	0	1,157	29,465
NeoGenomics	Fort Myers, FL	1,185	25,862	53	66	1,176	28,342
Dr. Li/Florida Cancer Specs	Fort Myers, FL	1,205	25,779	111	17	1,096	28,208

Quest Nichols Institute	Chantilly, VA	1,384	24,797	0	215	1,246	27,642
Dr. Olson/Florida Cancer Specs	Fort Myers, FL	1,154	24,931	94	0	1,076	27,255
Cytometry Specialists	Alpharetta, GA	861	22,494	59	371	2,560	26,345
Histopathology Services LLC	Suffern, NY	797	19,457	115	26	1,310	21,705
AmeriPath Texas	Irving, TX	790	19,254	30	95	1,277	21,446
siParadigm LLC	Oradell, NJ	842	18,945	13	230	1,229	21,259

Source: Medicare Part B Provider Utilization Data for 2015

CMS OFFICIALS SAY THEY ARE ON SCHEDULE (*cont'd from p. 1*)

According to Julie Khani, president of the American Clinical Laboratory Association (ACLA), officials at the meeting said there are 60 low-volume test codes for which they received inadequate data during the PAMA data collection process to determine preliminary market-based pricing and CMS is seeking input on how these codes should be priced. Khani said she had not seen the list of the 60 codes and noted that CMS still has not shared how many laboratories actually submitted data under the repricing initiative.

"We found comments by the agency this week troubling," Khani tells *Laboratory Economics*. "Questions remain about the integrity and accuracy of the data submitted. We don't believe CMS will be ready for the January implementation [of the new payment system]."

ACLA sent a letter to CMS Administrator Seema Verma in early June that urged the agency to revise its definition of "applicable laboratory" so that hospital laboratory outreach claims data is included in the calculations of new payment rates. ACLA has recommended delaying the effective date for the new CLFS rates until July 1, 2018 (or later).

Julie Allen, Senior Vice President of the District Policy Group, also is concerned about CMS's plans to move forward with the repricing initiative, but says she remains hopeful that the agency will delay the January 1, 2018, implementation, especially since the agency solicited comments on the initial data collection and reporting periods as part of its Physician Fee Schedule proposal issued July 21.

"That tells me that The Department of Health and Human Services (HHS) is trying to be thoughtful about this," says Allen, who represents the National Independent Laboratory Association (NILA). "I think HHS may be reflecting on the data received and trying to understand what if any problems exist and what is allowable for them to do under statute."

Automated Test Panels

During the meeting, CMS also sought input on how to price automated tests panels (ATPs). Under the current Medicare payment system, laboratories bill CMS using 23 CPT codes for chemistry analytes that Medicare pays as bundled services. PAMA stipulates that CMS must re-price individual CPT codes as the weighted median of private payer rates; however, many commercial payers use their own algorithms to bundle payments for these CPT codes. There has been ongoing concern that CMS would not be able to obtain valid data from laboratories for the individual CPT codes since prices are based on panels, not each individual component.

ACLA and NILA weighed in on the ATP conundrum during the Aug. 1 meeting of the Advisory Panel on Clinical Diagnostic Laboratory Tests. David Smalley, PhD, president of American Esoteric Laboratories, testified that payers are inconsistent in how they pay for ATPs and typically do not break out payment for each component of the bundle.

"When this happens, it is not possible for a laboratory to break out what is paid for each test because the payment issued is not attributed to the CPT codes billed," he said. "The complexity and inconsistency of how payers pay for chemistry tests, coupled with CMS's decision to impose a retrospective reporting process that our billing systems could not comply with, raises significant concerns about the integrity of the data CMS received."

At last year's meeting, the advisory panel proposed three possible options for paying for ATPs, including paying for individual tests but capping total payment or creating a new bundling system and establishing new codes for various combinations of tests. However, both NILA and ACLA say that neither one of those options is allowed under the statute.

"The statute says that the payment amount shall be equal to the weighted median that is derived from the information reported for each test," says ACLA in its comments. "Elsewhere, the statute states that CMS shall calculate a weighted median for each laboratory test with respect to which information is reported for a data collections period. This is regardless of how much data is reported for a particular test or from how many laboratories, and regardless of whether Medicare would pay more or less for a test than it has in the past."

Allen agrees, noting that the statute is clear and that NILA opposes any attempt by CMS to circumvent the statute to achieve its stated goal of capping payments. "Even before PAMA, CMS wanted to make significant reductions to test prices based on their perception of technological changes," she says. "I believe they're still trying to do that, even with PAMA in place."

Phased-In Medicare Rate Reductions of as Much as 50%

Meanwhile, at the 22nd Annual Financial Analyst Briefing as part of the American Association for Clinical Chemistry (AACC) recent meetings in San Diego, Charles Root, PhD, President and CEO of CodeMap LLC, presented his estimates on the new payment rates under PAMA. CMS is scheduled to announce the new CLFS rates for each code in September 2017. Remember that no code will be reduced by more than 10% in any given year from 2018-2020, and by no more than 15% per year thereafter. As the table below shows, Root anticipates that Medicare rates for most routine tests may ultimately be cut by 50% over the next few years.

POTENTIAL PAMA CUTS TO ROUTINE CODES

Test Name (Code)	*Current Medicare Reimbursement*	*Possible PAMA Price*	*% Change*
Lipid Panel	$18.24	$8.00	-56%
Comp. Metabolic Panel	14.39	6.00	-58%
PSA	25.06	12.00	-52%
TSH	22.89	12.00	-48%
A1C	13.22	7.00	-47%
CBC	10.59	5.00	-53%
Vitamin D	40.33	25.00	-38%

Source: Dr. Charles Root, CodeMap LLC.

QUEST LIKELY TO REGAIN UHC CONTRACT IN 2018 (*cont'd from p. 1*)

Quest had lost its contract with United Healthcare effective January 1, 2007. United Healthcare had been Quest's biggest customer, accounting for 7%, or $425 million, of its revenue in 2006. When the contract loss was announced in late 2006, Quest's former CEO Surya Mohapatra, PhD,

said that "it would have been fiscally irresponsible" to sign a new contract with United, given its "unreasonable demands" and "unilateral provisions."

Steve Rusckowski succeeded Mohapatra as Quest's CEO in 2012, and it's clear that regaining the United contract has been a top priority since then. Among the strategic steps taken by Quest to achieve that goal have been:

1) Quest hired Michael Cole as National Vice President of Health Plans in January 2015. Cole's previous experience included 10 years at United Healthcare, where his most recent title was National Vice President, Employer and Individual Markets.
2) Effective in November 2016, Quest outsourced its billing operations to United's subsidiary Optum. Under the 10-year contract, Quest's 2,400 revenue-cycle employees were hired by Optum.
3) As part of the Optum deal, Quest became the primary vendor for biometric screening services (wellness screenings) that Optum provides to its own employees and other employer/health plans.
4) Quest's AmeriPath never lost its contract with United and has remained an in-network provider for anatomic pathology services for more than 10 years.
5) Solstas Lab Partners (Greensboro, NC and Knoxville, TN), which Quest acquired in 2014, has remained a preferred provider for all United Healthcare plans in North and South Carolina and Tennessee.
6) Despite being out-of-network, Quest never stopped competing for United's patients. And Quest never took United off its Insurance Payer Lists given to ordering physicians, but instead added an asterisk with fine print that reads: "Quest Diagnostics accepts United Healthcare Products as an out-of-network provider through a complimentary network and discounts may apply." As a result, a significant amount of leakage has flowed to Quest at the expense of United, its members, and LabCorp.

A Quest spokesperson says that Quest has provided in-network coverage for United on a regional basis for many years and continues to have a large book of business with United today. However, Quest would not address the question of whether or not it would regain national in-network status with United next year.

LABCORP GETS EXCLUSIVE CONTRACT WITH AMERIHEALTH NJ

AmeriHealth New Jersey (Cranbury, NJ) is making LabCorp its exclusive national outpatient laboratory effective May 1, 2018. As part of the arrangement, AmeriHealth is ending its contracts with the following labs:

- Quest Diagnostics will be an out-of-network provider effective October 1, 2017.
  (Note: Quest is also losing its contract with AmeriHealth Pennsylvania effective October 1, 2017.)
- Bio-Reference Labs will be an out-of-network provider effective March 1, 2018.
- Health Network Labs will an out-of-network provider effective May 1, 2018.

The change applies to all AmeriHealth New Jersey product lines and members (all HMO, POS, PPO and EPO plans), including individual and group members and AmeriHealth administered plans. In total, AmeriHealth covers approximately 260,000 members throughout New Jersey.

AmeriHealth New Jersey says it will keep contracts with about 20 small community labs and specialty reference labs including Atlantic Diagnostic Laboratories, Brookside Clinical Laboratories, Exact Sciences, Genomic Health, Millennium Laboratories, NeoGenomics and Shiel Medical Laboratory.

AmeriHealth New Jersey says the "exclusive national outpatient laboratory network concept has been effective in helping other insurers contain costs without affecting quality."

AmeriHealth is majority-owned by Independence Blue Cross (IBC-Philadelphia), which covers 2.2 million members in the Philadelphia region. In July 2014, IBC ended its contract with Quest and signed an eight-year contract making LabCorp its exclusive national lab provider (see *LE*, April 2014).

HARD TRUTHS ABOUT LABORATORY BENEFIT MANAGEMENT

Third-party payers (i.e., health insurers) are increasingly contracting with fourth parties (i.e., laboratory benefit management companies) to enforce their medical necessity policies and control lab costs. That's adding another mouth to feed at the reimbursement table at the expense of labs and pathologists (patient + health insurer + lab benefit manager + lab/pathologist provider). It's also adding significant new manual administrative processes that labs must complete in order to get paid.

These were some of the takeaways from *Laboratory Economics'* special teleconference, "The Disruption of Lab Benefit Management: Hard Truths and Practical Tips for Labs," on July 27. Featured speakers included Jerry Garner, Vice President for Payer Relations at Bio-Reference Labs, and Steve Stonecypher and Andrew Stimmler from Shipwright Healthcare.

Some highlights from the teleconference follow:

BeaconLBS

LabCorp's BeaconLBS manages a prior notification system covering 80 routine tests for some 500,000 fully-insured United Healthcare members in Florida (expansion into Texas has been delayed). Garner says Bio-Reference initially resisted joining the BeaconLBS Laboratory of Choice (LOC) network, which requires price concessions from UHC's contracted rates in return for increased visibility and ease of ordering by referring physicians.

Jerry Garner

Garner says Bio-Reference and its GeneDx subsidiary became BeaconLBS LOC members effective January 1, 2017, primarily to improve collections. He notes that labs that are not part of the LOC network have difficulty obtaining the required AN (advanced notification) number from the BeaconLBS system which creates payment challenges.

As an LOC member, Garner says Bio-Reference has seen some marginal improvement with payment response and increased marketing visibility. According to Garner, challenges have included: 1) some physicians are still not using the BeaconLBS software; 2) BeaconLBS is not interfaced with all bi-directional EMRs; 3) very slow integration process with BeaconLBS and Bio-Reference's online ordering product; and 4) slow development of BeaconLBS' PDS-Q back-end product for non-interfaced physicians.

Separately, United Healthcare has announced plans to implement a pre-authorization program for genetic and molecular tests effective October 1, 2017 (see *Laboratory Economics*, June 2017). The program will apply to United's fully-insured commercial members nationwide, except in Florida and Texas. United has not yet announced which LBM company will administer this program.

Avalon Healthcare

Since January 1, 2016, Avalon Healthcare Solutions (Tampa, FL) has managed a lab network for BCBS of South Carolina that covers lab tests performed at hospitals (POS 22 and 19), physician offices (POS 11) and independent labs (POS 81). Effective March 1, 2017, Avalon is also managing a lab network for BCBS of North Carolina covering only independent labs (POS 81).

Steve Stonecypher

Avalon takes on financial risk to guarantee to payers a certain level of lab spend savings achieved by negotiating lower rates from in-network labs and managing utilization.

Stonecypher estimates that the level of rate cuts demanded by lab benefit network managers (Avalon or BeaconLBS) ranges from 10-30% off current fees. "They are pushing for the biggest cut a lab is willing to take. Since there is no specific fee schedule, or a take it or leave it schedule, for any of the LBNs, there is some flexibility to the cut. So the cuts can be smaller, or larger, depending on how hard the lab pushes back, as well as how bad the LBN wants them in the network," according to Stonecypher.

Garner said that Avalon's in-network labs receive one electronic remittance advice (ERA), or 835 file, from the health plan with claim payment information, and a second adjusted ERA from Avalon that shows the discounted lab network rate that is actually paid. As a result, labs have to adjust their systems so that autopost claim payments from the health plan do not overstate revenue.

eviCore Healthcare

eviCore, formerly named CareCore National, was initially focused on utilization management of diagnostic imaging services, but has been expanding into prior authorizations for high-cost molecular and genetic tests. Its health plan clients include Aetna, Cigna and various BCBS plans. eviCore currently has one of the less intrusive LBM programs, although it has indicated that it may begin offering lab network management services.


Andrew Stimmler

Stimmler noted that eviCore recently agreed to pay $54 million to settle a False Claims lawsuit accusing it of blindly approving hundreds of thousands of unnecessary radiology tests between 2007 and 2013 for Medicare and Medicaid patients (see *Laboratory Economics*, June 2017). Stimmler said the case illustrates the potential for LBM companies to underestimate and get overwhelmed by the volume of test orders.

Garner noted that in some cases, eviCore's medical necessity policies for some lab tests have contradicted those developed by its health plan clients, causing unnecessary denials. "The role of a lab's accounts receivables manager and their ability to contest denied claims has become more important than ever."

Anthem's AIM Specialty Health

Effective July 1, AIM has begun performing pre-authorization reviews on most genetic testing for Anthem's fully-insured members, except in California and Virginia. The program requires in-network physicians to use an online AIM portal when ordering some 45 different types of genetic tests, including prenatal genetic testing, pharmacogenomics tests linked to cancer drugs and genetic tests for hereditary cancer risk.

AIM requires that the ordering provider request the pre-authorization (PA) within two weeks of the date of service. Unlike the policies of other LBM companies, AIM does not allow the laboratory personnel to file the PA request on behalf of the ordering physician. "Labs need to have the ability to file a PA because we're bearing the financial liability of an unpaid claim or the expense of appealing a claim."

Garner notes that obtaining prior authorization from an LBM company does not guarantee that the claim will get paid. This is usually due to the claim not matching the PA approval. For example, when the claim is submitted with CPT codes that don't align with the original request. These can often be appealed on the back-end.

Finally, Garner advises labs to designate a specific individual to be the liaison to maintain an active dialogue with each LBM company. "LBM companies are intended to augment the expertise in laboratory medicine for health plans. However, sometimes the individuals actually working for lab benefit management companies don't have any lab experience either, which seem to be contradictory to the whole point."

SPOTLIGHT INTERVIEW WITH EXACT SCIENCES' ANA HOOKER

Exact Sciences, the maker of Cologuard, has experienced tremendous growth since launching the noninvasive colorectal cancer screening test in 2014, due in part to increased insurer coverage and a direct-to-consumer marketing campaign. *Laboratory Economics* recently spoke with Ana Hooker, Senior Vice President of Operations, about the company's growth.

Ana Hooker

How many labs do you operate and where? What type of capacity do you have?
We operate one laboratory in Madison, Wisconsin. We have capacity for about 1 million Cologuard tests per year, but we are expanding our current laboratory to double that. We are also building a new laboratory in the Madison area.

Cologuard has grown rapidly from performing just over 100,000 tests in 2015 to 244,000 in 2016. To what do you attribute this growth? What is the potential market for this test?
The potential market for the test is about 80 million people – anyone who is older than 50 and at average risk for colon cancer. In 2017, we expect to complete at least 550,000 Cologuard tests. More insurance companies are covering the test after the U.S. Preventive Services Task Force included it in its colon cancer screening recommendations in 2016. Also, we have been using direct-to-consumer advertising, which has really helped build awareness. We have a very effective sales team as well that works directly with physician offices. We have more than 250 people doing outside sales and more than 100 doing inside sales. Since Cologuard was launched, about 81,000 providers have ordered it, a number that's increasing at more than 800 per week.

What are the benefits of Cologuard versus a traditional colonoscopy?
Cologuard is non-invasive and can be completed in the privacy of a person's home. There is no prep required, and people can complete Cologuard at a time that's convenient. Also, because Cologuard is a DNA-based test, the results from our lab are consistent for detecting cancer and pre-cancer, thus avoiding any human error.

What were your revenues in 2016? What are your projections for 2017?
In 2016, our revenues were more than $99 million, which was a 125% increase over 2015. For 2017, we are projecting $230 million to $240 million in revenue. The average revenue per Cologuard test is about $428.

Do you have other tests in the pipeline?
Yes, we've been working with Mayo Clinic since 2009, and right now we are identifying different DNA biomarkers for other deadly cancers, such as lung cancer. We are looking at the potential of a blood-based biomarker test. We did a study with Mayo that found methylation markers that are capable of detecting all types and stages of lung cancer with more than 90% sensitivity and specificity. We're still trying to decide how we'll go forward with this, but it could be something that helps to aid in the diagnosis of lung cancer.

How will the new Medicare payment system for clinical laboratory tests, scheduled to take effect January 2018, affect your bottom line?
We believe that since Medicare is the largest insurer, they should get the best price, so we negotiate payment with insurers at or above the Medicare rate. We don't anticipate big changes to payment from the new Medicare payment system. Cologuard is billed under CPT 81528 at a national Medicare rate of $512. Medicare was about 62% of Cologuard volume during the second quarter of 2017.

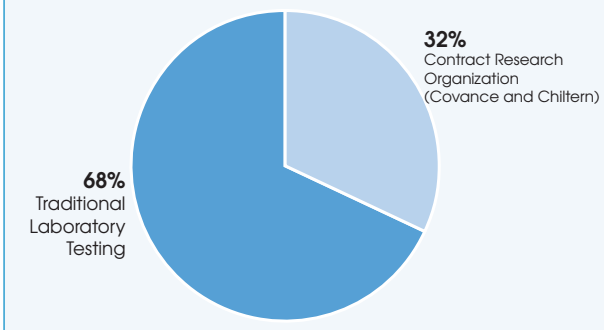
What are your biggest challenges?
Recruiting and staffing and making sure we have enough people. We currently have more than 1,000 employees and about 250 open positions. It depends on the role, but we get the majority of the workforce from the local area.

LABCORP TO ACQUIRE CHILTERN FOR $1.2 BILLION

LabCorp has agreed to buy Chiltern (London, UK and Wilmington, NC) in a $1.2 billion all-cash deal expected to close in the fourth quarter. Chiltern is a contract research organization (CRO) that provides clinical services for pharmaceutical and medical device companies. Chiltern will be merged into LabCorp's Covance segment, which it acquired for $6.1 billion in February 2015.

Chiltern has more than 4,500 employees around the world with forecasted 2017 revenue and adjusted EBITDA of about $550 million and $95 million, respectively. Based on the deal price, LabCorp is paying a 2.2 times sales multiple and 12.6 times adjusted EBITDA multiple for Chiltern.

LabCorp's Revenue Mix



Source: *Laboratory Economics*

The $1.2 billion purchase will put some pressure on LabCorp´s balance sheet. LabCorp ended the second quarter with $300 million in cash and a net debt load of $5.8 billion, a number that will jump to $7 billion with the purchase of Chiltern.

The acquisitions of Covance and now Chiltern are diversifying LabCorp's revenue and lowering its risk from likely substantial Medicare rate cuts for its laboratory business starting in 2018. With the addition of Chiltern, LabCorp will have total annual revenue of more than $10 billion, including 68% from its lab business and 32% from its CRO segment.

On the other hand, LabCorp's expansion into CRO services has its own risks. Covance has lagged in performance since becoming part of LabCorp. Covance's operating earnings were $91.9 million for the six months ended June 30, 2017, a decrease of 34% over operating earnings of $138.4 million in the same period of 2016. Covance's revenue decreased 2.6% to $1.39 billion during the latest six-month period.

LabCorp at a Glance (based on projections for 2017, in $ millions)

	LabCorp Diagnostics	*LabCorp Covance*	*Chiltern*	*Total*
Revenue	$7,100	$2,880	$550	$10,530
Pretax income	$1,230	$260	$75	$1,565
Employees	36,500	15,500	4,500	56,500

Source: *Laboratory Economics*

QUEST PAYS $150 MILLION FOR MED FUSION AND CLEAR POINT

Quest Diagnostics reports that it completed its previously announced acquisition of Med Fusion and ClearPoint Diagnostic Labs (both based in the Dallas area) on July 14. Quest paid $150 million in an all-cash transaction for both lab companies (see *LE*, June 2017).

In addition, Quest reports that it paid $102 million to acquire the outreach laboratory services operations of PeaceHealth Laboratories on May 1. Under a professional laboratory services agreement, Quest will also manage 11 laboratories, which PeaceHealth will continue to own (see *LE*, March 2017).

INVITAE TO BUY GOOD START GENETICS AND COMBIMATRIX

Invitae Corp. (San Francisco, CA), which specializes in genetic testing for hereditary disorders, has announced two separate acquisition deals:

On August 4, Invitae purchased Good Start Genetics (Cambridge, MA) for $40 million, including approximately $16 million worth of Invitae stock, or approximately 1.7 million shares, plus $24 million in cash. Good Start markets pre-pregnancy genetic testing and carrier screening for inherited disorders. The company was founded in 2008 and had raised a total of approximately $60 million from equity and debt offering from four private investment firms: OrbiMed Advisors, Safeguard Scientifics, SV Life Sciences and CRG LP. Good Start recorded a net loss of $18.1 million on revenue of $22.5 million in 2016.

Invitae has also agreed to buy CombiMatrix Corp. (Irvine, CA) in a deal expected to close by year's end. Invitae will exchange approximately $33 million worth of its shares for CombiMatrix's common stock and warrants. CombiMatrix operates a 13,000-square-foot laboratory and office in Irvine, California, focused on miscarriage analysis testing and preimplantation genetic testing for women undergoing in vitro fertilization. CombiMatrix recorded a net loss of $888,000 on revenue of $8 million for the six months ended June 30, 2017.

Invitae projects that combined company (Invitae, Good Start and CombiMatrix) will record a total net loss of approximately $120 million on revenue of approximately $97.5 million in pro forma full-year 2017. Invitae anticipates that it will turn cash-flow positive by the end of 2018.

Financial Snapshot of Invitae ($ millions)

	Actual 2016 Results				*Projected*
	Invitae	*Good Start Genetics*	*CombiMatrix*	*2016 Total*	*2017 Total*
Revenue	$25.0	$22.5	$12.9	$60.4	$90 to $105
Operating loss	-100.2	-15.0	-4.1	-119.3	-100 to -120
Net loss	-100.3	-18.1	-4.1	-122.5	-115 to -125

Source: Invitae Corp.

UNION OPPOSES SALE OF OUTREACH LAB TO QUEST

A Massachusetts healthcare union is seeking to block Cape Cod Healthcare's proposed sale of its outreach lab testing business to Quest Diagnostics (see *LE*, July 2017). The deal will result in the loss of 55 hospital lab jobs and potentially slow turnaround times jeopardizing patient safety, according to Jerry Fishbein, Vice President at 1199 SEIU United Healthcare Workers East. Members of 1199 SEIU sent a letter in early August to Massachusetts Health Policy Commission Executive Director David Seltz explaining their concerns. The transition requires approval by the Commission.

In a statement, Cape Cod Healthcare (CCH) said that it is being forced to outsource its outreach lab services because private insurers and government payers have "made it clear that they do not expect to continue to reimburse us for the full cost of our lab testing in the long term."

If the transaction is finalized, Quest plans to shift outreach lab testing now performed at core labs at Cape Cod Hospital and Falmouth Hospital to Quest's regional lab in Marlborough, Massachusetts (located approximately 100 miles north).

SONIC AND NYU LANGONE HEALTH TO FORM JOINT VENTURE

Sonic Healthcare USA (Austin, TX) and NYU Langone Health (New York City) have entered into a definitive agreement to form a joint venture, which will operate under the name of NYU Langone Diagnostics LLC. The partnership will focus on insourcing outreach laboratory services for NYU's more than 2,000 affiliated physicians at some 250 ambulatory facilities and physician practice locations throughout the New York City region.

Lab services for many of NYU's ambulatory sites are currently provided by competing labs such as Quest, LabCorp and Bio-Reference Labs. Noel Maring, Vice President of Hospital Affiliations for Sonic Healthcare USA, says testing for the JV will be performed by NYU labs as well as Sonic's Sunrise Medical Labs in Long Island with esoteric testing provided by Sonic Reference Laboratory in Texas. "There is no set menu or division of testing. Who performs which tests will vary depending on a number of factors, including the location of the physician and the capabilities of the closest NYU lab," according to Maring.

Sonic will become the primary reference laboratory for the JV. Inpatient referral testing from NYU Langone Health will not change immediately, and is still in discussion. This will be handled separately from the JV agreement, according to Maring.

The JV will become effective is September. Sonic will initially own 20% of the JV, with the potential to move to 51% ownership over time.

NYU Langone Health includes NYU Langone Medical Center Tisch Hospital (1,044 beds with a lab budget of $104 million per year), NYU Lutheran Medical Center in Brooklyn (388 beds with an annual lab budget of $16 million) and NYU Winthrop University Hospital in Long Island (591 beds with an annual lab budget of $29 million).

The joint venture with NYU Langone Health follows similar agreements that Sonic reached earlier this year with Western Connecticut Health Network and Baptist Memorial Health Care (Memphis, TN). Maring says Sonic has a strong pipeline of other potential health system deals in the United States.

Sonic Healthcare USA Reports 5% Growth

Separately, Sonic Healthcare reported that its U.S. lab division grew its revenue by 5.2% to $903 million in the 12 months ended June 30, 2017. Excluding the benefit of acquisitions, Sonic's U.S. lab revenue grew 3%.

Sonic CEO Colin Goldschmidt, MD, said potential decreases to Medicare lab rates scheduled for 2018 would impact about 20% of the company's U.S. revenue. But he added that rate cuts will put pressure on smaller and medium-sized labs that have high levels of exposure to Medicare and could create new M&A opportunities for Sonic.

ARUP NAMES NEW CEO AND PRESIDENT

ARUP Laboratories (Salt Lake City, UT) has selected Sherrie Perkins, MD, PhD, as Chief Executive Officer, and Andrew Theurer as President.

Perkins has been serving as Senior Vice President of Research and Development at ARUP, as well as Professor, Vice-Chair, and Division Chief of Clinical Pathology. Theurer has been serving as Senior Vice President and Chief Financial Officer at ARUP. They will be replacing Edgar Braendle, MD, PhD, who has served as CEO and President of ARUP Laboratories for the past year.

ARUP, which is owned by the University of Utah, has 3,500 employees and annual revenue of more than $500 million.

LAB STOCKS UP 49% YTD

Sixteen lab stocks have risen by an unweighted average of 49% year to date through August 14. In comparison, the S&P 500 Index is up 12%. The top-performing lab stocks so far this year are Exact Sciences, up 190%; Cancer Genetics, up 189%; and CombiMatrix, up 183%. At the two largest public labs, LabCorp is up 22% and Quest Diagnostics is up 16%.

Company (ticker)	Stock Price 8/14/17	Stock Price 12/31/16	2017 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$3.90	$1.35	189%	$77	NA	2.8	3.7
CombiMatrix (CBMX)	7.50	2.65	183%	22	NA	1.5	3.5
Enzo Biochem (ENZ)	11.31	6.94	63%	525	15.9	4.9	5.9
Exact Sciences (EXAS)	38.74	13.36	190%	4,610	NA	27.2	13.9
Foundation Medicine (FMI)	39.60	17.70	124%	1,430	NA	11.9	11.2
Genomic Health (GHDX)	30.79	29.39	5%	1,070	NA	3.2	6.6
Invitae (NVTA)	9.90	7.94	25%	425	NA	10.6	5.1
LabCorp (LH)	156.50	128.38	22%	15,930	21.5	1.7	2.8
Myriad Genetics (MYGN)	27.87	16.67	67%	1,900	59.6	2.5	2.5
NeoGenomics (NEO)	9.34	8.57	9%	740	NA	3.0	4.4
Opko Health (OPK)	6.16	9.30	-34%	3,450	NA	2.9	1.6
Psychemedics (PMD)	20.95	24.99	-16%	115	14.1	2.7	7.0
Quest Diagnostics (DGX)	106.46	91.90	16%	14,520	21.4	1.9	3.2
Rosetta Genomics (ROSG)	1.69	5.04	-66%	4	NA	0.4	0.7
Sonic Healthcare (SHL.AX)	23.08	21.40	8%	9,680	21.8	1.9	2.6
Veracyte (VCYT)	8.09	7.74	5%	274	NA	3.8	5.1
Unweighted Averages			49%		25.7	5.2	5.0

Source: Capital IQ

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