

# LABORATORY



# ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## ACLA Wins Appeals Court Decision; HHS Likely To Request Rehearing

**O**n July 30, the U.S. Court of Appeals for the District of Columbia ruled in favor of the American Clinical Laboratory Assn. (ACLA) in its suit against the U.S. Department of Health and Human Services (HHS) regarding implementation of the Protecting Access to Medicare Act (PAMA). The ruling overturned a D.C. District Court decision that dismissed ACLA’s lawsuit on the grounds that PAMA law prohibits judicial review of CMS’s “establishment of payment amounts” for clinical lab tests.

However, before the case goes back to D.C. District Court for review on its merits, HHS is likely to request either a rehearing of the D.C. Court of Appeals’ three-judge panel decision or petition for a rehearing en banc from a broader panel of judges. *Continued on page 4.*

## Technical Rates for Many Pathology Services To Get Small Boost Under Proposed MPFS

**T**he Proposed Medicare Physician Fee Schedule (MPFS) for 2020 includes a 5% hike to the technical component for CPT 88305, which, if finalized, would raise it to \$32.12. Meanwhile, the rate for the professional interpretation is being lowered by a proposed 1% to \$39.34. Overall, the global rate for CPT 88305 will increase by a proposed 2% to \$71.46.

In general, technical component fees for many key surgical pathology services (e.g., CPT 88305, 88307 and 88309) and special stains (e.g., CPT 88312 & 88313) are proposed to increase, while most professional interpretation rates are set for no change or small reductions.

Meanwhile, a few areas where pathologists and labs will see significant rate reductions are cytopathology, flow cytometry and prostate biopsies. *Continued on page 5.*

## Three Genomic Labs Raise \$573 Million From IPOs

**I**n spite of payer coverage, reimbursement and claims denial challenges, three genomic testing lab companies raised a combined \$573.5 million from IPOs in June and July. None of the three companies—Adaptive Biotechnologies, Personalis Inc. and Castle Biosciences—is profitable, but shares of each company skyrocketed on their first day of trading with gains ranging from 34% to 101%. *Full details on page 2.*

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**Three Genomic Labs Raise \$573 Million From IPOs** *(cont'd from page 1)*

**ADAPTIVE BIOTECHNOLOGIES** (Seattle, WA) raised gross proceeds of \$345 million from the sale of 17.25 million shares at a public offering price of \$20. Its shares jumped 101% to close at \$40.30 on their first day of trading on the Nasdaq on June 27.

Adaptive markets a proprietary test named ClonoSEQ that detects and monitors the remaining number of cancer cells present in a patient's bone marrow during and after treatment. In October 2018, the FDA cleared ClonoSEQ for use in patients with multiple myeloma and acute lymphoblastic leukemia, and Adaptive is working on getting the test approved for use in chronic lymphocytic leukemia and non-Hodgkin's lymphoma. Testing is performed at Adaptive's CLIA-certified lab in Seattle and is billed using the miscellaneous code CPT 81479. The price per ClonoSEQ test is approximately \$1,800.

In partnership with Microsoft, Adaptive is also developing a diagnostic product, immunoSEQ Dx, that may diagnose dozens of diseases at once from a single blood test. As part of the deal, Microsoft invested \$45 million in Adaptive in late 2017. In return, Adaptive committed to spending a minimum of \$12 million on Microsoft's Azure cloud services over the lifetime of the seven-year deal.

In addition, Adaptive is developing new T-cell cancer drugs through a collaboration agreement with Roche subsidiary Genentech.

Chief Executive Chad Robins, age 44, and his brother Chief Scientific Officer Harlan Robins, PhD, age 45, co-founded Adaptive in September 2009. Each brother owns 4.2 million shares of Adaptive currently worth about \$176 million.

During the latest available 12-month period (ended March 31, 2019), Adaptive recorded a net loss of \$52.4 million on revenue of \$58.6 million. Adaptive has accumulated losses totaling \$314.5 million since being formed 10 years ago.

Adaptive will receive net IPO proceeds of approximately \$317 million after deducting \$28 million of investment bank commissions and other expenses. The company plans to use the proceeds to commercialize and market its tests, and to fund continued research and development for its drug discovery initiatives.

**PERSONALIS INC.** (Menlo Park, CA) raised gross proceeds of \$155 million from the sale of 9.1 million shares at a public offering price of \$17. Its shares rose by 68% to close at \$28.49 on their first day of trading on the Nasdaq on June 20.

Personalis has developed a next-gen sequencing system (ImmunoID Next platform) that analyzes all 20,000 human genes on the DNA and RNA level, thus offering a comprehensive analysis of a tumor from a single tissue sample. The company is also developing a complementary liquid biopsy test, which can perform the same broad 20,000-gene analysis from a blood sample. Testing is performed at the company's CLIA-certified lab in Menlo Park.

Among the company's biggest clients is the U.S. Department of Veterans Affairs, which is conducting a 10-year research (2011-2021) project on up to one million veterans aimed at better understanding how genetic variations affect health. Other clients have included Merck and Pfizer. In addition to contract research testing, Personalis plans to start marketing a clinical diagnostic test based on its ImmunoID Next platform by year's end.

Personalis was founded in 2011 as a Stanford University spin-out by its Chief Executive John West, age 62, and four Stanford professors, Euan Ashley, MD, PhD, Atul Butte, MD, PhD, Russ Altman, MD, PhD, and Michael Snyder, PhD. West owns 1.6 million shares of Personalis currently worth approximately \$30 million. Stanford University owns 1.4 million shares valued at about \$26 million.

During the latest available 12-month period (ended March 31, 2019), Personalis recorded a net loss of \$20.2 million on revenue of \$47.7 million. Personalis has accumulated losses totaling \$121.2 million since its inception.

Personalis received net IPO proceeds of approximately \$141 million after deducting \$14 million of investment bank commissions and other expenses. The funds will be used to expand research and development, facilities expansion, and sales and marketing expenditures.

**CASTLE BIOSCIENCES INC.** (Friendswood, TX) raised gross proceeds of \$74 million from the sale of 4.6 million shares at a public offering price of \$16. Its shares rose by 34% to close at \$21.40 on their first day of trading on the Nasdaq on July 25.

Castle markets a proprietary test named DecisionDx-Melanoma for predicting metastatic risk in patients diagnosed with early stage cutaneous (skin) melanoma. The test analyzes 31 genes from a tissue sample and is used to decide whether or not to perform a sentinel lymph node biopsy surgical procedure. The test is performed at Castle's 12,000-square-foot CLIA-certified lab in Phoenix, Arizona at a list price of \$7,193.

During the latest available 12-month period (ended March 31, 2019), Castle recorded a net loss of \$4.1 million on revenue of \$27.8 million. Castle has accumulated losses totaling \$58.8 million since its inception.

Chief Executive Derek Maetzold, age 57, founded Castle Biosciences in September 2007. Maetzold owns 1.9 million shares of Castle currently worth approximately \$42 million.

Castle received net IPO proceeds of approximately \$68.4 million after deducting \$5.2 million of investment bank commissions and other expenses. The company intends to use about \$17 million for sales and marketing, including expansion of its sales force; \$17 million for R&D; and the remainder for working capital and general corporate purposes.

### Genomic Testing Lab IPO Summary

	Adaptive Biotech (ADPT)	Personalis Inc. (PSNL)	Castle Biosciences (CSTL)
Annual Revenue (TTM)	\$58.6 M	\$47.7 M	\$27.8 M
Annual EBITDA (TTM)	-\$50.3 M	-\$15.4 M	-\$1.0 M
Annual Net Loss (TTM)	-\$52.4 M	-\$20.2 M	-4.1 M
Year Founded	2009	2011	2007
Accumulated Losses	-\$314.5 M	-\$121.2 M	-\$58.8 M
IPO Date	June 27, 2019	June 20, 2019	July 25, 2019
IPO Gross Proceeds	\$345.0 M	\$154.9 M	\$73.6 M
Lead Underwriters	Goldman Sachs, JP Morgan, BofA Merrill Lynch	Morgan Stanley, BofA Merrill Lynch, Cowen	SVB Leerink, Baird
Market Cap (8/15/2019)	\$5.94 B	\$526.7 M	\$341.3 M
Market Cap/Revenue	101.4x	11.0x	12.3x

Source: *Laboratory Economics* from IPO Prospectuses

## ACLA Wins Appeals Court Decision (cont'd from page 1)

The D.C. Court of Appeals concluded that the statutory provision stripping jurisdiction to review payment amounts does not cover the statute's data-collection provision. It ruled that the case be sent back to D.C. District Court to determine whether or not HHS/CMS violated PAMA by excluding hospital outreach labs from the first private-payer payment survey used to set Medicare CLFS rates for 2018 to 2020.

HHS has 45 days to petition for either a rehearing or rehearing en banc. The D.C. Court of Appeals has ordered that the case be held from being sent back to the D.C. District Court "until seven days after disposition of any timely request for rehearing or petition for rehearing en banc."

It's unlikely that any request by HHS for a rehearing will be granted, but the process will delay final resolution of the lawsuit, which is now approaching two years since initially being filed in late 2017.

More likely than not, the D.C. Court of Appeals will uphold its initial decision and send the lawsuit back to D.C. District Court. But the D.C. District Court proceedings could be lengthy, taking anywhere from six months to more than two years, before a decision is rendered.

Nonetheless, the Appeals Court decision is a victory for ACLA that will put pressure on HHS/CMS to negotiate with ACLA for a potential settlement of the lawsuit. ACLA and its biggest members, LabCorp and Quest Diagnostics, are lobbying hard to delay the next private-payer payment data reporting period (currently scheduled for January 1 to March 31, 2020) by one year. In addition, the lab industry wants CMS to use statistical sampling when it calculates new CLFS rates for 2021 to ensure that all lab segments (independents, hospital outreach labs and POLs) are properly represented.

### Timeline of PAMA Lawsuit

April 1, 2014	President Obama signs The Protecting Access to Medicare Act (PAMA) into law.
June 17, 2016	CMS issues Final Rule excluding hospital outreach labs from reporting their private-payer payment amounts.
December 11, 2017	ACLA files lawsuit challenging CMS's narrow definition of "applicable labs" required to report.
January 1, 2018	First round of 10% rate cuts for most lab tests on the CLFS takes effect.
September 21, 2018	D.C. District Court dismisses ACLA's lawsuit due to "Lack of Jurisdiction."
October 19, 2018	ACLA appeals D.C. District Court's ruling.
November 1, 2018	CMS issues Final Rule broadening its definition of "applicable labs." Hospital outreach labs are now required to report in the second PAMA reporting cycle (January 1 to March 31, 2020).
January 1, 2019	Second round of 10% rate cuts for most lab tests on the CLFS takes effect.
July 30, 2019	D.C. Court of Appeals overturns the D.C. District Court's September 2018 ruling and sends case back to the D.C. District Court for adjudication.
August/September 2019	HHS expected to petition D.C. Court of Appeals for rehearing or petition for rehearing en banc.
January 1, 2020	Third round of 10% rate cuts for most lab tests on the CLFS is scheduled to take effect.
January 1, 2021	The second PAMA rate setting cycle takes effect with potential annual rate cuts raised to a max of 15% for lab tests on the CLFS.

Source: Laboratory Economics

**TC Rates for Most Pathology Services To Get A Small Boost** *(cont'd from p. 1)*

Overall, including a 0.1% hike in the Conversion Factor, CMS estimates that the proposed changes will have no overall effect on Medicare Part B professional payments made to pathologists in 2020 compared with 2019, while lab technical rates will increase by 1%. Final rates are expected to be announced in October/November and will become effective January 1, 2020.

**Special Stains**

The global rate for CPT 88312 (Special stains, group 1) is proposed to increase by 4.7% to \$106.83; professional interpretation up 0.1% to \$27.79; technical component up 6.5% to \$79.04.

The global rate for CPT 88313 (Special stains, group 2) is proposed to increase by 4% to \$76.87; professional interpretation up 0.2% to \$12.63; technical component up 4.8% to \$64.24.

**Immunohistochemistry**

The global rate for CPT 88342 (IHC, first stain procedure) is proposed to decrease by 1.2% to \$107.19; professional interpretation down 0.8% to \$36.81; technical component down 1.4% to \$70.37.

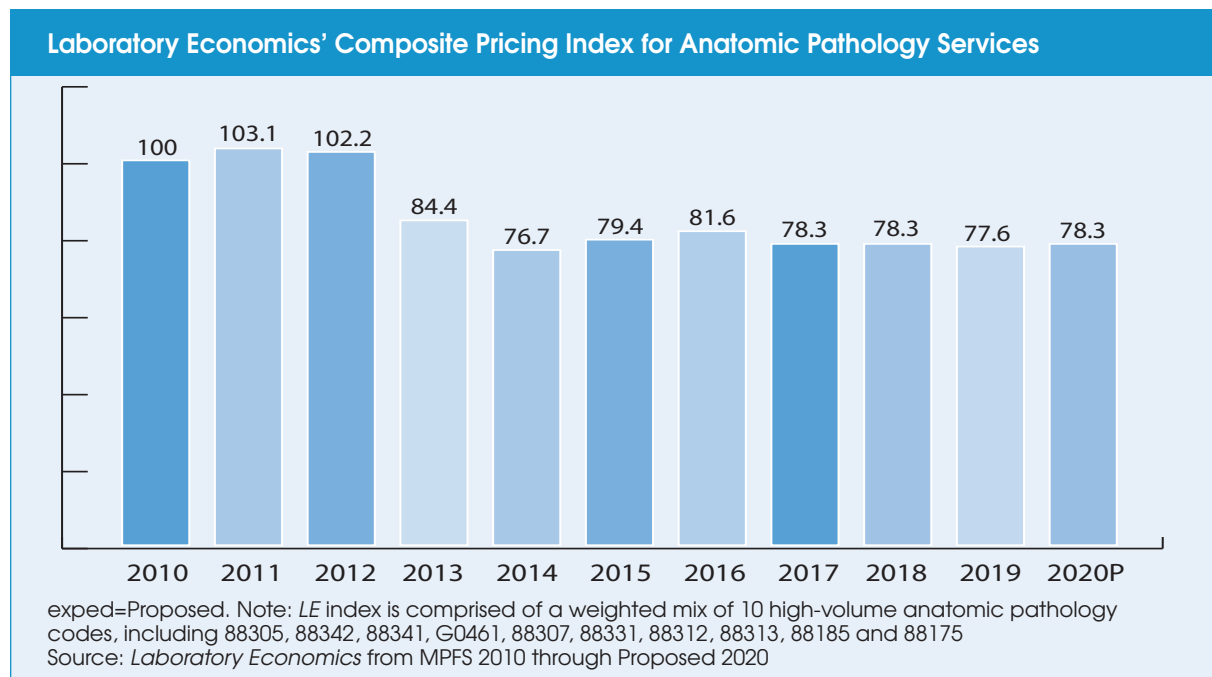
The global rate for CPT 88341 (IHC, additional slide) is proposed to decline by 0.2% to \$94.19; professional interpretation up 0.1% to \$29.95; technical component down 0.4% to \$64.24.

**Prostate Biopsies**

Global reimbursement for G0416 is proposed to decline by 10% to \$347.54, including a 19% cut to the technical component. If finalized, global reimbursement for the typical 12-core prostate biopsy will have been slashed by a whopping 73% over the past eight years. The good news is that 2020 will be the last year of the phase-in cuts to G0416 from its most recent misvalued code revaluation in 2015/2016.

**Flow Cytometry**

Following significant cuts made in 2017-2019, a final cut for the key flow cytometry procedure CPT 88185 (flow cytometry, TC, add on) is proposed for 2020. CPT 88185 is scheduled to drop by 10% to \$22.38. This will complete the phased-in cuts for CPT 88185 under Medicare's Misvalued Code Initiative.





**Proposed Medicare Rate Changes for Key Pathology Codes for 2020**

<b>CPT/HCPCS</b>	<b>Short Description</b>	<b>Proposed 2020<sup>1</sup></b>	<b>Actual 2019<sup>2</sup></b>	<b>Proposed Rate % Change</b>
88120-Global	FISH-manual, 3-5 probes	\$587.18	\$608.70	-3.5%
88120-26	FISH-manual, 3-5 probes	60.27	60.19	0.1%
88120-TC	FISH-manual, 3-5 probes	526.91	548.52	-3.9%
88121-Global	FISH-computer assisted, 3-5 probes	448.59	488.33	-8.1%
88121-26	FISH-computer assisted, 3-5 probes	50.89	51.18	-0.6%
88121-TC	FISH-computer assisted, 3-5 probes	397.71	437.15	-9.0%
88184-TC only	Flow cytometry/1st marker	67.85	67.75	0.1%
88185-TC only	Flow cytometry/each add'l marker	22.38	24.87	-10.0%
88187-26 only	Flow cytometry, read 2-8	38.98	38.92	0.2%
88188-26 only	Flow cytometry/read 9-15	66.41	65.95	0.7%
88189-26 only	Flow cytometry, read 16 & greater	88.06	88.30	-0.3%
88305-Global	Tissue exam by pathologist	71.46	70.28	1.7%
88305-26	Tissue exam by pathologist	39.34	39.64	-0.8%
88305-TC	Tissue exam by pathologist	32.12	30.63	4.9%
88307-Global	Level V, tissue exam by pathologist	281.50	273.54	2.9%
88307-26	Level V, tissue exam by pathologist	86.98	86.85	0.1%
88307-TC	Level V, tissue exam by pathologist	194.52	186.68	4.2%
88309-Global	Level VI, tissue exam by pathologist	426.94	415.53	2.7%
88309-26	Level VI, tissue exam by pathologist	152.66	153.53	-0.6%
88309-TC	Level VI, tissue exam by pathologist	274.28	262.00	4.7%
88312-Global	Special stains, group 1	106.83	101.99	4.7%
88312-26	Special stains, group 1	27.79	27.75	0.1%
88312-TC	Special stains, group 1	79.04	74.24	6.5%
88313-Global	Special stains; group 2	76.87	73.88	4.0%
88313-26	Special stains; group 2	12.63	12.61	0.2%
88313-TC	Special stains; group 2	64.24	61.27	4.8%
88331-Global	Pathology consult during surgery	100.33	99.11	1.2%
88331-26	Pathology consult during surgery	65.32	65.59	-0.4%
88331-TC	Pathology consult during surgery	35.01	33.52	4.4%
88341-Global	Immunohistochemistry (Add'l stain)	94.19	94.42	-0.2%
88341-26	Immunohistochemistry (Add'l stain)	29.95	29.91	0.1%
88341-TC	Immunohistochemistry (Add'l stain)	64.24	64.51	-0.4%
88342-Global	Immunohistochemistry (1st stain)	107.19	108.48	-1.2%
88342-26	Immunohistochemistry (1st stain)	36.81	37.12	-0.8%
88342-TC	Immunohistochemistry (1st stain)	70.37	71.36	-1.4%
G0416-Global	Prostate biopsy, any method	347.54	386.34	-10.0%
G0416-26	Prostate biopsy, any method	185.5	185.60	-0.1%
G0416-TC	Prostate biopsy, any method	162.04	200.74	-19.3%

<sup>1</sup>Payments based on the 2020 conversion factor of 36.09; <sup>2</sup>Payments based on the 2019 conversion factor of 36.04

Source: *Laboratory Economics* from CMS

## LabCorp Mid-Year 2019 Review

LabCorp (Burlington, NC) reported net income of \$376 million for the six months ended June 30, 2019, down 7.6% from the \$407 million in the same period for 2018. Overall, LabCorp's reported half-year revenue was down by 0.7% to \$5.673 billion.

Looking specifically at LabCorp's lab testing business, revenue was down 2.8% to \$3.483 billion, including -2.9% from the sale of its food and forensic testing services businesses. On July 25, the company held a conference call with analysts and investors to discuss its mid-year results. Here's a summary of some key topics discussed:

### Volume Trends

Total volume (measured by requisitions and excluding the disposition of businesses) was flat with volume from acquisitions adding 0.1% and organic volume down by 0.2%. Volume was hurt by weakness in LabCorp's ancestry testing business whose primary client is 23andMe. LabCorp's 23andMe contract was a strong contributor to volume growth in previous years, but is now expected to trend flat to down for the foreseeable future, according to CEO Dave King. Meanwhile, growth areas included allergy testing and companion diagnostics for cancer drugs.

### United's Preferred Laboratory Network (PLN)

LabCorp is not expecting any significant boost from being in United's PLN in 2019. "The real long-term opportunity is in benefit design and it's also in creating appropriate incentives for patients and for physicians to use the more efficient lower-cost providers versus referring either out of network or to higher-cost providers who are in the network," said King. "I'm hopeful that in 2020, we're going to see some nice benefit from it," he added.

### Walgreens Patient Service Centers

"Our LabCorp Walgreens partnership is on track to have at least 125 stores by the end of this year, including sites at new space at major metropolitan markets [e.g., southern California and New Jersey]. We are on track to achieve our target of at least 600 locations by 2022," said King.

### Digital Pathology and AI

"I don't think you're going to see any material near-term impact. The idea with Mount Sinai [see *LE*, July 2019] is to introduce digital pathology, do side-by-side comparisons with actual pathologists and see how we optimize the use of digital pathology...to direct the pathologist toward the more complex and difficult cases," explained King. In related news, LabCorp recently made an investment in PathAI (Boston, MA) for an undisclosed amount. PathAI is developing AI-based decision support tools for digital pathology.

### LabCorp Mid-Year Financial Summary (\$ millions)

	6/30/2019	6/30/2018	% Chg
Total revenue	\$5,672.9	\$5,714.6	-0.7%
LabCorp Diagnostics	3,482.9	3,584.2	-2.8%
Covance Drug Development	2,201.0	2,132.6	3.2%
Operating cash flow	419.3	567.1	-26.1%
Capital expenditures	179.4	159.7	12.3%
Free cash flow	239.9	407.4	-41.1%
Pretax income	524.7	554.2	-5.3%
Net income	376.0	407.0	-7.6%
Diluted EPS	\$3.79	\$3.94	-3.8%
Est'd number of requisitions*	79.9	80.0	-0.1%
Est'd revenue per requisition*	\$44.58	\$44.45	0.3%

\*Excluding impact of divested food and forensic testing services businesses  
Source: LabCorp and *Laboratory Economics'* estimates

## Quest Diagnostics Mid-Year 2019 Review

Quest Diagnostics (Madison, NJ) reported net income of \$390 million for the six months ended June 30, 2019, down 1.5% from \$396 million in the same period for 2018. Overall, Quest's reported half-year revenue was up 1.1% to \$3.844 billion. Looking specifically at Quest's lab testing business: revenue was up 1.3% to \$3.684 billion, including 1.9% gained from acquisitions. On July 23, the company held a conference call with analysts and investors to discuss its mid-year results. Here's a summary of some key topics discussed:

### Catholic Health Systems Deal in Long Island

Quest recently won a contract to provide Catholic Health Services of Long Island with reference testing services as well as management of lab equipment, supplies, and procurement processes. The agreement covers six CHS hospitals, a core lab, a cancer center and an infusion center. Its flagship hospitals include Good Samaritan Hospital (537 beds/900 physicians), St. Catherine of Siena Medical Center (536 beds/800 physicians) and Mercy Medical Center (375 beds/700 physicians). Quest can typically save hospital labs anywhere from 10% to 20% of their costs under these types of agreements, according to Quest CEO Steve Rusckowski.

### Anthem's Rate Alignment Strategy

Anthem BCBS plans across the country have been cutting their hospital outreach rates for clinical lab and pathology services to levels that match their independent lab peers. "There are wide variations [in lab test pricing] where hospital rates can be 2 to 10 times higher than our rates.... We mentioned Anthem but I will also share that there is pressure from other payers, typically with those that we work with, to push down the [hospital] rates for all the ancillary services and obviously that includes lab tests.... Given the high percentage of health plans that have high deductibles and high out-of-pocket costs for these expensive hospital-based services, the payers are looking at more aggressive strategies to normalize the rates," noted Rusckowski.

### Preauthorization Requirements

"Preauthorization has been a huge driver of [payment] denials." Some of Quest's contracts with health insurance plans now include a waiver of preauthorization requirements. "It's an advantage for us from a physician ordering perspective.... and it's another element that we've gotten in some of our contracts," according to Quest CFO Mark Guinan.

### Retail-Based Patient Service Centers

"Right now, we have roughly 200 patient service centers between our Safeway relationship and Walmart. Walmart is about 70 of that. And we continue to evaluate the best path forward to eventually have about 50% of our 2,200 patient service centers in more retail-like settings," according to Rusckowski.

### Quest Diagnostics Mid-Year Financial Summary (\$ millions)

	6/30/2019	6/30/2018	% Chg
Total revenue	\$3,844	\$3,803	1.1%
Lab testing	3,684	3,638	1.3%
Other revenue	160	165	-3.0%
Operating cash flow	596	503	18.5%
Capital expenditures	132	151	-12.6%
Free cash flow	464	352	31.8%
Pretax income	478	493	-3.0%
Net income	390	396	-1.5%
Diluted EPS	\$2.86	\$2.84	0.7%
Est'd number of requisitions	87.3	83.9	4.0%
Est'd revenue per requisition	\$42.06	\$43.18	-2.6%

Source: Quest Diagnostics and *Laboratory Economics'* estimates



## LabCorp To Buy South Bend Med Foundation's Clinical Lab Business

LabCorp has reached an agreement to purchase the clinical laboratory testing business, including Pap testing, from South Bend Medical Foundation (SBMF-South Bend, IN) for an undisclosed amount. The deal is expected to close by the end of September. Reference tests will be sent to LabCorp's regional laboratory in Dublin, Ohio.

SBMF is keeping and will continue to operate its anatomic pathology and blood banking services. The not-for-profit SBMF says it will use the proceeds from the sale of its clinical lab to modernize its facilities and fund retiree pensions.

SBMF, which was formed in 1910 by a group of physicians, currently has more than 500 employees, including 14 pathologists. The company reported revenue of \$85.5 million in 2017, down from \$87.9 million in 2016, according to its latest available Form 990 tax reports.

South Bend Medical Foundation's Annual Revenue



## Cancer Genetics Inc. Sells Businesses To Raise Cash & Lower Debt

Cancer Genetics Inc. (Rutherford, NJ) has sold its clinical lab business to siParadigm LLC (Pine Brook, NJ) for an initial payment of approximately \$1 million, plus an earn-out based on test volume over the next 12 months. Cancer Genetics' clinical lab business specializes in cancer testing, and reported revenue of \$7.4 million in 2018, down from \$10.8 million in 2017.

siParadigm operates a cancer testing lab in northern New Jersey. The company was founded by its President Sherif A. Nasr, MD in 2003. Prior to founding siParadigm, Nasr was an Associate Medical Director at Quest Diagnostics.

In a separate transaction, Cancer Genetics sold its biopharma services business to Interpace Diagnostics (Parsippany, NJ) for approximately \$23.5 million, including assumed debt. The biopharma business, which reported revenue of \$14.8 million in 2018, performs molecular tests at labs in Rutherford, NJ and Research Triangle Park, NC for cancer drug development clients.

Following these transactions, Cancer Genetics will focus on its remaining discovery services business, which performs preclinical studies and provides testing services to guide new drug development for biotech and pharmaceutical companies. The company's discovery business generated revenue of \$5.2 million in 2018, up from \$3.7 million in 2017.

Cancer Genetics aims to lower debt, raise cash and trim losses through the sale of the two businesses. Since its inception in April 1999 through March 31, 2019, Cancer Genetics has accumulated losses of \$162 million. Most recently, the company reported a net loss of \$4.7 million on revenue of \$6.8 million for the three months ended March 31, 2019.

Cancer Genetics went public through an IPO in June 2013 and shortly thereafter its stock hit an all-time high of \$21 per share giving it a market value of \$100+ million. Most recently, its shares were trading at \$0.12 for a market capitalization of \$7 million.

## True Health Files For Chapter 11 Bankruptcy

**T**True Health Diagnostics (Frisco, TX) filed for Chapter 11 bankruptcy protection on July 30, blaming CMS's suspension of its Medicare payments since May 2017.

In its bankruptcy filing, True Health said it had less than \$50,000 of assets, and more than \$100 million in liabilities. The company's largest unsecured creditors include the investment bank Houlihan Lokey Capital (owed \$2 million), Roche Diagnostics (\$1.8 million) and the law firm Perkins Coie (\$1.3 million).

True Health, which markets advanced lipid test panels, was founded in 2014 by its CEO Chris Grottenthaler. The company jumped in size when it purchased Health Diagnostics Laboratory (HDL-Richmond, VA) for \$37 million from a bankruptcy court auction in late 2015. HDL went bankrupt in June 2015 soon after agreeing to pay the federal government \$47 million to settle claims it paid kickbacks to physicians in the form of a \$20 per specimen process and handling fee.

True Health operates a small lab and administrative office in the Dallas area and a 100,000-square-foot lab in Richmond. Prior to its Medicare suspension of payments, the company had a total of 400 employees and estimated annual revenue of approximately \$80-\$100 million, including more than \$25 million from Medicare.

True Health's problems began in May 2017 when CMS suspended its Medicare payments on the basis of "credible allegations of fraud." As part of this suspension, CMS imposed a 100% hold of all Medicare payments to True Health for services rendered to Medicare beneficiaries. At the time, this amounted to approximately \$2 million per month, or about 30% of True Health's total revenue.

In June 2017, CMS reduced the suspension to 35% of Medicare payments, withholding roughly \$800,000 per month from True Health. But this June, CMS raised the suspension back up to 100% once again based on "credible allegations of fraud."

True Health filed a lawsuit against CMS in early July seeking an emergency motion for a temporary restraining order. The company contends that it never received an adequate opportunity to challenge the merits of the suspension. "This Kafka-esque system, under which CMS can withhold over \$20 million without an explanation or an opportunity to challenge the suspension, and continually extend and complicate the suspension...has left True Health in financial ruin," according to the lawsuit.

A federal court dismissed True Health's lawsuit on July 22, enabling CMS to continue withholding payments. True Health laid off 80 employees on July 29, and says that unless additional funding is found or a "white knight" appears, it may need to shut down by the end of September.

Prior to its problems with CMS, True Health had quickly risen to the top of advanced lipid testing labs. True Health served 66,890 Medicare beneficiaries in 2016 and received \$41.2 million in Medicare Part B payments, according to data from CMS.

### Medicare Part B Payment Comparison for Advanced Lipid Testing Labs for 2016

Laboratory Company	Location	Total Beneficiaries Served	Total Tests	Total Medicare Payment	Avg. Payment Per Beneficiary	Avg. # Tests Per Beneficiary
True Health Diagnostics	Frisco, TX	66,890	1,917,778	\$41,224,413	\$616	29
Boston Heart Diagnostics	Framingham, MA	56,246	1,411,448	25,924,326	461	25
Quest/Cleveland HeartLab	Cleveland, OH	47,255	485,562	9,725,438	206	10
Spectracell Laboratories	Houston, TX	11,894	216,344	4,016,997	338	18
Atherotech/VAP Diagnostics	Birmingham, AL	19,216	172,055	3,176,746	165	9
Unweighted Averages					357	18

Source: Medicare Provider Utilization & Payment Data for 2016

## AMCA Data Breach Victim List Continues To Grow—What A Mess!

The list of laboratories affected by the data breach at American Medical Collection Agency (AMCA), which filed for bankruptcy on June 17, continues to grow. So far, at least 24 labs and more than 25 million patients are estimated to have been affected by the incident.

AMCA had been the nation's largest debt collector for past-due lab test bills. Hackers gained access to AMCA's online payment system between Aug. 1, 2018 and March 30, 2019. The target was patient credit card information, which is now being sold on the dark web (see *LE*, July 2019).

In addition to Quest Diagnostics, LabCorp and BioReference Labs, other former AMCA lab clients affected by the hack include many of Sonic Healthcare USA's subsidiary labs including Clinical Pathology Labs, Sunrise Medical Labs, CBLPath and American Esoteric Labs. In addition, Sonic acquired Aurora Diagnostics in January and many of its subsidiary labs had been AMCA clients as well. Other labs affected by the breach include CompuNet Clinical Labs, Inform Diagnostics, Natera and Penobscot Community Health Center in Maine.

The AMCA data breach is a huge headache for both the legal and information technology departments at affected labs. For example, Quest Diagnostics says that approximately 31 class action lawsuits related to the AMCA data hack have been filed against it. In addition, Attorneys General offices from numerous states and the District of Columbia and certain U.S. senators are investigating the situation and requesting information from affected labs.

And finally, there is also the question of what happens to the legitimate past-due balances owed by more than 25 million patients to the affected labs? Assuming an average past-due balance of \$20 per patient and a collection rate of 10% suggest there might be a total of \$50 million worth of writeoffs incurred by former AMCA lab clients.

## Exact Sciences To Buy Genomic Health For \$2.8 Billion

Exact Sciences (Madison, WI) has agreed to acquire Genomic Health (Redwood City, CA) for \$2.8 billion, comprised of \$1.1 billion of cash and \$1.7 billion in stock. The deal works out to be a total of roughly \$2.5 billion, after accounting for the \$243 million of cash that Genomic Health has on its balance sheet. At \$2.5 billion, Exact is paying 5.8x for Genomic Health trailing 12-month revenue of \$429 million and 50x its net income of \$50 million.

Genomic Health's flagship product is OncotypeDx, which analyzes 21 genes in a patient's breast cancer tumor tissue to guide treatment. The test is performed at the company CLIA-certified lab in northern California. Medicare reimbursement is \$3873 (CPT 81519).

Exact Sciences performs its FDA-cleared Cologuard colorectal cancer screening test at its lab in Madison, Wisconsin. Medicare reimbursement is \$509 (CPT 81528).

Both labs are expected to remain in operation and Exact only expects to achieve \$25 million of annualized cost savings, primarily through reduced public company costs and certain purchasing volume savings. *Laboratory Economics* will take a closer look at this deal in our next issue.

### Exact Sciences & Genomic Health (\$ millions)

	<i>Exact Sciences</i>	<i>Genomic Health</i>	<i>Combined</i>
Revenue (TTM)	\$623.2	\$428.8	\$1,052.0
EBITDA (TTM)	-164.2	56.9	-\$107.3
Net income (TTM)	-220.8	50.1	-\$170.7
Accumulated losses	-1,157.2	-207.4	-\$1,364.6
Total Employees	1,977	829	2,806

TTM=trailing 12 months ended June 30, 2019

Source: *Laboratory Economics* from Exact Sciences and Genomic Health

## Lab Stocks Up 35% Year To Date

Nineteen lab stocks have risen by an unweighted average of 35% year to date through August 16. In comparison, the S&P 500 Index is up 15% so far this year. The top-performing lab stock thus far in 2019 is Guardant Health, which has jumped 170%, followed by Invitae, up 128%, and Veracyte, up 104%. Shares of LabCorp are up 31%, while Quest Diagnostics is up 21%.

Company (ticker)	Stock Price 8/16/19	Stock Price 12/31/18	2019 Price Change	Enterprise Value (\$ millions)	Enterp Value/ EBITDA	Enterp Value/ Annual Revenue
LabCorp (LH)	\$166.15	\$126.36	31%	\$23,460	12.4	2.1
Quest Diagnostics (DGX)	100.60	83.27	21%	17,970	12.1	2.4
Sonic Healthcare (SHL.AX)	27.28	22.11	23%	15,130	16.3	2.6
Exact Sciences (EXAS)	119.82	63.10	90%	14,890	NA	23.9
Guardant Health (GH)	101.52	37.59	170%	8,940	NA	61.6
Genomic Health (GHDX)	74.64	64.41	16%	2,600	45.7	6.1
NeoGenomics (NEO)	25.24	12.61	100%	2,470	54.3	7.2
Invitae (NVTA)	25.17	11.06	128%	2,280	NA	12.9
Myriad Genetics (MYGN)	25.35	29.07	-13%	1,970	19.2	2.3
Natera (NTRA)	28.26	13.96	102%	1,900	NA	7.0
Opko Health (OPK)	1.96	3.01	-35%	1,420	NA	1.5
Veracyte (VCYT)	25.64	12.58	104%	1,030	NA	9.4
CareDx (CDNA)	23.63	25.14	-6%	943	NA	9.2
Enzo Biochem (ENZ)	3.22	2.78	16%	94	NA	1.1
Castle Biosciences (CSTL)	20.25	16.00	27%	93	NA	3.3
Psychemedics (PMD)	7.44	15.87	-53%	42	5.0	1.1
Interpace Diagnostics (IDXG)	0.76	0.80	-5%	25	NA	1.0
Cancer Genetics Inc. (CGIX)	0.11	0.24	-51%	22	NA	0.8
Biocept (BIOC)	0.92	0.86	7%	7	NA	1.8
Unweighted Averages			35%	\$95,285	23.6	8.3

Source: *Laboratory Economics* and Capital IQ

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