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Startup LabFinder Wants to Better Connect Patients with the Right Labs

A New York City physician has started up a business that aims to be a price and services clearinghouse and records depository for patients wishing to choose specific laboratories.

Robert Segal, M.D., is a cardiologist rather than a pathologist. But he said he founded LabFinder because of the ongoing stream of complaints he received from his insured patients about charges from out-of-network labs they thought their insurance carrier covered.

“We want to make the jobs of patients easier, and complement individual laboratories and their patient portals,” Segal said. He added that the ultimate goal is closer interworking relationships among patients, labs, physicians and insurers, which he noted are often siloed. LabFinder has about \$5 million in financial backing from private in-

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Quest Enters Into Management Agreement with Denver-Based Hospital System

Quest Diagnostics has continued its expansion into the sphere of hospital laboratory operations, this time entering into a pact with the Denver-based HealthONE System. An affiliate of the for-profit HCA, Inc. chain, HealthONE operates eight hospitals in Colorado.

Under the terms of the agreement, Quest will manage the laboratories of six of the facilities in the Denver area: The Medical Center of Aurora; North Suburban Medical Center; Presbyterian/St. Luke’s Medical Center; Rose Medical Center; Sky Ridge Medical Center; and Swedish Medical Center.

“The partnership with Quest Diagnostics will benefit our patients, physicians and hospitals,” said Gary Winfield, M.D., HealthONE’s chief medical officer. “Quest’s experience and expertise in these operations is excellent and the partnership will bring increased efficiency to our clinical labs along with enhanced quality, consistency and communication.”

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■ QUEST ENTERS INTO MANAGEMENT AGREEMENT, *from page 1*

The deal is structured differently from some recent transactions involving Quest and hospital laboratories. According to Quest spokesperson Denny Moynihan, this transaction will not include the acquisition of any outreach operations. Instead, the deal will focus on inpatient laboratory operations exclusively.

“We are pleased to partner with HealthONE and bring our expertise to their laboratory operations, allowing HealthONE hospitals to focus on delivering great patient care.”

— Steve Rusckowski, CEO, Quest

Quest will operate the inpatient labs at the hospitals with the intent of reducing costs for HealthONE, according to Moynihan. Typically, Quest can reduce annual operating costs for a lab in a range of about 10 to 20 percent.

About 300 laboratory employees will remain with HealthONE, while 14 management positions will transfer to Quest.

Moynihan noted that some of the testing may be transferred to Quest’s Denver laboratory and possibly another facility in Alexa, Kansas. He did not disclose the annual test volumes of the HealthONE hospital labs.

“This is an important partnership for health care because it signifies that major hospitals and health systems are increasingly transitioning non-core businesses to independent providers in order to enhance quality and value,” he said in an email.

The deal is the seventh management partnership with a hospital or hospital system Quest has executed in recent years, with the company taking advantage of the fact that many providers don’t wish to invest the resources in operating their own labs.

The most recent deal involved the Barnabas Health hospital system in New Jersey, which was completed late last year. It involved the management of laboratories serving seven hospitals, and like HealthONE, did not include an outreach acquisition. Other deals have involved Dignity Health and MemorialCare Health in California and UMass Memorial Medical Center in Massachusetts. Those deals also included the acquisition of outreach operations.

“We are pleased to partner with HealthONE and bring our expertise to their laboratory operations, allowing HealthONE hospitals to focus on delivering great patient care,” said Quest CEO Steve Rusckowski. “Quest partners with hospitals around the country to help them build a lab strategy that benefits patients and at the same time reduces costs.”

Financial terms of the transaction were not disclosed. Moynihan said the transfer of test volumes to Quest management should be completed by the end of this year.

Takeaway: Quest is continuing to make inroads into the hospital laboratory business, but in a different way than in recent deals involving health care systems. 

Novitas Issues Favorable LCD Criteria for OPKO Prostate Cancer Test

Novitas has posted a local coverage determination for Florida-based OPKO Health’s predictive prostate cancer blood test, 4Kscore® Test, opening up the door for it eventually being covered by the Medicare program.

According to the Novitas LCD, the test would be considered reasonable and necessary for any patient with prostate-specific antigen (PSA) levels of three or above who have not undergone a biopsy, or three or above with at least one prior negative biopsy but considered to be at higher risk for contracting prostate cancer.

The LCD criteria appears generous for OPKO. The National Cancer Institute (NCI) notes on its website that a PSA score of up to four is considered normal, and any score above that would be abnormal and predictive of a higher prostate cancer risk. However, the NCI also noted recent studies citing incidence of prostate cancer in patients with a PSA score of four or below.

"This first MAC determination is a major milestone for the 4Kscore Test as it expands access to a potentially life-saving tool."

— Phillip Frost, M.D.,
CEO, OPKO

An OPKO spokesperson said that if the cutoff were as low as 1.5, virtually no aggressive prostate cancer would go undetected.

In addition to diagnosing cancer or predicting a patient's risk, the test can also provide insights about the potential aggression of any current or future cancers.

"This first MAC determination is a major milestone for the 4Kscore Test as it expands access to a potentially life-saving tool," said Phillip Frost, M.D., OPKO's chief executive officer. "We believe this decision by Novitas will help accelerate further coverage decisions by other payers, and will encourage adoption of the 4Kscore Test by physicians and patients. More importantly, it will allow broader access to this important test, which can assist patients and physicians in further defining a patient's risk of having a high-grade prostate cancer that requires immediate or aggressive treatment."

The test is seen as a way of avoiding an invasive prostate cancer biopsy, which usually ranges in price from the low to mid four figures. In some instances, the patients are placed under general anesthesia, increasing the risk for complications. A study published earlier this year in the journal *Reviews in Urology* concluded the 4Kscore test substantially cut down on the use of the procedure across all risk categories of patients.

OPKO has seen the 4Kscore as a potential blockbuster assay for the company, which is trying to find its footing after its acquisition last year of the much larger Bio-Reference Laboratory.

Marion Janic, an OPKO spokesperson, said that the company had also received coverage from some commercial payers at around 50 percent of the test's retail price of \$1,900.

"We expect to obtain broad reimbursement by the end of the year," Janic said in an email. He added that the Medicare price continued to be under negotiation. Medicare pricing tends to be significantly below that of commercial reimbursement.

For the first quarter of 2016, OPKO reported a loss of \$12 million on revenue of \$291 million. That compares to the first quarter of 2015, when the pre-merger OPKO lost \$118 million on revenue of \$30 million.

Takeaway: OPKO appears to have scored a victory on Novitas' LCD for its predictive prostate cancer test. 

Inside The Lab Industry

PAML's Well-Traveled CEO Pushes the Company Forward

Pathology Associates Medical Laboratory—better known as PAML—is the biggest laboratory in the Pacific Northwest, and one of the civic fixtures of Spokane, Wash., where it's headquartered.

An affiliate of not-for-profit hospital operator Providence Health & Services, PAML is also one of the oldest continuously operating lab enterprises in the western U.S., founded in 1957 and growing fairly steadily since. In recent years, it is not only branching into other parts of the country but into personalized health and the direct-to-consumer markets.

"Frank has done a lot with PAML to continue their growth. He's been able to diversify their business, and introduce more consumer-oriented products. It's a very contemporary business model."

— Alan Mertz, President, ACLA

Altogether, PAML has more than 1,800 employees. It serves more than 14,000 individual clients, including more than 130 hospitals. Test volumes are more than 11 million annually (the company does not release exact figures or data on revenue). They have been growing at around a 5 percent clip in recent years, although they grew nearly 10 percent between 2012 and 2013.

That was the first year in the tenure of PAML's Chief Executive Officer, Francisco "Frank" Velázquez, M.D. He is in some ways the exact opposite of PAML's steady-as-it goes ethos of its operational approach. He arrived at the position after working in clinical and management jobs in pretty much every region of the continental United States. He is also a relative rarity at the reins of a lab PAML's size: A pathologist by training with many years of clinical practice under his belt before turning to the management suite.

But industry observers say he's a great fit for managing a large lab business.

"Frank has done a lot with PAML to continue their growth," said Alan Mertz, president of the American Clinical Laboratory Association, of which PAML is a member. "He's been able to diversify their business, and introduce more consumer-oriented products. It's a very contemporary business model."

A native of Spain, Velázquez was sent to Puerto Rico at a young age to be raised by his maternal grandparents—both of his parents were in medical school at the time. They later moved to Puerto Rico and practiced medicine there; Velázquez attended both undergraduate and medical school on the island.

Velázquez moved to the mainland U.S. after medical school to train as a pathologist, with residencies and an internship at the University Hospital Medical Center and the Veterans Administration Medical Center in Boston.

Although Velázquez professes a deep fondness for Boston—he spent more than a decade in the area after finishing medical school—it seems he has also worked just

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about everywhere else. His 19-page résumé includes a stint as medical director of the Detroit Medical Center University Laboratories; chief pathologist at Kaleida Health in Buffalo, N.Y.; chief of the pathology department at the Parkland Health and Hospital System in Dallas; and managing director at the Quest Diagnostics' Nichols Institute in Southern California, among others. Along with that last post, Velázquez held a senior position at the Quest affiliate Focus Diagnostics.

Under Velázquez' tenure, high-margin esoteric testing has grown significantly, and the equipment and infrastructure at PAML's main lab in Spokane has been repeatedly upgraded.

Bill McGuire, who noted he had “parachuted” into Kaleida Health as CEO to perform an operational turnaround in 2006, said Velázquez was among the few star managers he had inherited. The laboratory business was among the few moneymakers within the 10-hospital system at the time of his appointment.

“He’s broadly knowledgeable, clearly understood health care and the hospital sector, and where the industry was going,” McGuire said. “Frank was the best in my career experience in terms of running a clinical lab operation.” He also gave credit to Velázquez for

being able to spot and nurture talented managers and delegating tasks while ensuring they were still executed effectively.

Velázquez had been at Quest in the senior ranks for three years when he was recruited by PAML. Although he foresaw promising opportunities at Quest, “I wanted to be able to lead my own company,” he said.

Under Velázquez' tenure, high-margin esoteric testing has grown significantly, and the equipment and infrastructure at PAML's main lab in Spokane have been significantly upgraded. Looking forward, Velázquez has been focused on expanding PAML's presence on several fronts, gradually expanding it from a large regional lab to one with a presence in multiple regions of the U.S. Growth outside of Washington State has been primarily through joint ventures in relatively close California, Utah and Colorado. But it also has a small book of business in Kentucky, and is targeting much of the Southern and Northeast U.S. for future growth.

Some of this expansion had been planned prior to Velázquez joining PAML, but there were some growing pains. He placed a temporary moratorium on joint ventures after issues developed in the Colorado market that had led to lower client retainment than projected. But those issues were quickly resolved and that region actually exceeded sales and retainment projections last year.

“We hadn't really standardized the metrics; our general managers they all reported to someone different,” Velázquez recalled. “A lot of that has to do with having the right people and right tools and the right processes in place.”

All five of Velázquez's top managers are women, although he said this was coin-

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cidental to his recruiting the top people available. He describes himself as a demanding manager who values loyalty and honesty but prefers hiring people who do not think like him.

"It seemed whoever screamed the loudest got what they were looking for. There wasn't a lot of coordination between the departments."

— Clarissa Willett, CFO, PAML

Clarissa Willett, who had worked briefly with Velázquez at Nichols before being recruited as PAML's chief financial officer in 2013, said she took the position partly because of his ability to properly align goals and management structure to pursue new opportunities. "That vision is really one of the main reasons I started working with PAML. He's really excellent at it," she said. It also helped Willett impose more discipline on capital expenditures after her arrival.

"It seemed whoever screamed the loudest got what they were looking for. There wasn't a lot of coordination between the departments," Willett recalled of what she found when she arrived. That resulted in "side-loaded initiatives" that were not properly integrated into PAML's long-term planning and execution.

Nowadays, Willett noted that capital expenditures and improvements are pursued knowing how the specific market functions, if the processing capacity is available, and whether providers and patients have the appropriate access through online portals and other means. She likened the rationale to an ATM machine: Pretty much any card issued by any bank will work in any ATM. Such accessibility should also be part of health care delivery.

Another way PAML is meeting that challenge is by the launch of more consumer-friendly products. Cinch, introduced in 2014, provides a menu of basic direct-to-consumer tests with clear pricing. Patients are notified of their results by email or text, and are provided an easy-to-use chart to determine how their results compare to the normal range.

Last year, it launched AION Laboratories, which focuses on Baby Boomers, many of whom are expected to pay cash for test panels that are intended to assist in aging management. Patients can have their blood drawn by mobile phlebotomists. That division is already profitable, according to Velázquez.

Both divisions represent a tiny proportion of PAML's overall revenue, but Velázquez is heartened by what he has seen. Cinch, for example, experienced double-digit sales growth last year.

"It's quite remarkable," he said, adding an observation that suggests where the lab sector is heading: "We don't advertise, but we are on Facebook."

Takeaway: PAML is forging its way forward in the 21st century while still retaining the stability that has kept it in business for nearly 60 years. 

■ **STARTUP LABFINDER WANTS TO BETTER CONNECT PATIENTS WITH THE RIGHT LABS**, *from page 1*
vestors. It is providing similar coordination for seeking and using imaging services as well, which can also lead to surprise out-of-network bills for some patients.

LabFinder's website allows patients to order tests at labs that are within their insurers' network. It has about 95 tests on its menu—mostly basic urine or blood tests and panels. Or patients can use their physician scrip to order other assays. Each test request is then synced to the networks of about 100 different insurers or third-party administrators to determine which lab is covered for that patient. For patients without insurance or willing to pay out of pocket, they can order tests with a specific price attached, typically in the low to mid two figures for a urinalysis or blood test.

"Labs do a great job marketing to doctors, but they don't do a great job marketing to patients."

— Robert Segal, M.D.

"We have sort of created an (electronic medical records system) without the physician notes," Segal said. He noted that in many instances patients are seeing a primary care physician and a variety of specialists, often making the appropriate sharing of lab results among the parties in a timely fashion challenging.

Once the results are available, patients can view them through a portal. The data is also easily shareable with other providers who need access to the test results.

In addition to helping patients, Segal also envisions the LabFinder site as a promoter of walk-in patients to laboratories. Participating labs pay a monthly fee of \$300 a month per draw center or testing site. Segal noted that the fee usually pays for itself after the first couple of tests are ordered.

"Labs do a great job marketing to doctors, but they don't do a great job marketing to patients," Segal said.

The service launched in March after three years of planning. So far, 2,200 patients have registered to use the service, and about 1,000 tests are being processed per month through LabFinder. Segal said both numbers have exceeded his expectations.

So far, LabFinder has five labs in its network, primarily small to medium-sized regional operators, including Manhattan Labs, Empire City Laboratories and Sunrise Medical Labs. But it recently signed up BioReference Laboratories, one of the biggest regional labs in the Eastern United States and a wholly-owned subsidiary of OPKO Health. That will allow LabFinder to expand into New Jersey and Connecticut, where BioReference has a large presence. It also will allow LabFinder to operate outside of the highly rigid regulatory environment for laboratory operations in New York State.

That will pave the way for an expansion into other parts of the U.S. Segal said he eventually hopes for the service to go national.

None of the labs participating in the LabFinder network were immediately available to comment.

Takeaway: LabFinder is putting a new twist on patient portals and direct-to-consumer services for laboratory testing. 

INDUSTRY BUZZ

Foundation Will Assist AstraZeneca in Expanding Capabilities of Cancer Drug

Massachusetts-based Foundation Medicine has entered into an agreement with pharmaceutical giant AstraZeneca to develop a diagnostic assay for the cancer drug Lynparza.

The agreement is the first specific step in a broader deal between the two companies announced in May. Approved by the U.S. Food and Drug Administration in 2014, Lynparza is used to treat certain victims of ovarian cancer by blocking enzymes used to repair damaged DNA. It is believed to be particularly effective in treating women who have damaged BRCA genes.

The FDA approved the drug in tandem with the use of Myriad Genetics' BRCAAnalysis CDx assay. That test and the drug is specifically for treating ovarian, fallopian tube and peritoneal cancers. However, AstraZeneca would like to be able to expand the usages of its drug. It will develop a series of clinical trials using the Foundation testing platform.

"Utilizing Foundation Medicine's leading capabilities in molecular information will help our work to assess the potential of the medicine to address unmet patient need across a number of cancers driven by DNA repair deficiencies, including and—significantly—beyond the BRCA mutations," said Nina Mojas, AstraZeneca's global medicine lead for Lynparza.

AstraZeneca sold \$94 million worth of the drug last year, but its ramp-up was extremely swift during calendar 2015, with virtually no patients taking the drug in January, but more than 2,500 doing so by the end of the year. The company eventually forecasts annual sales of at least \$2 billion.

"Following our new master collaboration agreement with AstraZeneca, we are pleased to launch this first strategic initiative to support and advance the development of Lynparza in a number of cancers," said Steven Kafka, Foundation Medicine's president. "The work we've undertaken with AstraZeneca underscores the importance and potential of utilizing our rigorously validated, comprehensive profiling approach to make available to physicians an FDA-approved universal companion diagnostic solution for use with targeted medicines."

Terms of the agreement between Foundation and AstraZeneca were not disclosed.

Takeaway: Foundation Medicine is using an agreement with AstraZeneca to expand into the development of companion diagnostics. 

References

American Clinical Laboratory Association
202-637-9466

AstraZeneca
800-236-9933

Foundation Medicine
617-418-2200

HealthONE
303-788-2500

LabFinder
855-452-2346

Novitas
877-235-8073

OPKO Health
305-575-4100

PAML
509-755-8600

Quest Diagnostics
800-222-0446

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