

THE WALL STREET JOURNAL.



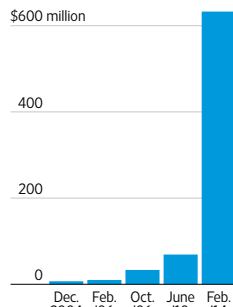
TESTING THERANOS

A hot laboratory startup hits snags



Popular Investment

Theranos has raised at least \$750 million from investors.

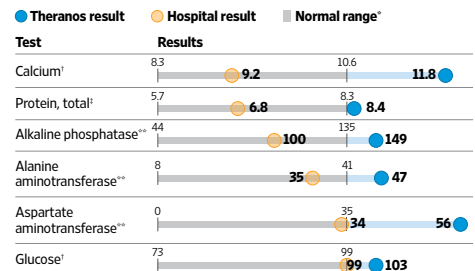


Source: Company filings
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Same Patient, Different Results

For one Arizona woman, Theranos found abnormally high levels for six tests. Hospital tests two days later were normal. Theranos says variation across labs is commonplace and can be caused by medicines and diet.



[†]As stated by Theranos ^{††}in milligrams per deciliter [‡]in grams per deciliter
^{**}liver enzyme test, in units per liter
 Sources: Theranos and HonorHealth Scottsdale Shea Medical Center via Nicole Sundene and Maureen Glunz
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A Prized Startup's Struggles

Silicon Valley lab Theranos is valued at \$9 billion but isn't using its technology for all the tests it offers



MARTIN E. KLIMEK

Theranos's Elizabeth Holmes at the company's Palo Alto, Calif., headquarters. Her ownership stake is valued at more than \$4.5 billion.

BY JOHN CARREYROU

OCTOBER 15, 2015

On Theranos Inc.'s website, company founder Elizabeth Holmes holds up a tiny vial to show how the startup's "break-through advancements have made it possible to quickly process the full range of laboratory tests from a few drops of blood."

The company offers more than 240 tests, ranging from cholesterol to cancer. It claims its technology can work with just a finger prick. Investors have poured more than \$400 million into Theranos, valuing it at \$9 billion and her majority stake at more than half that. The 31-year-old Ms. Holmes's bold talk and black

turtlenecks draw comparisons to Apple Inc. cofounder Steve Jobs.

But Theranos has struggled behind the scenes to turn the excitement over its technology into reality. At the end of 2014, the lab instrument developed as the linchpin of its strategy handled just a small fraction of the tests then sold to consumers, according to four former employees.

One former senior employee says Theranos was routinely using the device, named Edison after the prolific inventor, for only 15 tests in December 2014. Some employees were leery about the machine's accuracy, according to the former employees and emails reviewed by The Wall Street Journal.

In a complaint to regulators, one Theranos employee accused the company of failing to report test results that raised questions about the precision of the Edison system. Such a failure could be a violation of federal rules for laboratories, the former employee said.

Theranos also hasn't disclosed publicly that it does the vast majority of its tests with traditional machines bought from companies like Siemens AG.

The Palo Alto, Calif., company says it abides by all applicable federal lab regulations and hasn't exaggerated its achievements. It disputes that its device could do just 15 tests, declining to say how many tests it now handles or to respond to some questions about its lab procedures, citing "trade secrets."

But Theranos's outside lawyer, David Boies, acknowledges that the company isn't yet using the device for all the tests Theranos offers. The transition to doing every test with the device is "a journey," he says.

Asked about the claim on the company's website, Mr. Boies replied that using the device for the "full range" of blood tests is a goal Theranos will eventually achieve.

Theranos points out that it has publicly disclosed doing "certain esoteric and less commonly ordered tests" with traditional machines on blood drawn with smaller needles from veins.

During the Journal's reporting, Theranos deleted a sentence

on its website that said: “Many of our tests require only a few drops of blood.” It also dropped a reference to collecting “usually only three tiny micro-vials” per sample, “instead of the usual six or more large ones.” Heather King, the company’s general counsel, says the changes were made for “marketing accuracy.”

Ms. King and Mr. Boies say Theranos’s lab work is accurate. Theranos has performed tests on millions of patients referred by thousands of doctors and has received highly positive feedback, they say.

Ms. Holmes, Theranos’s chairman and chief executive, declined interview requests from the Journal for more than five months. Last week, the company said she would be available to comment, but her schedule didn’t allow it before publication of this article.

User-friendliness

Some doctors appreciate the company’s user-friendliness. Results sometimes arrive within 15 minutes, says Scott Wood, a primary-care doctor in Menlo Park, Calif. “That’s exciting and could be very useful in emergency situations,” he says. When patients ask about trying Theranos, he replies: “Sure, go ahead.”

Other doctors said they stopped steering patients to Theranos because of results they didn’t trust. “I don’t want my patients going there until more information and a better protocol are in place,” says Gary Betz, an internist in Phoenix.

Ms. Holmes launched Theranos in 2003 when she was 19 and dropped out of Stanford University in her sophomore year.

Theranos is built around Ms. Holmes’s self-professed phobia of needles. She has said in numerous public appearances that drawing a tiny amount of blood at a time from each patient’s finger and avoiding the large syringes used by traditional labs will make patients less reluctant to get blood tests. That will lead to earlier diagnoses and save lives, according to Ms. Holmes.

Her first idea was a small arm patch to screen blood for infectious diseases and deliver antibiotics, according to Phyllis Gardner, a Stanford medical-school professor with whom Ms. Holmes

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consulted at the time. The patch never made it to market.

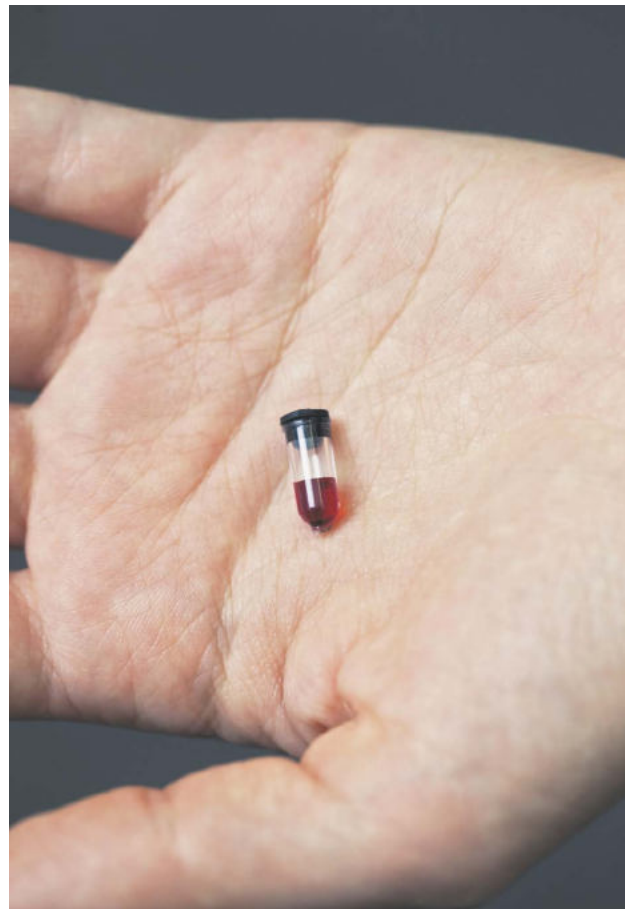
“She was a young kid with only rudimentary engineering training and no medical training,” says Dr. Gardner, whose husband was a member of a Theranos advisory board and still owns shares in the company.

In 2005, Ms. Holmes hired Ian Gibbons, a British biochemist who had researched systems to handle and process tiny quantities of fluids. His collaboration with other Theranos scientists produced 23 patents, according to records filed with the U.S. Patent and Trademark Office. Ms. Holmes is listed as a co-inventor on 19 of the patents.

The patents show how Ms. Holmes’s original idea morphed into the company’s business model. But progress was slow. Dr. Gibbons “told me nothing was working,” says his widow, Rochelle.

In May 2013, Dr. Gibbons committed suicide. Theranos’s Ms. King says the scientist “was frequently absent from work in the last years of his life, due to health and other problems.” Theranos disputes the claim that its technology was failing.

After Dr. Gibbons’s widow spoke to a Journal reporter, a lawyer representing Theranos sent her a letter threatening to sue her if she continued to make “false statements” about Ms. Holmes and disclose confidential information. Ms. Gibbons owns Theranos shares that she inherited from her husband.



A 'nanotainer' helps Theranos run tests from a few blood drops.

MARTIN E. KLIMEK

Two giant rivals

Theranos began offering tests to the public in late 2013. It opened 42 blood-drawing “wellness centers” in the Phoenix area, two in California and one in Pennsylvania. Most are in Walgreens Boots Alliance Inc. drugstores.

Ms. Holmes successfully lobbied for an Arizona law that allows people to get tests without a doctor’s order. Theranos’s promise of fast results and prices that are “a fraction” of other labs pits it against Quest Diagnostics Inc. and Laboratory Corp. of America Holdings, which dominate the \$75 billion-a-year blood-testing industry in the U.S.

While the biggest venture-capital firms specializing in health care aren’t listed as Theranos investors, Oracle Corp. co-founder Larry Ellison and venture-capital firm Draper Fisher Jurvetson, have bought stakes in Theranos, according to data from Dow Jones VentureSource.

Theranos has raised several rounds of financing, most recently in June 2014. Like most closely held companies, Theranos has divulged little about its operations or financial results.

Clinical labs usually buy their testing instruments from diagnostic equipment makers. Before those makers can sell to labs, they must undergo vetting by the Food and Drug Administration.

Because Theranos doesn’t sell its Edison machines to other labs, it didn’t need the FDA’s approval to start selling its tests. Still, the company has sought clearance for more than 120 of its tests in an effort to be rigorous and transparent.

In July, Theranos announced the first FDA clearance of one of those tests, which detects herpes. The FDA and Theranos decline to comment on the status of the other submissions.

Whether labs buy their testing instruments or develop them internally, all are required to prove to the federal Centers for Medicare and Medicaid Services that they can produce accurate results. The process is known as proficiency testing and is administered by accredited organizations that send samples to labs several times a year.

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Labs must test those samples and report back the results, which aren't disclosed to the public. If a lab's results are close to the average of those in a peer group, the lab receives a passing grade.

In early 2014, Theranos split some of the proficiency-testing samples it got into two pieces, according to internal emails reviewed by the Journal. One was tested with Edison machines and the other with instruments from other companies.

The two types of equipment gave different results when testing for vitamin D, two thyroid hormones and prostate cancer. The gap suggested to some employees that the Edison results were off, according to the internal emails and people familiar with the findings.

Senior lab employees showed both sets of results to Sunny Balwani, Theranos's president and chief operating officer. In an email, one employee said he had read "through the regulations more finely" and asked which results should be reported back to the test administrators and government.

Mr. Balwani replied the next day, copying in Ms. Holmes. "I am extremely irritated and frustrated by folks with no legal background taking legal positions and interpretations on these matters," he wrote. "This must stop."

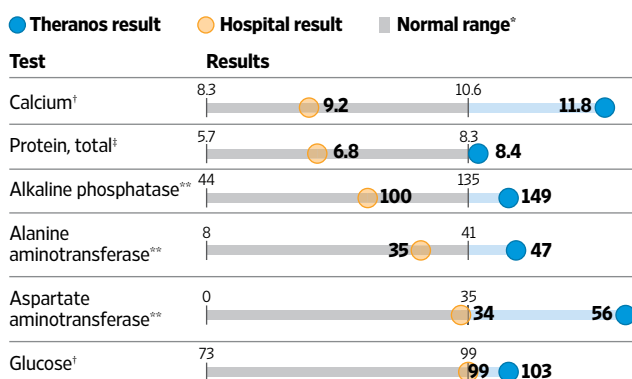
He added that the "samples should have never run on Edisons to begin with."

Former employees say Mr. Balwani ordered lab personnel to stop using Edison machines on any of the proficiency-testing samples and report only the results from instruments bought from other companies.

The former employees say they did what they were told but were concerned that the instructions violated federal rules, which state that a lab must handle "proficiency testing samples. . . in the same

Same Patient, Different Results

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Sources: Theranos and HonorHealth Scottsdale Shea Medical Center via Nicole Sundene and Maureen Glunz THE WALL STREET JOURNAL.

manner as it tests patient specimens” and by “using the laboratory’s routine methods.”

In its everyday business at the time, Theranos routinely used Edison machines to test patients’ blood samples for vitamin D, the two thyroid hormones and prostate cancer, the former employees say.

In March 2014, a Theranos employee using the alias Colin Ramirez alleged to New York state’s public-health lab that the company might have manipulated the proficiency-testing process.

Stephanie Shulman, director of the public-health lab’s clinical-lab evaluation program, responded that the practices described by the anonymous employee would be a “violation of the state and federal requirements,” according to a copy of her email.

What the employee described sounded like “a form of PT cheating,” Ms. Shulman added, using an abbreviation for proficiency testing. She referred the Theranos employee to the public-health lab’s investigations unit.

The New York State Department of Health confirms that it got a formal complaint in April 2014 “in regard to testing practices at Theranos” and forwarded it to the Centers for Medicare and Medicaid Services.

Asked about the complaint, Theranos confirms that the Edison system produced results for several tests last year that differed from results obtained from traditional equipment.

Leftover samples

But that comparison was based on “left-over proficiency testing samples” used “to conduct additional experiments and verify best practices,” says Ms. King, Theranos’s general counsel. The company has never failed proficiency testing, she adds.

She says Mr. Balwani’s instructions were consistent with the company’s “alternative assessment procedures,” which it adopted because it believes its unique technology has no peer group and can be thrown off by the preservatives used in proficiency-testing samples.

Theranos has been “upfront and transparent with regulators”

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about the procedures, Ms. King adds.

As of the end of 2014, Theranos did less than 10% of its tests on Edison machines, including tests for prostate cancer and pregnancy, one former senior employee says.

In addition to the 15 tests run on the Edison system, Theranos did about 60 more on traditional machines using a special dilution method, the former senior employee says. The company often collected such a small amount of blood that it had to increase those samples' volume to specifications required by those traditional machines, former employees say.

A third set of about 130 tests was run on traditional machines using larger samples drawn from patients' arms with a needle.

For tests done with dilution, the process caused the concentration of substances in the blood being measured to fall below the machines' approved range, three former employees say. Lab experts say the practice could increase the chance of erroneous results.

Most labs dilute samples only in narrow circumstances, such as when trying to find out by how much a patient has overdosed on a drug, say lab experts.

"Anytime you dilute a sample, you're adulterating the sample and changing it in some fashion, and that introduces more potential for error," says Timothy R. Hamill, vice chairman of the University of California, San Francisco's department of laboratory medicine. Using dilution frequently is "poor laboratory practice."

Theranos says dilution is common in labs but declines to say if it dilutes samples. Theranos's "methods for preparing samples for analysis are trade secrets and cannot be revealed," Ms. King says.

Those methods "have been disclosed" to regulators and don't "adversely impact the quality of its tests or the accuracy of its test results," she adds.

Former employees say diluting blood drawn from fingers

Investors have poured more than \$400 million into Theranos.

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contributed to accuracy problems early last year with a test to measure potassium. Lab experts say finger-pricked blood samples can be less pure than those drawn from a vein because finger-pricked blood often mixes with fluids from tissue and cells that can interfere with tests.

Some of the potassium results at Theranos were so high that patients would have to be dead for the results to be correct, according to one former employee.

Ms. King denies any problems with the potassium test and says Theranos has no indication that “inaccurate results were returned to patients.”

Theranos challenged interpretations of its test results by health-care providers and patients whose medical records were reviewed by the Journal.

After those people spoke to the Journal, Theranos visited some of them and asked them to sign prepared statements that said the Journal mischaracterized their comments. Two did and one refused.

Carmen Washington, a nurse who worked at a clinic owned by Walgreens in Phoenix, says she began to question Theranos’s accuracy after seeing abnormal results in potassium and thyroid tests.

She says she raised her concerns with the drugstore operator and Theranos’s lab director, asking for data to show that the company’s finger-prick testing procedures produced results as accurate as blood drawn from a vein.

“They were never able to produce them,” she says. Ms. King says the company did show detailed testing-accuracy data to the nurse.

A Walgreens spokesman says the nurse kept writing lab orders for Theranos tests until she stopped working at the clinic in February. Walgreens says its partnership with Theranos has gone smoothly overall.

About a dozen doctors and nurses complained about test results by phone or email to the company from late 2013 to late 2014, a person familiar with the matter says. The Arizona attor-

ney general's office, state health department and Better Business Bureau say they have received no complaints about Theranos.

A second opinion

Dr. Betz, the Phoenix doctor, says one of his female patients went to Theranos in August 2014 for a routine potassium test to monitor potential side effects from her blood-pressure medication. He says Theranos reported that her potassium level was close to the threshold considered critical.

Another lab reran the test three days later. The results came back normal.

Ms. King says Dr. Betz's nurses kept sending patients to Theranos until early this year.

Real-estate agent Maureen Glunz went to Theranos a few days before last Thanksgiving after complaining of ringing in her ear. Her blood was drawn from a vein in her arm. The results showed abnormally elevated levels of glucose, calcium, total protein and three liver enzymes.

Her primary-care doctor, Nicole Sundene, who is a naturopath, worried that Ms. Glunz might be at risk of a stroke and asked her to go to an emergency room. The hospital's tests two days later showed nothing abnormal.

Dr. Hamill of UC San Francisco says some of Ms. Glunz's results should "have fairly steady values . . . over relatively long time periods."

Ms. King says "some degree of variability in lab results across different laboratories is commonplace," adding that Ms. Glunz's medication and diet could have caused "fluctuations" in her results. None of the results were "close to the critical range," Ms. King adds.

It is misleading to draw conclusions from "a handful of patient anecdotes," she says.

Ms. Glunz says she likes Theranos's low prices and would go there again if she could be sure its tests are accurate. "But trial and error on people, that's not OK," she says.

Theranos's Growing Pains

Elizabeth Holmes's blood-testing ambition has collided with technological problems

BY JOHN CARREYROU

DECEMBER 28, 2015

The night before a big meeting with a Swiss drug company in 2008, Theranos Inc. founder Elizabeth Holmes and a colleague sat in a Zurich hotel, sticking their fingers with a lancet.

They drew drops of their own blood to try the company's testing machine, but the devices wouldn't work, says someone familiar with the incident. Sometimes the results were obviously too high. Sometimes they were too low. Sometimes the machines spit out only an error message.

After two hours, the colleague called it quits, leaving Ms. Holmes still squeezing blood from her fingers to test it again.

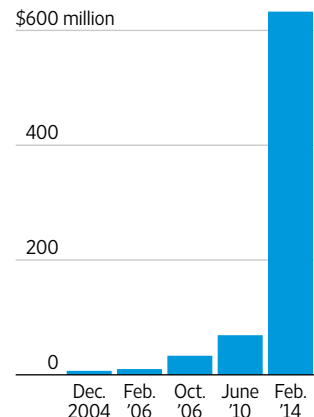
Ever since she launched Theranos in 2003 when she was 19 years old and dropped out of Stanford University, Ms. Holmes has been driven by ambition that is big even by Silicon Valley standards. Instead of a smartphone app to hail a car or order food, she wants to revolutionize health care with a vast range of diagnostic tests run with a few drops of finger-pricked blood.

Now 31, Ms. Holmes has emphasized a variety of strategies — a hand-held device, tests for drugmakers, drugstore clinics — while trying to turn her dream into a business. She often has collided with technological problems, according to interviews with more than 20 former Theranos employees, company emails and complaints filed with federal regulators.

In Switzerland, she went ahead and pricked her finger in front of a group of Novartis AG executives at the meeting the next day,

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Source: Company filings
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testing for a protein that measures inflammation, says the person familiar with the incident.

All three of her Theranos devices flickered with error messages, the person says. Ms. Holmes was unfazed, blamed a minor technical glitch and continued to pitch the vast potential of her technology.

Ms. Holmes and several current or former Theranos directors declined interview requests. A spokeswoman for Theranos, Brooke Buchanan, says Ms. Holmes recalls only one machine with an error message, because someone tripped over the cord. A second machine ran perfectly, and the third wasn't used, the spokeswoman says. A Novartis spokeswoman wouldn't comment.

Since a Wall Street Journal article in October, Ms. Holmes has defended the Palo Alto, Calif., company's laboratory work and promised to publish data proving the accuracy of its more than 240 tests, ranging from pregnancy to diabetes.

She said earlier this month that customer volume was higher than ever. The company has said it performed millions of tests, with highly positive feedback.

For now, though, Theranos has stopped collecting tiny samples of blood from patients' fingers for all but one of its tests while it waits for the Food and Drug Administration to review the company's applications for wider use of the small proprietary vials called "nanotainers." As a result, Theranos is using traditional lab machines for most of its tests.

Many technology startups struggle to overcome problems while developing their products. Theranos has always faced an extra burden because blood tests sometimes provide life-or-death answers.

David Philippides, an engineer who worked on Theranos devices from January 2013 to November 2014, says the company didn't show enough regard, based on his involvement in research while he was there, for the scientific rigor of medical research.

"The time was not taken to develop anything properly," Mr.



'Things change in any company...You improve with time, you test things, you do things differently.'— Theranos spokeswoman Brooke Buchanan about the strategy of Elizabeth Holmes, shown at the WSJDLive conference in October.

Philippides says. “This is science. You need time.” He says he was fired after refusing to go to Arizona to retrieve a broken machine.

The Theranos spokeswoman says he held only a “junior role” that gave him “no visibility into the extent of” the company’s research and development. She says the company employs more than 80 scientists with doctorates.

'I'm in a Hurry'

When she was a high-school junior at St. John’s School in Houston, Ms. Holmes offered a glimpse of herself in the year-book. “I tend to be a perfectionist so sometimes I’m up really late working,” she was quoted as saying. “But usually I can stay on top of things and everything works out.”

A senior-year student survey said her theme song was “I’m in a Hurry” and she would be “trying to save the world” in 20 years.

The daughter of a well-connected public servant and former

congressional aide, Ms. Holmes took chemical engineering classes at Stanford but had no medical training when she quit to start Theranos in 2003. She began approaching venture-capital firms to gauge their interest.

She got a meeting in 2004 with MedVenture Associates, which has invested in medical technology companies for 29 years. Ms. Holmes sat down at the firm's office across from five MedVenture partners.

Speaking fast, the young entrepreneur pitched them about putting blood tests on a chip, recalls Annette Campbell-White, MedVenture's managing partner. She says Ms. Holmes talked "from 30,000 feet about how these tests are going to change mankind" but provided no technical or scientific details.

When asked for more specifics, such as how the technology would differ from a portable blood-diagnostics device made by a company called Abaxis Inc., Ms. Holmes got annoyed, according to the venture capitalist.

"The more we tried to drill down, the more uncomfortable she got," Ms. Campbell-White says. After about an hour, Ms. Holmes stood up and left, "leaving us to look at one another in amazement," Ms. Campbell-White says.

Theranos's Ms. Buchanan says Ms. Holmes remembers the meeting very differently and would never leave a meeting so abruptly.

The spokeswoman says Ms. Campbell-White's memory might be biased by MedVenture's investment in Abaxis. Ms. Campbell-White says MedVenture exited the investment years before the meeting.

By the end of 2004, Ms. Holmes had raised at least \$6.9 million, valuing Theranos at about \$30 million, according to corporate filings.

The first \$1 million came from Tim Draper, a founder of Draper Fisher Jurvetson, through two of his funds. Ms. Holmes was a childhood friend of his daughter and came to him "with extraordinary energy and brilliance," he says.

The money enabled Ms. Holmes to hire scientists and engi-

neers. She believed the fastest route to getting revenue was by offering Theranos's blood tests to drug companies for use in clinical trials, former Theranos employees say.

In April 2005, Ms. Holmes said on the public-radio program "BioTech Nation" that she had created a hand-held device that would help drug companies tell in real time how well their drugs worked on patients using "a little tiny needle that pulls a little tiny drop of blood" from an arm or the hand.

Ms. Holmes called it the RDX Metabolic Profiler and said it was "going into the production phase," according to a recording of the interview. "We hope to release it, actually, to a pharmaceutical partner around mid to late this year."

Two people who worked at Theranos at the time say it was still years away from developing such a device. They say the company was still trying to figure out the chemistry of various blood tests.

Ms. Buchanan says the tone of the interview was "aspirational" rather than "literal." She says Ms. Holmes actually described two devices, one of which went into manufacturing within a year. Theranos did eventually enter into partnerships with drug-makers such as Pfizer Inc., she says.

A Pfizer spokesman says it has done "only very limited historical exploratory work with Theranos through a few pilot projects" and doesn't have any current or active projects with it.

In the interview, Ms. Holmes also showed less interest in finger-pricked blood than Theranos does now. "If you poke yourself in the arm or on the palm of your hand, it doesn't hurt as much as if you do it on the fingertip, because there's many nerves in your fingertip," she said.

Since then, says Ms. Buchanan, the company has invented techniques that make it less painful to extract blood from a finger.

"Things change in any company," she adds. "You improve with time, you learn, you test things, you do things differently."

By 2007, Theranos was valued at an estimated \$197 million after raising another \$43.2 million. The company had developed

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a device to test small quantities of blood, but it was the size of a personal computer tower and weighed 70 pounds, says a person who worked at Theranos. A later version weighed 23 pounds, the former employee recalls.

After the demonstration at Novartis, Ms. Holmes kept trying to get other drugmakers interested in the concept.

Oscar Laskin, then vice president of early drug development at Celgene Corp., recalls being told by Ms. Holmes in 2008 that Theranos could tell how certain markers in the blood were changing and then input the results into a computer model that would become more predictive over time.

He says she told him the technology could help Celgene make important adjustments during drug trials. When Mr. Laskin asked for an explanation of how it worked, Ms. Holmes said she couldn't reveal trade secrets.

"The level of sophistication required by what she was describing involved a paradigm shift," he says. "It sounded like something that was too good to be true." Ms. Buchanan says Theranos disagrees with Mr. Laskin's recollection but declines to comment further.

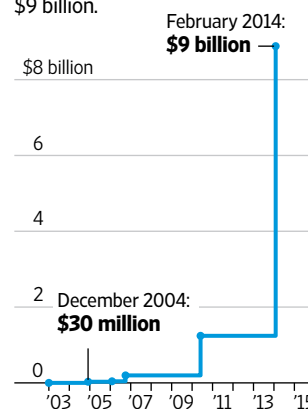
Nevertheless, Celgene signed a \$3 million contract with Theranos for a custom-made blood test and use of the company's computer model, two former Theranos employees say. It isn't clear if Theranos ever created the test. Ms. Buchanan says Theranos doesn't comment on confidential business relationships. Celgene declines to comment.

In 2009, Ms. Holmes returned to Stanford to give a talk about entrepreneurship. She described Theranos's accomplishments and said its testing system made it possible to poke the finger of a patient who had taken a drug "and see whether it works, whether it's safe and whether they have the right dose," according to a recording of her talk.

The same year, Theranos hired Sunny Balwani as president

Giant Jump

Investors last year increased Theranos's valuation to about \$9 billion.



Source: Company filings
THE WALL STREET JOURNAL.

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and chief operating officer. He had started and sold an e-commerce company during the dot-com boom.

Anthony Nugent, an engineer listed as co-inventor with Ms. Holmes on five patents, says the hiring seemed odd because Mr. Balwani lacked experience in blood diagnostics and didn't have a science or medicine background. Mr. Nugent worked at Theranos from 2007 to 2013.

Ms. Buchanan, the company's spokeswoman, responds that Mr. Balwani has an "extensive and successful background in technology." He declines to comment.

In 2010, another fundraising round boosted Theranos's valuation above \$1 billion. By then, the device was code-named Edison, after the famous inventor.

Safeway Inc. and Walgreens agreed to offer Theranos tests in stores. Mr. Nugent says he was surprised by the September 2013 announcement to "bring access to" Theranos's "lab testing service through Walgreens pharmacies nationwide" because he still considered the Edison an experimental device.

He recalls seeing the machines labeled "for investigational use only." Their accuracy "was not to the level you'd want."

Ms. Buchanan responds: "We are 100% confident of the accuracy of our tests when we rolled them out." She says Mr. Nugent seems to be confusing devices designed "for a non-clinical purpose. . .with those that are ultimately used in the clinical lab."

In November 2013, Theranos's lab in California got an order from a patient at a Walgreens for a blood test handled by the Edison, according to a former Theranos lab worker assigned to run the test.

Before doing the test, the employee put the device through three trial runs with a quality-control sample containing a known amount of the substance the test was supposed to measure.

The lab employee later told federal authorities that the results from the quality-control runs diverged from the known amount by more than two standard deviations, a red flag that suggested possible accuracy problems, according to a complaint filed by

the employee.

When the Theranos employee alerted superiors, someone from research and development came to the lab and deleted quality-control data to make the Edison's test runs look better, the former lab employee alleged in the complaint to the Centers for Medicare and Medicaid Services, or CMS.

The R&D employee then tested the patient's blood on the Edison and sent the results to the patient, according to a copy of the complaint. An agency spokeswoman declines to comment. CMS auditors inspected Theranos last month as part of a regularly scheduled audit the company says is continuing.

Ms. Buchanan says Theranos doesn't believe the incident happened. "If there ever were a circumstance like that, we would do a quality-control check on that device and not give out a patient result," she says.

Holmes started making her pitch to investors soon after starting Theranos.

CMS auditors did another scheduled inspection shortly after the alleged incident two years ago. Upstairs were the traditional lab instruments bought from outside companies and used to test most patient samples. That part of the lab was called Jurassic Park because Ms. Holmes and Mr. Balwani said Theranos's technology would soon make those machines obsolete, former employees say.

Edison machines were kept downstairs in the Normandy section of the lab, a reference to the D-Day invasion by Allied forces that evoked comparisons to how Theranos was taking the lab industry by storm.

Two former employees say managers told lab staff not to enter or exit Normandy during the audit. The inspectors toured Jurassic Park but never went downstairs or saw the Edison machines, the former employees say.

David Boies, Theranos's outside counsel and a company director since October, told the Journal in a letter in July that the company "never hid the existence of any laboratory." Inspectors were told about both sections but chose to visit only "the room that processed over 90 percent of the samples at the time."

Theranos passed. The agency won't comment beyond the inspection report.

Valued at \$9 billion

Last year, investors pumped another \$633 million into Theranos, increasing its valuation to about \$9 billion and Ms. Holmes's majority stake to more than half that.

In April 2014, she got a long email from another employee. The employee alleged that Theranos had cherry-picked data when comparing Edison machines to traditional lab machines to make the Edison look more accurate, according to a copy of the email.

For one test, the device's accuracy rate increased sharply after some information was deleted and manipulated, the employee wrote. Edison machines also allegedly failed daily quality-control checks often.

"I am sorry if this email sounds attacking in any way, I do not intend it to be," the employee told Ms. Holmes. "I just feel a responsibility to you to tell you what I see so we can work towards solutions."

Ms. Holmes forwarded the email to Mr. Balwani. He replied to the employee, who no longer works at Theranos, denied all the claims and questioned the employee's understanding of statistics and lab science.

Quality-control failures were due to the "newness of some of our processes, which we are improving every day," Mr. Balwani wrote.

He added: "This is product development, this is how startups are built." The reply ended with an edict that the "only email on this topic I want to see from you going forward is an apology that I'll pass on to other people."

Ms. Buchanan says the employee was too inexperienced to "make these types of comments" and "struggled" to grasp Theranos's scientific processes. The company has disclosed its test methods to regulators, she adds.

Hot Startup Dials Back Lab Tests at FDA's Behest



MARTIN E. KLIMEK

Theranos founder Elizabeth Holmes holds a 'nanotainer' of blood.

BY JOHN CARREYROU

OCTOBER 16, 2015

Under pressure from regulators, laboratory firm Theranos Inc. has stopped collecting tiny vials of blood drawn from finger pricks for all but one of its tests, according to a person familiar with the matter, backing away from a method the company has touted as it rose to become one of Silicon Valley's hottest startups.

The move is a setback to the Palo Alto, Calif., company's ambition to revolutionize the blood-testing industry. As a result of the halt, Theranos is operating more like a traditional lab that draws blood with needles from patients' arms. Theranos is valued at

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\$9 billion, or about as much as each of the industry's two largest companies in the U.S.

Food and Drug Administration inspectors recently showed up unannounced at Theranos, the person familiar with the matter said. The inspection was triggered by concerns the agency had about data Theranos had voluntarily submitted to the FDA in an effort to win approval for its proprietary testing methods, this person said.

During the inspection, FDA officials indicated to Theranos that the agency considers the "nanotainers" made and used by the company to collect finger-pricked blood an unapproved medical device, the person familiar with the matter said.

Theranos founder Elizabeth Holmes said in an interview on the CNBC show "Mad Money" that the company is "not even using our nanotainers except for FDA-cleared assays."

So far, the agency has approved just one of the more than 100 proprietary tests submitted by Theranos. That test detects herpes and was cleared by the FDA in July. Theranos still is allowed to use a finger prick and the nanotainers for that one test, the person familiar with the matter said.

Since the inspection by FDA officials, Theranos has also been audited by the Centers for Medicare and Medicaid Services, the main regulatory overseer of clinical labs, according to people familiar with the matter. A CMS spokeswoman declined to comment.

To resume broader use of the tiny vials, Theranos must have them vetted and officially approved by the FDA, the person familiar with the situation said.

The company's general counsel, Heather King, didn't immediately respond to questions about the inspections, but said that "Theranos has never been asked to stop using its finger stick technology." On Wednesday, Ms. King had said that "Theranos remains deeply engaged with regulators, including FDA."

A page-one article in The Wall Street Journal on Thursday detailed how the company has struggled to turn the excitement over its technology into reality. At the end of 2014, the proprietary lab

instrument Theranos developed as the linchpin of its strategy handled just a small fraction of the tests then sold to consumers, according to four former employees.

Theranos has since nearly stopped using the lab instrument, named Edison after the prolific inventor, according to the person familiar with the situation. By the time of the FDA inspection, the company was doing blood tests almost exclusively on traditional lab instruments purchased from diagnostic-equipment makers such as Siemens AG, the person says.

In Thursday's article, the Journal reported that Theranos was using the Edison for just 15 tests as of the end of 2014, citing one former senior employee. The company disputed that its device did only 15 tests but declined to say how many it handled, citing "trade secrets."

In the "Mad Money" interview, Ms. Holmes didn't quantify the number of tests run on its proprietary lab instrument when asked. She is the company's chairman and chief executive, and her ownership stake in Theranos is valued at more than \$4.5 billion. Investors have pumped more than \$400 million into Theranos.

Ms. Holmes has been widely hailed for her vision to create new technology that offers consumers more than 240 blood tests, ranging from cholesterol to cancer. Ms. Holmes, 31 years old, has publicly said she built Theranos around her self-professed phobia of needles.

The Journal reported Thursday that Theranos recently changed some of the wording used on its website. For instance, the company deleted a sentence that said: "Many of our tests require only a few drops of blood." Theranos also dropped a reference to collecting "usually only three tiny micro-vials" per sample, "instead of the usual six or more large ones."

Ms. King, Theranos's general counsel, said before the article was published that the wording changes were made for "marketing accuracy."

Those wording changes are consistent with the outcome of the FDA's surprise inspection. The company's outside lawyer, David Boies, said in an email Sunday that the changes "did not result

from any recommendation, request or complaint about the website from any regulator.”

Most of Theranos’s blood-drawing sites, which it calls “wellness centers,” are located inside Walgreens Boots Alliance Inc. drug-stores. Forty of the blood-drawing sites are at Walgreens stores in the Phoenix area, and two more are in Walgreens stores in northern California.

James Cohn, a spokesman for Walgreens, referred questions from the Journal about the FDA inspection and any changes in Theranos’s blood-drawing methods to Theranos. A blood-drawing technician at a Walgreens in the Phoenix area, reached by phone late Thursday, said Theranos had “temporarily suspended” finger-prick draws and was only drawing blood from patients’ arms with needles at that store.

During the FDA’s inspection, federal officials told Theranos that it will have to resubmit data for many of the proprietary blood tests it has previously sought clearance for from the FDA, according to the person familiar with the matter.

The FDA concluded that data Theranos submitted before the inspection and additional data gathered during the examination were insufficient to prove the accuracy of many of its tests, this person said.

Theranos has previously said it has submitted data for tests using its proprietary technology to the FDA in an effort to be rigorous and transparent.

In a news release, Theranos called the Journal article Thursday “factually and scientifically erroneous and grounded in baseless assertions.” Theranos said the Journal had “declined an opportunity” to get a demonstration of the company’s proprietary technology.

A Journal spokeswoman said The Wall Street Journal “fully stands by Thursday’s article about Theranos, which was richly sourced and thoroughly researched.” She added that the newspaper had sought permission to visit Theranos’s offices to view the technology since late April.

Walgreens Scrutinizes Theranos

Drug chain says it won't expand testing to more stores while it seeks answers from startup

BY MICHAEL SICONOLFI, JOHN CARREYROU
AND CHRISTOPHER WEAVER
OCTOBER 24, 2015

Walgreens Boots Alliance Inc. won't open any new Theranos Inc. blood-testing centers until the startup company resolves questions about its technology, according to a Walgreens official.

On Thursday, a team from the drugstore chain met with senior Theranos executives, including founder and Chief Executive Elizabeth Holmes, at the startup's headquarters in Palo Alto, Calif.

The meeting was requested by Walgreens after its directors and officials learned from last week's article in The Wall Street Journal that the proprietary lab instrument developed by Theranos as the anchor of its growth strategy handled just a small fraction of the tests sold to consumers at the end of 2014, according to people familiar with the matter.

These people said Walgreens officials also were concerned after finding out in a follow-up article in the Journal that Theranos had stopped collecting tiny vials of blood drawn from finger pricks for all but one of its more than 240 tests.

Walgreens officials also were unaware of the Food and Drug Administration's surprise inspection of Theranos facilities in August and September, the people added.

While the talks between Theranos and Walgreens are continuing, the drugstore chain has "no concrete plans at this stage" to expand the partnership beyond the 41 stores in Arizona and California that now include Theranos "wellness centers," the Walgreens official said.

"We're trying to figure out where we are and what we do going forward. We need to understand the truth," the official added.

Heather King, Theranos's general counsel, said Friday: "Wal-

greens is our business partner and we meet with them regularly. We would not comment on ongoing discussions with any business partner, of course. Our partnership with Walgreens has been a positive one, realized through our program in Arizona, and we are continuing to work with them on future opportunities and arrangements.”

The drugstore chain has an equity stake in Theranos as part of the partnership, according to a person familiar with the matter.

The two companies announced the partnership in September 2013.

A news release said the “long-term” deal aimed to “bring access to” Theranos’s “lab testing service through Walgreens pharmacies nationwide.”

The release didn’t specify how fast the partnership might expand.

Walgreens, based in Deerfield, Ill., operates a total of 8,240 drugstores in all 50 U.S. states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands.

“Walgreens is everywhere and makes it easy for Theranos to get its products out into consumer hands,” said William Quirk, a research analyst at Piper Jaffray & Co., part of Piper Jaffray Cos.

If the partnership isn’t expanded, Theranos would have to “start selling more in physicians’ offices or establish a separate collection network” and “likely need a lot more capital,” Mr. Quirk said.

At Thursday’s meeting in Palo Alto, Theranos executives told Walgreens officials that the blood-testing company believes the Journal mischaracterized the company’s technology, said a person familiar with the meeting.

The person said Theranos reiterated its view that the Journal’s articles were false and misleading.

On Wednesday, Ms. Holmes criticized the articles at the WSJD Live global technology conference in Laguna Beach, Calif. On Thursday, Theranos posted a long response to the articles on the company’s website.

The Journal responded in its own statement that nothing said

by Ms. Holmes and “nothing in Theranos’s report undermines the accuracy of the articles.”

Walgreens directors held a regularly scheduled meeting on Oct. 15, the day of the first Journal article. Some of the directors huddled to set a strategy for how Walgreens should proceed, said people familiar with the matter. The full board didn’t formally discuss the matter, one person adds.

Some of the directors discussed how to reach out to Theranos, how they would try to understand any regulatory review and scrutinize why Theranos sharply narrowed its use of tiny vials of blood from finger pricks without telling Walgreens officials, these people said.

Walgreens formed a small team to investigate, according to people familiar with the matter.

That group is examining scientific and legal questions raised by the two Journal articles.

In their 2013 news release, Theranos and Walgreens said blood samples “are either taken from a tiny finger stick or a micro-sample taken from traditional methods, eliminating the need for larger needles and numerous vials of blood.”

For Walgreens, the deal was part of a larger push to make “back-of-store” pharmacies more valuable, while luring more customer traffic to the “front end,” where beauty products, snacks and other higher-margin products are sold, according to current and former Walgreens executives.

The drugstore chain’s chief executive and finance chief at the time, Gregory Wasson and Wade Miquelon, were photographed with Ms. Holmes at a ribbon-cutting ceremony when the first wellness center opened at Walgreens.

Messrs. Wasson and Miquelon, who since have left Walgreens, couldn’t be reached for comment.

The drugstore chain’s clinical-services group typically vets the science and practices of prospective outside medical partners early in the process, but was brought in later with Theranos, according to current and former Walgreens officials.

The Theranos deal “went down a different route,” one former

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Walgreens executive said. The Walgreens spokesman declines to comment.

Earlier this year, Walgreens executives looked into questions raised about Theranos by Mr. Quirk, the Piper Jaffray analyst, in a research report. In his report, Mr. Quirk described a test he took to compare blood tests at Theranos and two hospitals.

Despite the company's marketing claims of fast turnaround, the Theranos results came back in 70 hours, nearly three times as long as the hospital labs, according to Mr. Quirk's report.

After their review of the report, Walgreens executives took no action, according to people familiar with the matter.

The drugstore chain's spokesman declined to comment on the analyst's report.

Theranos has said it has performed tests on millions of patients referred by thousands of doctors and has received highly positive feedback.

Ms. King has previously said it is misleading to draw conclusions from "a handful of patient anecdotes." Some doctors have said they appreciate the company's user-friendliness and speed.

Safeway, Theranos Split After \$350 Million Deal

BY JOHN CARREYROU

NOVEMBER 11, 2015

Safeway Inc. spent about \$350 million to build clinics in more than 800 of its supermarkets to offer blood tests by startup Theranos Inc.

But the tests never began, the clinics are now used largely for flu shots and travel-related vaccines, and the two companies have been negotiating to officially dissolve their partnership, according to people familiar with the matter.

Current and former Safeway executives said Theranos missed deadlines for the blood-testing rollout. They also said several Safeway executives questioned the accuracy of results Theranos gave to Safeway employees tested at a clinic in the supermarket chain's headquarters in Pleasanton, Calif.

Safeway was a big growth opportunity for Theranos, based in Palo Alto, Calif. The project, code-named "T-Rex" at Safeway, hasn't been publicly disclosed by either company but goes back to at least 2011.

Safeway's chief executive, Steven Burd, told investors and analysts in 2012 that the company was "contemplating a significant. . .wellness play," without identifying Theranos by name. Former Safeway executives said the CEO was referring to Theranos.

The deal was struck before Theranos announced in 2013 a different partnership to offer blood tests to the public through Walgreens drugstores. Safeway signed on as the exclusive supermarket provider of Theranos tests, and Safeway built clinics in roughly half of its stores at the time, one former executive said.

Walgreens Boots Alliance Inc. won't open any new Theranos

blood-testing centers beyond the current 41 until Theranos resolves questions about its technology raised by an article in The Wall Street Journal last month, according to a Walgreens official.

That article reported that the proprietary lab instrument developed by Theranos as the anchor of its growth strategy handled just a small fraction of the tests sold to consumers at the end of 2014, according to people familiar with the matter. The article also said some of the startup's former employees were leery about the machine's accuracy.

Theranos has said its laboratory work is accurate and it has performed tests on millions of patients referred by thousands of doctors, with highly positive feedback. Theranos also has said that it is "continuing to work with" Walgreens on "future opportunities and arrangements."

In an email Tuesday, Theranos's general counsel, Heather King, said: "We don't comment on discussions with other companies. The questions and information you have presented. . . are inaccurate and defamatory." She declined to comment on the claims by former Safeway executives.

A Safeway spokesman declined to comment.

The valuation of Theranos, started by Elizabeth Holmes in 2003 when she was 19 and dropped out of Stanford University, jumped to \$9 billion last year.

A merger earlier this year made Safeway part of Albertsons Cos., the second-largest grocery company in the U.S. behind Kroger Co. Albertsons has about 2,200 stores and is controlled by private-equity firms that include Cerberus Capital Management LP.

"T-Rex" was rooted in Mr. Burd's enthusiasm for health-care innovation, according to the former Safeway executives. They said he managed the partnership directly with Ms. Holmes. Mr. Burd declined to comment, citing a nondisclosure agreement. He retired in May 2013.

Safeway and Theranos have been negotiating to dissolve their partnership.

The plan called for Safeway to build upscale clinics that would house Theranos's blood analyzers and provide patients with rapid test results, according to current and former Safeway executives.

The \$350 million price tag was equivalent to more than half of Safeway's net income of \$596.5 million in 2012. Safeway had revenue of \$44.21 billion. Safeway also invested more than \$10 million in Theranos, one former Safeway executive said.

In an initial phase of the project, Safeway had Theranos conduct blood testing at the headquarters clinic, current and former Safeway executives said.

Theranos often drew the same employee's blood twice, first with blood from a finger prick and then the traditional method of a needle in the arm, according to one former Safeway executive.

The former executive said he worried that Theranos's finger-prick process was still a work in progress. "If the technology is fully developed, why would you need to do a venipuncture?" this person said, using the term for a traditional blood draw.

The concerns deepened when Theranos's test results for several Safeway employees differed from the results the same employees got from other laboratories, according to the former executive. Another former Safeway executive confirmed those recollections.

It isn't clear how many Safeway employees got blood tests from Theranos or whether the varying results came from finger-prick or venous tests.

One Safeway executive got a frighteningly high result from Theranos on a test to gauge his prostate-specific antigen, according to two former Safeway executives. They said the test suggested that the executive had prostate cancer. Retesting by another lab came back normal.

Two of the former Safeway executives said they told Mr. Burd, Safeway's chief executive, about the varying employee test results.

The former executives said Mr. Burd told them he had been reassured by Ms. Holmes. Mr. Burd continued to support the

partnership with Theranos, according to the former Safeway executives.

Theranos also backed away from putting its blood analyzers in Safeway's clinics so patients could get the results quickly, the current and former executives said.

Instead, Theranos said blood samples collected at Safeway would have to be shipped to a central lab for analysis, according to the former executives.

By early 2013, some stores in California had hired phlebotomists, or the technicians who specialize in drawing blood, according to the current and former Safeway executives.

But Theranos kept delaying the rollout of its blood-testing services, those people said.

In April 2013, Mr. Burd was less enthusiastic about the financial possibilities of the Theranos partnership. Asked by an analyst about the "wellness initiative," Mr. Burd said: "It hasn't happened yet."

Mr. Burd retired the next month. After that, Theranos's Ms. Holmes stopped interacting with Safeway executives and delegated the handling of the relationship to Theranos's president and chief operating officer, Sunny Balwani, according to the former Safeway executives.

The project has been largely dormant for more than a year. Safeway's clinics remain open but are used mostly to administer vaccines, the current and former executives said. The clinics feature granite countertops, wood paneling, glass walls and flat-screen video monitors.

FDA Raps Lab Startup Theranos

BY JOHN CARREYROU

OCTOBER 28, 2015

The Food and Drug Administration declared the tiny vials used by Theranos Inc. to collect finger-pricked blood from patients an “uncleared medical device” that the laboratory company was shipping across state lines.

Inspection reports posted on the agency’s website Tuesday also showed that the FDA found deficiencies in Theranos’s processes for handling customer complaints, monitoring quality and vetting suppliers.

Government officials also warned the Palo Alto, Calif., company that it would receive a formal warning letter if it didn’t take action on the vials, called nanotainers, according to a person familiar with the matter.

In a statement Tuesday, Theranos’s general counsel, Heather King, said company officials “addressed and corrected” all the observations made by FDA inspectors “at the time of, or within a week of, the inspection and have submitted documents to FDA that say so, including extensive documentation.”

The FDA declined to comment beyond the two inspection reports it released. An article in The Wall Street Journal earlier this month said Theranos had stopped using the vials for all but one test.

The move amounted to a retreat from a method the company has touted as it rose to become one of Silicon Valley’s hottest startups. The Journal had said the company sharply scaled back its use of the vials amid FDA pressure, while Theranos described the decision as voluntary.

The surprise inspection, conducted from Aug. 25 to Sept. 16, was prompted by research data Theranos submitted to the FDA in an attempt to get its proprietary blood tests approved by the agency, according to the person familiar with the matter.

Some federal officials remain broadly concerned about the

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quality of Theranos's data and the reliability and accuracy of the company's tests, the person said.

The FDA doesn't have formal oversight powers for blood tests that clinical laboratories develop with their own proprietary techniques, but the agency decided to examine the nanotainers under the FDA's authority as a medical-device regulator, the person said.

In one of the inspection reports, FDA inspectors wrote that the agency considers the nanotainer a "Class II medical device," a category that requires special controls such as labeling requirements, mandatory performance standards and post-market surveillance. Examples of other Class II devices include powered wheelchairs and infusion pumps.

The FDA said it found that Theranos identified the nanotainer as "a Class I exempt medical device," the category of medical devices subject to the least regulatory control. Most Class I devices can be used without obtaining marketing authorization from the FDA.

"You are currently shipping this uncleared medical device in interstate commerce, between California, Arizona, and Pennsylvania," the report said.

The reports included 14 "observations" that Theranos must correct promptly to remain in compliance with the agency's regulations. According to the FDA, Theranos told the agency that it corrected or promised to correct within seven days a total of 13 of the observations.

The agency's conclusion that the nanotainer is an "uncleared medical device" was described by the FDA as "under consideration."

Theranos's Ms. King said the FDA's findings were "preliminary," adding that the agency approved in July the use of nanotainers for a herpes test. That approval included clearance of the proprietary laboratory technology Theranos uses to analyze tiny blood samples collected with the nanotainer, she said.

Some officials remain concerned about the quality of Theranos's data.

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In discussions with the FDA, Theranos determined that “it was appropriate to temporarily pause use of the nanotainer tubes for all tests except our cleared [herpes] test as we cut over to FDA quality systems, and wait for clearance,” Ms. King said.

A Journal article earlier this month said the lab instrument developed as the linchpin of its strategy handled just a small fraction of the tests sold to consumers at the end of 2014.

The Journal article also said some former employees, doctors and patients had raised questions about the accuracy of Theranos’s testing.

Theranos has said its tests are accurate and reliable, calling the Journal’s articles misleading in a statement on the company’s website last week. Some doctors have said they appreciate the company’s user-friendliness and speed.

The Journal has responded that “nothing in Theranos’s report undermines the accuracy of the articles.”

At a conference Monday sponsored by the Cleveland Clinic, Theranos founder and Chief Executive Elizabeth Holmes said Theranos would address criticism of the company in the scientific community by starting to publish data validating the accuracy and reliability of its tests.

“We were never against that,” she told conference attendees. “Data speaks the truth.” She didn’t specify whether Theranos would seek to publish in peer-reviewed medical journals.

Theranos is the most valuable health-care company among at least 125 companies world-wide that are valued at \$1 billion or more by venture-capital investors, according to Dow Jones VentureSource. Theranos has raised more than \$400 million from investors and has been valued at about \$9 billion.

Some investors have begun to question lofty private-company valuations of technology companies against the backdrop of a chilly market for initial public offerings.

In the past few days, Theranos removed from a prominent spot on its website a picture of Ms. Holmes holding up a nanotainer between her thumb and index finger. Ms. King didn’t respond to a request for comment on the change.

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The company now offers more than 200 blood tests to consumers through 45 blood-drawing sites it calls “wellness centers.” Forty-one of those are at Walgreens Boots Alliance Inc. drugstores. Walgreens won’t open any new Theranos blood-testing centers until the startup company resolves questions about its technology, according to a Walgreens official.

Ms. King of Theranos said last week that the partnership with Walgreens “has been a positive one.”

Theranos Remains In ‘Pause Period’



NIKKI RITCHER FOR THE WALL STREET JOURNAL

Theranos CEO Elizabeth Holmes

BY JOHN CARREYROU

OCTOBER 22, 2015

Theranos Inc. founder and Chief Executive Elizabeth Holmes said Wednesday that the Silicon Valley laboratory company is in a “pause period” as it seeks to get its proprietary technology approved by the U.S. Food and Drug Administration.

“We have to move, as a company, from the lab framework and quality systems to the FDA framework and quality systems,” Ms. Holmes said, speaking at the WSJD Live global technology con-

ference in Laguna Beach, Calif.

At the conference, she confirmed that the company is down to offering just one test using a few drops of blood and is performing the other more than 240 blood tests it offers consumers by using larger blood samples drawn with needles from patients' arms.

Ms. Holmes's appearance came a week after The Wall Street Journal reported that Theranos, under pressure from the FDA, had stopped collecting tiny vials of blood drawn from finger pricks for all but one of its tests -- a departure from the company's stated plan to revolutionize the blood-testing industry by conducting a wide range of tests from finger pricks.

"I read what was written in the article. We disagree with it," Ms. Holmes said. "We think it was false, and we think it was misleading." She also challenged the veracity of the Journal's sources, raising questions about the quality and knowledge of sources that were unnamed in the article.

In a statement, The Wall Street Journal reiterated that its articles about Theranos have been "thoroughly reported, fair and wholly accurate" and noted that its "sources were well positioned to know the information they provided about Theranos, and they were vetted before publication."

The Journal also reported last week that Theranos had cut back use of its proprietary lab instrument and was conducting most of its blood tests on traditional lab instruments purchased from major diagnostic-equipment makers like Siemens Healthcare, a unit of Siemens AG.

During the roughly half-hour interview, Ms. Holmes said Theranos's shift away from tiny finger-prick blood draws had "nothing to do . . . with the accuracy or performance" of the company's testing technology. The conference interview came after Ms. Holmes declined interview requests from the Journal for 5 1/2 months leading up to its articles.

Ms. Holmes confirmed that Theranos was subject to an "unannounced" inspection by the FDA, as the Journal had reported.

After the FDA inspection, which Ms. Holmes said was in late

August, Theranos scaled back the use of the tiny vials it calls “nanotainers” to collect blood from fingers to just one test, a test to detect herpes, a person familiar with the matter said. That test received approval from the FDA in July.

Ms. Holmes, 31 years old, has publicly said she built her company around her phobia of needles and has been widely hailed for her vision to create new blood-testing technology using only a few drops of blood. Theranos, which she founded 12 years ago after dropping out of Stanford University, has 45 blood-drawing sites. Most of them are located in Walgreens Boots Alliance Inc. stores in the Phoenix area.

Ms. Holmes acknowledged that Theranos had recently made changes to the wording of statements on its website to reflect its reduced finger-prick test offering. The FDA process has “affected the overall offering that we provide and so, on an ongoing basis, as we do this work, we update our language,” she said.

Ms. Holmes also confirmed that Theranos uses an alternative process for proficiency testing, the system that regulators rely on to monitor laboratories’ testing accuracy. Proficiency testing is administered by accredited organizations that send samples to labs several times a year. Labs must test those samples and report back the results to those organizations. If a lab’s results are close to the average of those in a peer group, the lab receives a passing grade.

Theranos doesn’t submit test results obtained from its proprietary finger-prick technology during proficiency testing, Ms. Holmes acknowledged. Instead, she said, the company uses an alternative procedure that she said had been endorsed by the Centers for Medicare and Medicaid Services, labs’ chief regulatory overseer. A spokesperson for CMS didn’t comment on Ms. Holmes’s statement.

Ms. Holmes said Theranos had never diluted the small blood samples collected from patients’ fingers in order to run some of its tests on traditional lab instruments. However, former employ-

*‘I read what was written....
We disagree with it.’*

ELIZABETH HOLMES

ees say the company did engage in this practice, which they say was meant to increase the samples' volume so that they would fit the specifications of those traditional machines. Lab experts say diluting blood samples should only be done in narrow circumstances and increases the chance of errors if used routinely.

Asked about a statement made earlier this week to Business Insider by Google Ventures executive Bill Maris, in which he said the venture-capital firm passed on investing in Theranos in 2013 after sending an employee to get tested there and being disappointed by what it found, Ms. Holmes said, "He's never met with us, he's never reached out to us, we've had zero communications . . . If he wants to just talk badly about us, he can talk badly about us."

In a statement provided by Google Ventures, Mr. Maris responded: "Our team constantly looks at opportunities in life sciences and as a part of the process, we looked at Theranos. We had one of our team members take the test and were underwhelmed by the results and experience. We did not pursue an investment. ~~Bigger picture: The critical issue is that there are a lot of patients~~ who deserve to know whether their blood test results are accurate. That's what really matters."

Ms. Holmes was also asked about an Internet post by former Apple Inc. executive Jean-Louis Gasse over the weekend in which Mr. Gasse described big discrepancies between test results he got from Theranos and results he got from Stanford Hospital. Mr. Gasse told the Journal he emailed Ms. Holmes to ask for an explanation on July 1 and never heard back from her.

"Unfortunately, I personally did not receive this letter. I wish he'd called our call center," she said. "We absolutely are going to follow up with him now that we're aware of this."

Reached by phone Wednesday afternoon, Mr. Gasse said he sent Ms. Holmes an email, not a letter, at info@theranos.com. "For a healthcare company, pretending not to have received a documented email message from a patient with serious health issues is simply unacceptable," he said, adding that Theranos hasn't followed up with him about his test results.

U.S. Probes Theranos Complaints

Blood-testing startup's practices investigated over concerns about accuracy, protocol



CEO Elizabeth Holmes has defended Theranos's testing.

BY JOHN CARREYROU

DECEMBER 21, 2015

U.S. health regulators are investigating complaints about laboratory and research practices at Theranos Inc. by two former employees of the blood-testing startup company, according to people familiar with the inquiries.

A complaint filed in September by a former Theranos lab employee to the Centers for Medicare and Medicaid Services alleged that management instructed lab employees to keep testing patients with the company's own blood-analysis devices despite

indications of “major stability, precision and accuracy” problems with those devices.

The second complaint was sent to the Food and Drug Administration earlier this month by another ex-employee, who alleged that the study submitted by Theranos last year to win the agency’s approval for a herpes test was tainted by breaches in research protocol.

Copies of both complaints were reviewed by The Wall Street Journal. Last week, an FDA scientific reviewer interviewed the person who filed the complaint with that agency, according to a person familiar with the matter. CMS auditors inspected Theranos’s lab in Newark, Calif., in November as part of a regularly scheduled audit that the company says is continuing.

A spokeswoman for Theranos, Brooke Buchanan, said the company hasn’t been provided with “a copy of any alleged complaint, so we have no basis to evaluate what is in it or even if a complaint has been filed.”

She added: “Agencies have a process for evaluating complaints, and many complaints are not substantiated. We trust our regulators to properly investigate any complaints, and we look forward to continuing our strong and productive relationships with them.”

CMS and FDA spokeswomen declined to comment.

Theranos, based in Palo Alto, Calif., was valued at \$9 billion in a funding round last year, making the company one of the highest-valued startups in Silicon Valley.

A Journal article in October said that the lab instrument developed as the linchpin of Theranos’s strategy handled just a fraction of the tests sold to consumers at the end of 2014, citing four former employees. The vast majority of tests were done with traditional lab instruments, the former employees said.

October’s article also said some employees were leery about the accuracy of Theranos’s in-house machine, called the Edison, noting that some doctors and patients also were concerned about test results.

Theranos has said that all its lab work is accurate and reliable.

In recent weeks, Elizabeth Holmes, the company's founder and chief executive, has defended Theranos in public appearances and pledged to publish peer-reviewed data on its tests. Ms. Buchanan, the spokeswoman, said the data aren't ready and declined to specify when the information will be published.

In response to questions from the Journal, Theranos last week made available three senior company scientists, who discussed their work and certain documents and regulatory submissions by Theranos. However, the company said the documents couldn't be disclosed by the Journal or reflected in this article because they contained confidential information and trade secrets.

In the complaint to CMS, the former lab employee alleged that Theranos managers were made aware of accuracy problems with its Edison devices in 2013 and 2014 but pressured lab employees to keep processing patient samples without taking corrective actions.

Edison machines would sometimes produce "radically different results" for the same patients, the former employee alleged. Referring to a thyroid test known as thyroid-stimulating hormone, the employee wrote that "a patient would swing between" hypothyroidism and hyperthyroidism, or too little of the hormone and too much, when the test was repeated the same day.

Daniel Young, a Theranos vice president and director of its Arizona laboratory, said he is "not aware of any pressure from upper management to release errors or unreliable results. That goes against everything I know about how Theranos operates."

He said Theranos has performed internal validation studies in which tests were run on both its proprietary technology and FDA-approved machines. The validation studies proved the accuracy of Theranos's proprietary tests, he added.

The ex-employee also echoed an allegation made by a Theranos employee to New York regulators last year. That employee had claimed the company might have manipulated the process known as proficiency testing that is used by CMS to monitor the accuracy of labs.

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Dr. Young said Theranos uses alternative assessment procedures for proficiency testing and has briefed regulators on these procedures. “I have full confidence that our procedures are sound,” he said.

The former employee who filed the complaint with CMS also sent the agency a follow-up email in October that alleges the company did a category of tests known as general chemistry tests by diluting tiny samples of blood collected from patients’ fingers and running them on traditional lab machines.

Quality-control checks of that testing method often failed, especially on tests designed to measure levels of carbon dioxide, calcium, sodium or potassium in the blood, according to the former Theranos employee.

Another former Theranos lab employee says the company kept using the dilution practice until May. Outside lab experts say diluting blood samples increases the risk of errors.

Dr. Young declined to comment about alleged dilution, saying prior statements by Theranos adequately and fully address the matter.

Ms. Holmes, Theranos’s chief executive, has denied diluting blood samples from patients’ fingers to run them on traditional machines. “I bet you if you tried that, it wouldn’t work because it’s just not possible to dilute a sample and put it on to a commercial analyzer,” she said at the WSJDLive conference in October. “I mean, there are so many things that are wrong with that.”

The complaint to the FDA alleged that Theranos hadn’t fully assembled the proprietary machines used for the herpes study when the experiments began. The former employee also alleged that the company underreported the rate at which the machines broke down during the study.

The employee also alleged that some crucial parts of the devices, including polystyrene tips that drop into blood samples, were modified to improve their accuracy. Scientists disapprove of making changes during a study because that can taint the integrity of the resulting data, according to outside experts.

Theranos denied the allegations and said its herpes study ad-

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hered to accepted scientific protocols and that the information it submitted to the FDA was truthful and complete.

The FDA approved Theranos's herpes test in July. The company has cited that approval as evidence that its proprietary blood-testing technology is reliable and fit for widespread use.

Theranos's spokeswoman, Ms. Buchanan, said Theranos believes that the former employee who filed the FDA complaint is "uninformed" and "disgruntled." The FDA's approval was "hard earned and the product of significant efforts by dozens of exemplary scientists and engineers — honest, hardworking, highly qualified individuals."

In September, the FDA declared the tiny vials used by Theranos to collect finger-pricked blood an "uncleared medical device" after inspecting the company's California facilities. Following the inspection, Theranos narrowed its use of the "nanotainers" to just the FDA-approved herpes test. In October, Ms. Holmes said the company was in a "pause period" while it awaits the agency's approval of the firm's other proprietary tests.

Theranos Searches for Director To Oversee Laboratory

BY JOHN CARREYROU

NOVEMBER 6, 2015

Diagnostics startup Theranos Inc. is seeking to hire a laboratory director to oversee one of its key facilities amid questions raised in laboratory circles about the qualifications of a physician who now runs the lab.

The blood-testing company has been operating its Newark, Calif., lab for the past 10 months under the supervision of Sunil Dhawan, a dermatologist without a degree or board certification in pathology or laboratory science.

The lab houses proprietary blood analyzers on which Theranos was running some of its more than 240 blood tests before scaling back their use earlier this year, former employees and a person familiar with the facility say. Those proprietary machines were developed to test tiny blood samples pricked from a patient's finger.

A page-one article in The Wall Street Journal last month cited concerns from some former employees, patients and doctors about the accuracy of Theranos's blood tests. Theranos says its lab work is accurate and the concerns unfounded.

Dr. Dhawan, 56 years old, meets federal and state requirements to be a lab director because he is a medical doctor and has experience overseeing a lab. Theranos said he has supervised the lab affiliated with his dermatology practice for over 21 years.

However, some lab specialists say there is a difference between the skills required to analyze tissue specimens for signs of skin cancer, for instance, and those necessary to oversee a full reference laboratory, meaning one that performs a wide range of blood tests.

Theranos has said its technological breakthroughs "have

made it possible to quickly process the full range of laboratory tests from a few drops of blood,” vaulting the company into the ranks of Silicon Valley’s most prized startups.

“When you consider the complexities of a reference lab with an expansive test menu, it would be next-to-unheard of to have anything less than a full-time pathologist or laboratory scientist with a Ph.D. as the laboratory director,” says Ed Thornborrow, medical director of the clinical labs at the University of California, San Francisco. He said Theranos approached him about the lab-director job it is advertising.

Dr. Dhawan didn’t respond to messages left at his dermatology practice in Fremont, Calif., or to an email inquiring about his lab experience.

Heather King, Theranos’s general counsel, said “Dr. Dhawan is qualified to be the laboratory director of a high-complexity lab, and has many years of experience in that capacity,” adding, “His training and expertise is highly relevant to the work that he performs for Theranos.”

Dr. Dhawan’s credentials as a dermatologist were previously reported by the Financial Times.

The company’s Newark lab, then located in Palo Alto, was inspected by the Centers for Medicare and Medicaid Services, laboratories’ chief regulator, in 2013, before Dr. Dhawan joined Theranos, according to an inspection report.

The inspectors listed several deficiencies, including results for several blood tests that they termed “unacceptable” and a lack of documented corrective actions on those and other issues. Theranos says that none of the deficiencies were serious, and that it promptly corrected them.

The lab’s director at the time had extensive lab training and experience, having completed a three-year residency in clinical pathology at a Boston hospital and five years as director of a Pittsburgh lab. He left Theranos in December 2014, at which point Dr. Dhawan took over.

In recent weeks, Theranos has advertised the Newark lab-director position on its website and has approached directors of

other labs in California to gauge their interest, according to people familiar with the matter and emails from Theranos recruiters reviewed by the Journal.

The first qualification Theranos lists on its website for the Newark lab-director job is “M.D. degree with Board Certification in Pathology.”

On its site, Theranos has also posted three other senior positions at the Newark lab: lab manager; manager of quality assurance and quality control; and laboratory general supervisor. Lab experts say the four posts typically are a lab’s senior leaders.

Ms. King, Theranos’s general counsel, said: “We are a growing company and, simply because we have job openings posted or are interviewing people for those roles, does not mean that the laboratory does not already have such personnel; laboratories commonly have multiple people on staff serving with the same titles.”

A Theranos lab employee who recently left the company says Dr. Dhawan didn’t have a presence at the Newark lab.

Theranos’s Ms. King, said that information was “at a minimum, misleading.”

Theranos recently stopped drawing tiny blood samples from patients’ fingers for all but one of its blood tests after the Food and Drug Administration inspected its facilities and deemed the miniature vials it used to collect the blood an “uncleared medical device.” Theranos said the move was voluntary.

Theranos Authorizes New Stock, Filing Says

BY ROLFE WINKLER AND JOHN CARREYROU

OCTOBER 29, 2015

Theranos Inc. authorized new shares that would value the laboratory startup at more than \$10 billion, a regulatory filing shows, three days before a Wall Street Journal article detailed the company's struggles to turn excitement over its reported breakthroughs in blood-testing technology into reality.

Some legal experts say such a filing typically signals that a company has raised, or is planning to raise, new funds from private investors. Theranos says that isn't the case with this authorization, and it wouldn't say if the new shares have been issued.

Separately, Theranos has raised nearly twice as much capital from investors as previously widely reported. As of April, Theranos had raised \$752 million, according to other regulatory filings.

Theranos founder and Chief Executive Elizabeth Holmes declined to comment on the higher figure when asked about it at last week's WSJ.D Live conference, reiterating the company's prior statements that it has raised "over \$400 million."

Theranos authorized the new shares on Oct. 12 by filing an amendment to its certificate of incorporation in Delaware. The Journal's article on Theranos, for which the company provided input over a period of more than five months, was published in both the newspaper's print and online editions on Oct. 15.

The share authorization also came a little less than a month after the completion of a surprise inspection of Theranos by the Food and Drug Administration.

That inspection became public only when it was disclosed in a second Journal article on Oct. 16, which also reported that Theranos had stopped using its tiny vials to collect blood samples for

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all but one of its more than 240 tests.

The FDA posted documents summarizing the inspection's findings this week.

Theranos said the FDA's findings were "preliminary," that the company "addressed and corrected" the observations made by FDA inspectors, and voluntarily scaled back its use of the vials.

The document Theranos filed Oct. 12 with the Delaware Division of Corporations, which was signed by Ms. Holmes, says that the executive committee of the company's board adopted resolutions establishing 10.9 million new "Series C-3" shares at \$20 a share, \$3 a share more than in Theranos's previous funding round.

The Journal reviewed a copy of the document supplied by VCExperts, a firm that provides data on private companies. Fortune.com referred to the document in an article on Wednesday.

When first asked about the document on Oct. 18, Theranos said: "The filing didn't have anything to do with financing or attempted financing."

Asked about the document on Oct. 21 at the WSJ.D Live technology conference in Laguna Beach, Calif., Ms. Holmes said the share authorization wasn't intended to raise funds.

Instead, she said it was being used to "reclassify" some shares from a previous class of stock designated as "C-2," to prevent "excess shares" from getting into "secondary markets."

Ms. Holmes said Theranos wanted to keep control of its "small shareholder base," and "didn't want shares stuck under a past round that is closed out."

On Wednesday, a Theranos spokesman said the "C-2" shares that Theranos was reclassifying had never been issued. The spokesman didn't respond to requests for clarification on how shares that hadn't been issued could get into secondary markets.

Heather King, Theranos's general counsel, said: "As a private company we do not comment publicly on company filings."



Theranos's Elizabeth Holmes

NIKKI RITCHER FOR THE WALL STREET JOURNAL

Several legal experts consulted by the Journal say they weren't aware of any other company creating a new class of shares in order to reclassify old, unissued shares.

Asked about the document Theranos filed in Delaware, Robert Borghese, a professor of legal studies at the University of Pennsylvania's Wharton School, said: "It looks like they're going out and raising more money."

"It looks fairly plain vanilla to me," he added. "I'm not seeing anything here that suggests this is anything other than a straight additional fundraising round."

The \$20 share price for the new shares is an 18% markup from the company's prior round of financing, and implies a valuation of \$10.5 billion for Theranos.

Theranos investors include Oracle Corp. co-founder Larry Ellison and venture-capital firm Draper Fisher Jurvetson, according to Dow Jones VentureSource.

A spokeswoman for Oracle, Mr. Ellison's company, declined to comment. A spokeswoman for Draper Fisher Jurvetson said the firm only made a seed investment in Theranos in 2004.

Theranos shares have been readily available in secondary markets in recent months, say people involved in those markets, as early investors likely sought to cash in some of their gains when the valuation jumped to \$9 billion last year.

Geno Zawrotny, director of the Private Securities Group at SharesPost Financial Corp., which matches buyers and sellers of private company shares, sent an email to investors on Sept. 30, saying SharesPost was "taking indications of interest at this time for next tranche" of Theranos shares in addition to other companies.

Mr. Zawrotny said confidentiality agreements prevented him from commenting on Theranos share trading. Theranos didn't respond to requests for comment on private share sales.

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For access to articles, use
login: wsjcontests@gmail.com
password: judges

Reaction

The Wall Street Journal was widely credited with breaking the news that Theranos was receiving attention from FDA inspectors:

New York Times columnist Farhad Manjoo called the Journal's first story "incredible":

Theranos, a Blood Test Start-Up, Faces F.D.A. Scrutiny

By Andrew Pollack and Reed Abelson | Published: Oct. 16, 2015

"The company's action was reported by The Wall Street Journal, which said the F.D.A. was concerned about the company's data and had conducted an unannounced inspection. The Journal also raised questions about the reliability of Theranos's tests and said that most of the tests the company ran were done on standard laboratory equipment bought from other vendors, not its proprietary system that it has promoted as a disruptive technology in the industry."

<http://nyti.ms/1LpZvof>

Farhad and Mike's Week in Tech: A Square Deal

By Farhad Manjoo and Mike Isaac | Published: Oct. 17, 2015

"The Theranos story is incredible. In the past few years Elizabeth Holmes, Theranos's 31-year-old founder and chief executive, has been hailed as a genius on the cover of just about every glossy magazine other than Garden and Gun. But per The Journal, the company is using its proprietary technology for just a single one of the more than 100 medical tests it offers."

<http://nyti.ms/1QE6Kfy>

Reaction

The Los Angeles Times's Michael Hiltzik reported on the story in a column called "The Theranos Affair: When Silicon Valley hype outpaces reality"

Bloomberg also followed:

Washington Post's Wonkblog called the article "deeply reported," closing with "New innovations can't simply surf on excitement when people's lives are at stake."

The Theranos Affair: When Silicon Valley hype outpaces reality

By Michael Hiltzik | Published: Oct. 16, 2015

"That changed last week, when articles in the Wall Street Journal reported that the firm has struggled to show that its technology works, and suggested that it may have been misleading the public, and possibly government regulators, about the effectiveness and accuracy of its technology."

<http://fw.to/Orun6vf>

Theranos Disputes Report, Says Tests Are 'Accurate and Reliable'

By Melissa Mittelman | Published: Oct. 15, 2015

<http://bloom.bg/1RK2bBu>

Theranos Limits Blood Technology to a Single Test Out of 200

By Caroline Chen and Zachary Tracer | Published: Oct. 15, 2015

<http://bloom.bg/1KckkkX>

The wildly hyped \$9 billion blood test company that no one really understands

By Carolyn Y. Johnson | Published: Oct. 15, 2015

<http://wpo.st/bpI11>

Reaction

Business Insider walked through the company's attempts to kill the story.

Jason Calacanis, startup investor and journalist, from the "Best of 2015" episode of his online show "This Week in Startups":

Multi-billion dollar health startup Theranos tried to kill a report questioning how well its 'revolutionary' blood test actually works

By Lucy England | Published: Oct. 15, 2015

<http://read.bi/1QwSwx5>

E608: News Roundtable: Best of 2015!

By Jason Calacanis | Published: Dec. 28, 2015

"Is Theranos not emblematic of the fact that there are no—or few—tech journalists left with the budgets to do investigative reporting and the teeth, the gumption, the gall, the sharpness, the aggressiveness that we saw in '70s, '80s, even '90s investigative journalism? ... It's just few pockets left of people who want to challenge this powerful group of people."

"This is people's health ... This is very serious stuff, "All The President's Men," "The Insider" ... This could be one of the greatest frauds of our time."

About fudging facts and data:

"You know what? It's unacceptable if it's people's health ... People could die."

"This is a Big Tobacco/Enron kind of thing."

<http://thisweekinstartups.com/news-roundtable-best-2015-levy-mathews/>

Reaction

Quartz weighed in with skepticism about Theranos’s rebuttals to the Journal’s story, which it called “deeply reported.”

Jim Cramer hosted Holmes that evening for an appearance on CNBC’s Mad Money, telling her the article was “pretty brutal” and pressing her to answer repeated detailed questions about what her company’s tests can do.

Theranos still hasn’t provided the one thing that could reassure doubters for good

By Max Nisen | Published: Oct. 22, 2015

<http://qz.com/531012>



Theranos CEO fires back at WSJ: I was shocked

By Abigail Stevenson | Published: Oct. 15, 2015

<http://cnb.cx/1VVJwZh>

Reaction

The Journal's coverage set off a wave of soul-searching among some publications, as to how they (or their competitors) missed the story or whether they gave Theranos too much early hype.

A writer for Fortune penned a story titled "How Theranos Misled Me," after what he described as John Carreyrou's "now famous front-page article."

How Theranos Misled Me

By Roger Parloff | Published: Dec. 17, 2015

<http://for.tn/1IWhvuM>

BostInno's editor-in-chief pointed to the Journal's coverage as one that helped to "burst" the bubble about brash start-ups.

2015: The Year the Media Took Down the Millennial Founders & CEOs

By Galen Moore | Published: Dec. 21, 2015

<http://bostinno.streetwise.co/2015/12/21/millennial-founders-and-ceos-tech-bubble-take-downs-of-2015/>

Another article, from Forbes, warned readers to "Beware the Hype Machine Lessons from Theranos," saying the company's claims were called into question due to an investigation in The Wall Street Journal by John Carreyrou.

Beware The Hype Machine: Lessons From Theranos

By Chris Myers | Published: Nov. 2, 2015

<http://onforb.es/1M7j1Ga>

Reaction

Re/code ranked the Journal's original story as the "best" of five (otherwise puffy) cover pieces done on her career at Theranos.

Theranos CEO Elizabeth Holmes's Five Best Cover Story Appearances, Ranked

By Noah Kulwin | Published: Oct. 26, 2015

<http://on.recode.net/lkIpikZ>

Wired magazine cited, in an article called "Tech Giants That Fell From Grace," what it called a "meaty expose" in the Journal, saying that the Theranos controversy "revealed how the Silicon Valley hype cycle can spin wildly out of control."

Tech Giants That Fell From Grace

By Issie Lapowsky | Published: Dec. 22, 2015

<http://www.wired.com/2015/12/2015-losers/>

Other stories in the Theranos series also were widely credited. This Forbes article cites the Journal's coverage throughout, including its scoop about Theranos's problems in its partnership with Walgreens.

Walgreens Puts The Brakes On Theranos Roll Out—Are Lawsuits Next?

By Dan M. Turner | Published: Oct. 24, 2015

Reaction

Several news organizations cited the Journal for breaking the story that the FDA is investigating new allegations about the quality of its one FDA-approved test, for herpes.

Among them were Reuters:

U.S. Health Regulators Probe Theranos Complaints

By Sneha Teresa Johny | Published: Dec. 20, 2015

<http://reut.rs/1UU0qDI>

And CNBC:

US regulators investigate Theranos complaints: WSJ

By CNBC Staff | Published: Dec. 20, 2015

<http://cnb.cx/1UTUGcN>

Celebrity-chaser Gawker even got in on the story, crediting the Journal's reporting with pushing Holmes to "release data that will purportedly prove her company's tech works." Gawker went on to call Theranos's concession a turn from Holmes's original PR strategy, which chalked up the Journal article to disgruntled ex-employees and backward-thinking regressives who are afraid of Silicon Valley disruption." They continued their piece with compliments about the Journal's willingness to look deeper. "It's worth noting that before the Journal's report, major news outlets basically held up Holmes—a 31-year-old who dropped out of Stanford at 19, started Theranos, and is now a billionaire—as the second coming of Steve Jobs."

Theranos: Okay, Fine, We'll Release Data to Prove Our Blood Tests Work

By Jay Hathaway | Published: Oct. 27, 2015

<http://gawker.com/theranos-okay-fine-well-release-data-to-prove-our-bl-1738973189>

More Coverage

The reporters and editors hosting Journal's popular WSJD conference offered Holmes a chance to get her response out there. And the Journal live-blogged it.

Theranos CEO Elizabeth Holmes Goes on Stage at WSJDLive 2015 — Live Blog

By WSJ Staff | Published: Oct. 21, 2015

<http://on.wsj.com/1OSgBzF>



The WSJ statement on the WSJD appearance and Theranos's later lengthy commentary on the original article:

Wall Street Journal Statement Regarding Theranos CEO Interview at WSJD Live and Theranos's Subsequent Statement

Published: Oct. 21, 2015

<http://www.dowjones.com/press-room/wall-street-journal-statement-regarding-theranos-ceo-interview-at-wsjd-live/>