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EVERYTHING YOU NEED TO KNOW ABOUT THE THERANOS SAGA SO FAR

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Theranos founder and CEO Elizabeth Holmes
MATHEW SCOTT

IN THE BEGINNING, Theranos was called Real-Time Cures. Corny? Sure. But Elizabeth Holmes was barely 19 when she came up with it, a Stanford dropout aspiring to upend personalized medicine. Besides changing its name, Theranos has come a long way: It's raised hundreds of millions of dollars, signed deals with huge consumer health companies, received federal approval, and been the subject of glowing profiles in some of the world's most prestigious publications.

Theranos has also been the subject of

a damning Wall Street Journal
investigation that attacked the

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company's credibility, its business plan, and its technology. Theranos is a complicated, secretive company that is caught up in a scandal because it may have broken esoteric regulatory rules, and violated fundamental guidelines for how science is done. Its saga is fascinating. Also confusing. So it's best to just start at the beginning.

Early days

Legend has it, Elizabeth Holmes founded Theranos because she is afraid of needles. Which is an oversimplified version of what really happened. Holmes spent some of her freshman year at Stanford working in chemical engineering professor Channing Robertson's lab alongside PhDs. Over the summer, she interned in a lab in Singapore that was looking for ways to detect SARS in minute traces of blood and mucus. She came back charged, and spent days working on a patent for a patch-worn drug delivery system. She presented her patent to Robertson and told him she was dropping out of school to start a company. She asked him to join the board, and he agreed.

Things moved quickly after Stanford. Family friend and billionaire venture capitalist Tim Draper seeded her first million. She rented lab space and hired employees. And she kept raising money. In 2004, \$6.9 million. 2005, \$16 million. 2006, \$28.5 million. By 2014 she had \$400 million. On paper, investors valued the company at \$9 billion.

Along the way, Holmes changed her company's focus from drug delivery patches to fingerprick diagnosis. Originally, her plan was to sell them to [pharmaceutical companies](#)—Theranos would provide cheap, quick tests of chemical levels in patients' blood, to figure out dosing and effects of drugs in development. But by the time stories about the company started appearing in mainstream press, Theranos was in the business of consumer health.

The next Steve Jobs

And why not? Holmes was promising a health care revolution. Blood tests are a pain in the arm. Sharp. Inconvenient. Expensive. Theranos promised an antidote. Pain-free tests that could look for up to 70 different markers in a single drop of blood. Results delivered to your phone in hours. And every single test cost less than half the Medicare reimbursement rate, with [prices listed plainly on its website](#).

Theranos hit the mainstream in 2014 with a [cover feature in Fortune](#). The story established Holmes as Silicon Valley's next legend-in-the-making. "I realized that I could have just as well been looking into the eyes of a Steve Jobs or a Bill Gates," Robertson, her Stanford mentor, is quoted.

In the months and seasons to come, Holmes and Theranos made a grand tour of Important American Media: [Vanity Fair](#), [Bloomberg](#), [Forbes](#), [Inc.](#), [Fast Company](#), [CNBC](#), [CNN](#), [The Economist](#), [The New Yorker](#), [Time](#), [Glamour](#), [WIRED](#).

In their own way, each repeated similar points. Personalized blood tests would revolutionize medicine, Holmes was the next Steve Jobs (her black turtleneck uniform certainly helped perpetuate this), and Theranos' technology was wonderful and mysterious. But none were able to get Holmes to discuss exactly how that technology worked. Proprietary information, trade secrets, okay, sure.

While Holmes was being adored by the media, her company was sopping up partnerships. Capital Blue Cross would make Theranos tests available to patients in Pennsylvania. The Cleveland Clinic signed on, too. And Walgreens and Safeway both agreed to set up testing centers.

Theranos had other wins. In spring 2015, the company co-authored an Arizona bill that became law, making it legal for patients to get their blood tested without a doctor's note. That summer, the FDA announced that Theranos' nanotainers—the company's proprietary fingerprick blood collectors—were safe for testing for herpes simplex-1.

Blood tests do not require FDA approval. Rather, tests developed in clinical labs typically get approved through another regulatory framework called the Clinical Labs Improvement Amendments, or CLIA. Theranos used the FDA ruling to

hush the murmuring skeptics, who complained that Theranos' miracle technology had not been put through the peer review processes that are typical for consumer medicine.

Things fall apart

John Carreyrou was skeptical. He had read the New Yorker's profile of Holmes, and was bothered by her company's absurd, obsessive secretiveness. So the Pulitzer Prize-winning Wall Street Journal reporter started digging. Over the next several months, sources began trickling

information to him.

The general gist: Theranos' technology was not what it seemed. In fact, the company's blood testing device, a machine called Edison, couldn't accurately detect enough molecules in blood samples to provide accurate readouts. Blood behaves differently in small volumes, more like a pile of M&M's coated in honey than a proper fluid. Edison couldn't get things right, sources told Carreyrou, so Theranos had been diluting samples taken via the fingerstick and running them through blood testing devices manufactured by Siemens¹—the same type of equipment used by every other blood testing company. And in fact, Theranos was using these off the shelf machines to run most of its tests.

Front page, below the fold, the muted headline read, 'A Prized Startup's Struggles.'

On October 15, 2015, the Journal published Carreyrou's article. Front page, below the fold, the muted headline read, "A Prized Startup's Struggles." Along with the above revelations, his story alleged that Theranos had cheated on the proficiency tests CLIA requires.

That evening, Holmes appeared on CNBC's Mad Money with Jim Cramer to refute the Journal's reporting. "This is what happens when you work to change things, and first they think you're crazy, then they fight you and then all of a sudden you change the world," Holmes told the host.

The next day, the Journal followed up with a scoop that the FDA had recently showed up to Theranos' lab and told the company to stop using its nanotainers, because they were uncleared medical devices.

Theranos again fired back on October 21, appearing on stage at the Journal's own technology conference in Laguna Beach, California, and then the next day in a sprawling blog post that attempted to take down the Journal point by point. Still, the company provided no data to definitively refute the Journal's reporting.

The rest of the month brought a deluge of new allegations, as other media outlets started picking up threads that the Journal had left behind. The Financial Times reported that Theranos did not in fact have ongoing deals with drug companies Pfizer and GlaxoKlineSmith, as had been implied in The New Yorker's 2014 profile. Fortune found discrepancies in the amount of money Theranos had reportedly raised. And the New York Times discovered that the company had downsized and reorganized its powerfully stacked board of directors—which had included former Secretary of State Henry Kissinger, former CDC director Bill Foege, and former US senator Bill Frist, among others—to just five people. None of those new five have any significant medical experience. (The company did form a separate medical board.) And at the end of the month, the FDA released a pair of redacted documents that corroborated Carreyrou's reporting about the uncleared nanotainer, as well as outlining how Theranos had shoddy lab practices.

October's bad press impacted Theranos' business. Walgreens announced it would not build any more Theranos Wellness Centers until the company proved

its technology was sound. Safeway bailed completely. The Cleveland Clinic announced it would independently verify Theranos' technology.

The remainder of 2015 was not necessarily quiet for the company, but Theranos spend the rest of the year dealing with think pieces and the like, rather than damning revelations. The Journal owned the story, and everyone was waiting for what would happen next.

On January 24, it came. Carreyrou and two other Journal reporters reported that inspectors from the Centers for Medicare and Medicaid Services had found serious problems in Theranos' Newark, Ca lab. Enough so that the lab was at risk of losing its access to Medicare patients.

Whoever wrote the letter added that they were not sure Theranos had a clear understanding of how the regulations worked.

More bad news followed. Theranos had run a flawed blood-clotting test on over 80 patients for six months. Theranos' tests were throwing off medical decisions. Theranos's tests fail at least a third of all internal quality control checks. And on March 18, Theranos received a letter from CMS stating that it was not correcting its problems.

Whoever wrote the letter added that they were not sure Theranos had a clear understanding of how the regulations worked. If the company did not correct its deficiencies, CMS could institute penalties. Among the harshest, banning Holmes and Sunny Balwani, Theranos' president, for two years from owning or operating any blood testing labs.

The FDA and CMS weren't the only federal agencies interested in Theranos. On April 18, the Journal reported that the Securities Exchange Commission—the agency charged with protecting investors—and the Department of Justice had issued subpoenas to Theranos and several of its business partners.

Where we are now

Theranos has not been convicted of anything. CMS has not yet revoked its license, nor banned Holmes from the blood testing industry. It is still selling tests from 40 Walgreens locations in Arizona. It probably still has millions of dollars in the bank, though its \$9 billion dollar valuation is debatable at this point.

What comes next is binary, to an extent. The company either lied about its technology, or this is all just a protracted misunderstanding. Whatever happens, expect lawsuits. If the company is guilty of fraud, Theranos' investors are going to come clawing for their money. Customers might have some bones to chew on too, via class action attorneys pursuing wrongful treatment cases. If Theranos is absolved, the company will probably file libel charges at the Journal. No matter what, expect a movie. Stories like this don't come along every day.

¹ UPDATE: 05/04/2016 1:00pm ET — Previously, this sentence said Theranos had been diluting blood samples to run on their Edison machines. Apologies for the mix-up.

#ELIZABETH HOLMES #HEALTH #MEDICINE #THERANOS

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