



Bad Blood **Secrets and Lies in a Silicon Valley Startup** *By John Carreyrou*

At its peak in 2013/14, Theranos had a valuation of \$10 billion, representing incredible growth in the 10 years since its incorporation in 2003. The company claimed that it had developed and commercialized a revolutionary new blood testing solution. Viewed as a stunning start-up success, the Theranos board was a roster of well-known government and business leaders, including Henry Kissinger, James Mattis and Riley Bechtel. The buzz around Theranos was electric, and high-profile investors such as Betsey DeVos, the Walton family, and Rupert Murdoch invested hundreds of millions of dollars to fund the company.

At the helm was Elizabeth Holmes, founder and CEO. Holmes dropped out of Stanford Engineering in 2004 and used her tuition fees to help fund her brainchild. Blond, attractive, and possessed of an unusually deep baritone voice, Holmes was listed by Forbes as one of America's Richest Self-Made Women in 2015, with a net worth of over \$4 billion.

That same year, however, it all came crashing down when investigative reporter John Carreyrou of the Wall Street Journal revealed that the Theranos technology did not work as claimed. Carreyrou's exhaustive research uncovered a web of lies and cover-ups, dating back to the earliest days at Theranos. Today, the company is worth nothing and has been dissolved, investors have lost multi-millions, and Elizabeth Holmes was charged with massive fraud by the SEC in March, 2018. This riches-to-rags story has captured the public's imagination, and a movie based on Carreyrou's book (starring Jennifer Lawrence as Elizabeth Holmes), is slated for release in 2020.

So how did Holmes persuade so many smart people that Theranos was such a ground-breaking and potentially profitable enterprise? And how did she maintain the fiction for so long? Let's start with the technology concept that Holmes first envisioned, back in 2003.

The Technology

While still a student in the chemical engineering program at Stanford, Holmes spent the summer of '03 working as an intern at the Genome Institute in Singapore. At that time, Asia was hard hit by SARS and Holmes spent the internship testing blood from samples drawn by syringe and nasal swab specimens from patients. This was the crystallizing experience for Holmes, and the birth of the technology at the heart of the TheraPatch mythology. At the end of the summer she returned to Stanford and holed up for five days, emerging with a patent application for an innovative new product: an adhesive arm patch that would both diagnose and deliver treatment for medical conditions.

The initiative had impressive momentum from the start. Holmes was able to tap wealthy business friends of her parents, who supplied the first wave of start-up millions. In the initial prospectus, the “TheraPatch” was an adhesive patch with microneedles that would extract minute amounts of blood painlessly. Outfitted with a microchip sensing system, the TheraPatch would also conduct a blood analysis and determine how much of a drug to deliver. In addition, the patch would transmit all information to the wearer’s physician wirelessly.

As Holmes and her nascent team worked on the idea, the TheraPatch evolved from a patch into a cartridge-and-reader system that theoretically would analyze blood for multiple substances. The user had to prick their finger, dab the blood onto a cartridge card, and insert the card into a “reader” machine. The reader used microfluidics and biochemistry to separate the blood components and analyze the plasma, and sent the findings via cellular networks to physicians’ computers. The cartridge was about the size of a credit card, and the reader was about the size of a small microwave oven. A later iteration featured a “nanotainer,” a tiny vial which held just a drop of blood, obtained with a finger prick, which TheraPatch claimed was all that was necessary to run a multitude of tests using the reader technology.

The idea behind the technology was brilliant: eliminate the need to use painful syringes to draw large amounts of blood for tests, and replace the process with a tiny finger prick and miniscule blood draw. In addition to helping people with a fear of needles, the technology would make it possible to conduct instant blood analysis at drugstores, in the home, the workplace, or even on the battlefield, enabling rapid diagnoses, adjustments of medications and more.

If the concept had worked as intended, it would have had a truly revolutionary impact on healthcare. And that’s probably why so many investors and supporters failed to recognize – or even ignored – the red flags along the way, even when they were raised by very credible insiders.

Let’s take a look at some of the key players in the TheraPatch saga.

Elizabeth Holmes

With big blue eyes, blond hair, and that deep voice, Elizabeth Holmes was attractive, persuasive and charismatic. She modelled herself on Steve Jobs, and even dressed as Jobs had, in black turtlenecks and pants. Some critics think she faked the deep voice to seem more authoritative, and there are videos on YouTube that do seem to capture her speaking in a higher voice. She had an ability to gloss over any hiccups or stumbling blocks that didn't support her development plan. This, combined with her dismissive, even aggressive response to any challenges from her staff, helped to keep the lid on all the problems with the Theranos technology. In the Silicon Valley world of start-ups and unicorns, she was a rock star, posing for magazine covers and travelling with a large security entourage.

The Theranos Board

The Theranos board was a veritable who's who of American political and business leaders. In addition to Henry Kissinger (former US secretary of state), James Mattis (retired US Marine Corps general and former secretary of defense for President Trump), and Riley Bechtel (former board chair of Bechtel Group Inc.), the board line-up in 2015 included William Frist (a heart and lung transplant surgeon and former US senator), William H. Foege (former director of the Centers for Disease Control and Prevention), Richard Kovacevich (the former CEO of Wells Fargo), Sam Nunn (a former US senator), William Perry (former US secretary of defense), Gary Roughead (a retired US Navy admiral), and George Shultz (former US secretary of state). But among all of these heavy hitters, only two board members – Frist and Foege – had any medical experience. Compared to the boards of other companies in the medical field, which are typically composed of medical experts, academics and CEOs from medical companies, the Theranos board lacked any experience relating to hematology, blood analysis or even the medical device industry.

The Boyfriend

Ramesh “Sunny” Balwani was a married 37 year old when he met 18 year old Holmes in 2003. Born in Pakistan in 1965, Sunny Balwani came to the US in 1986, to study information systems at the University of Texas in Austin. After earning an undergraduate degree, and following stints at Microsoft and Lotus, he helped create a company called CommerceBid, which was sold in 1999, earning Balwani \$40 million. He then received an MBA from the University of California at Berkeley, and after that studied computer science at the graduate level for four years at Stanford, but dropped out without completing a degree.

In Balwani, Holmes saw a successful entrepreneur and mentor, and she brought

him on board at Theranos as executive vice chairman in 2009. The fact that Holmes and Balwani were in a romantic relationship and were living together was never disclosed to investors.

Balwani's management style was autocratic and aggressive. He chastised and bullied employees, showcased his wealth with expensive cars and clothes, and bragged that he'd written a million lines of code – an impossible achievement, given that expert teams of software engineers are able to write about 1,000 lines of code in a year. His area of expertise was supposed to be software, counterbalancing his utter lack of expertise in the medical field.

He was also an attack dog, coming out strongly against any perceived threats to Theranos. From employees questioning any aspect of the technology, to queries from regulatory agencies, Balwani (along with Holmes) typically responded with aggression and even threats. For the employees who had concerns about the Theranos system, especially once it went into use with real patients, this was stressful and frightening, and was very effective at suppressing any dissent that threatened the Theranos façade.

The Truth-Tellers

Along the development path, many employees at Theranos felt that the blood analysis technology had serious problems, and was not ready to be put into actual use. And these were experts in their fields, from engineers to biochemists to scientists, whose concerns should have been addressed and explored. Instead of listening to these people, Holmes and Balwani did everything they could to suppress any findings that didn't support their narrative, and squelched any concerns that might have slowed the Theranos momentum.

For those who did try to speak out, threats of lawsuits and visits from lawyers were usually enough to make them re-think any desire they had to speak the truth. Every employee had to sign a non-disclosure agreement, which was standard in the industry, but at Theranos, departing employees had to sign a slew of even more restrictive NDAs.

Even in the face of this aggression, many staff members tried to bring their concerns forward. Some felt defeated, and simply quit, while others tried to alert board members and regulatory agencies. Let's look at the experiences of two of these employees in more detail: Ian Gibbons and Tyler Shultz.

Ian Gibbons

Biochemist Ian Gibbons worked at Theranos from 2005 to 2010, leading chemistry activities. His area of specialization was blood testing. After he expressed his concerns about the quality of the testing achieved by the Theranos

machines, his issues with Holmes' management and her "loose relationship with the truth," he was fired, then re-hired as a lower-level consultant. He continued to be frustrated with the way things were going at Theranos, and felt that his replacement was more concerned with pleasing Holmes than achieving a quality result with the Theranos equipment. The results that they were getting were not up to the necessary medical standards, according to Gibbons, and he became frustrated arguing the point.

Things continued to go downhill for Gibbons, and he became extremely depressed and anxious. He was reluctant to quit, because he still believed that he could help Theranos fix its problems. However, the last straw was a deposition that he was scheduled to participate in, having to do with a patent lawsuit at Theranos. He was concerned that his testimony could invalidate Theranos's patents and this put tremendous pressure on him in his weakened state. The night before he was scheduled to testify, on May 16, 2013, Gibbons took an intentional overdose of acetaminophen. Although his wife found him while he was still alive, he died in hospital a week later.

His wife Rochelle called Holmes, and left a message to tell her about Ian's suicide attempt and hospitalization. Holmes never called back. Rochelle was contacted via email by a Theranos lawyer later that day, who requested that she return Ian's phone, laptop and any files as soon as possible. At Theranos, Holmes notified her senior team with an email about Ian's passing, but she didn't share the news with the rest of the company's employees. She never issued a sympathy note, or recognized Gibbons in any way, even though he had worked at Theranos for many years and had made significant contributions to the Theranos system.

Tyler Shultz

Another staffer who had serious concerns about the Theranos technology and testing practices was Tyler Shultz. His grandfather was George Shultz, former US secretary of state, Theranos board member and ardent supporter of Elizabeth Holmes. With an undergraduate degree in biology, Tyler Shultz started working at Theranos first as an intern, and then as a full-time employee. His role was to test the accuracy of the blood tests conducted by the Theranos devices. By this time, Theranos had signed contracts with a couple of companies to manage their blood testing. What these companies did not realize was that Theranos was using commercial blood testing machines from other manufacturers in its lab, since the Theranos technology wasn't fully operational. When any tests were done on the Theranos equipment, Shultz noticed that the problematic results he was obtaining were not being reflected accurately in the validation reports.

Shultz brought his concerns to Holmes, who directed him to Daniel Young, VP

and head of the Theranos biomath team. For every issue that Shultz cited, Young had counter arguments to negate his concerns. But instead of minimizing Shultz's worries, they increased. Shultz also looked up press coverage on Theranos, and saw that the claims being made by Holmes in news articles simply weren't true.

And he noticed that the proficiency testing required by law for all clinical laboratories was not being conducted properly at Theranos. Instead of testing the Theranos devices along with the commercial devices (from other manufacturers) that Theranos was using to analyze blood samples for its contracts, Theranos was reporting only on the tests done on the commercial machines. Even worse, when an inspector came to inspect the lab, they were only shown the machines from other manufacturers – the Theranos machines weren't shown, or even mentioned. This meant that Theranos was using unregulated, unproven equipment to test the blood of actual patients – and these patients were making major health decisions on the basis of these potentially faulty test results.

Tyler sent an anonymous email to the Clinical Laboratory Program with the New York State Department of Health, asking if this type of proficiency testing process was adequate. They replied that it was not. In fact, it was in violation of state and federal regulations. Armed with this information, Tyler met with his grandfather, George Shultz. George persuaded his grandson to talk to Holmes about his concerns, so Tyler sent her a very long email, outlining all of his findings.

In response, Tyler received a nasty email from Balwani, accusing him of ignorance and demanding an apology for all the trouble Tyler was causing. Tyler decided to resign.

Around the same time, a blogger called Adam Clapper got wind of the discrepancies at Theranos. He wrote a blog post calling out the lack of evidence-based proof that Theranos was able to deliver on any of its claims. A small group of people outside of Theranos was also forming, which included Ian Gibbon's widow Rochelle, who were very concerned about the company's practices. They made contact with Alan Beam, who had recently left his position as lab director at Theranos, who shared details on the many issues he had seen. The group shared this information with Adam Clapper, who realized that the story was going to be a lot bigger than a blogpost. Clapper then contacted John Carreyrou at the Wall Street Journal.

The Wall Street Journal Starts Investigating

John Carreyrou was able to track down Alan Beam, who agreed to speak with him only if he could remain anonymous. Theranos' lawyers had already done their work on Beam, threatening to cripple him financially and professionally if he shared any information. But Beam shared his information anyway, including

contact details for other Theranos staffers who might be willing to talk. But then he got too anxious to continue, telling Carreyrou that the stress was just too much for him.

Next, Carreyrou talked with Tyler Shultz. After seeing that Shultz had checked out his LinkedIn page, Carreyrou messaged him. Shultz spoke to Carreyrou with the promise that his identity would remain confidential. He forwarded his email exchange with Holmes and Balwani, where he had listed all of his concerns only to receive a harsh reprimand from Balwani. He also sent Carreyrou the emails he had exchanged with the New York State Health Department about the proficiency testing process at Theranos.

Carreyrou set out to find doctors who had sent blood tests to Theranos and who had received results that were clearly faulty. This was fairly easy to do, and he quickly found physicians who had received dubious results. These ranged from a test that showed a teenager who was on the cusp of a heart attack, based on sky-high potassium levels, and another that showed that a woman had deep-vein thrombosis. Both of these patients were re-tested at another facility, and the results of those tests were normal.

In the meantime, Carreyrou had reached out to Theranos, requesting an interview with Elizabeth Holmes. In the list of advance questions he provided, he had included a specific number relating to testing, which could only have been obtained through the proficiency testing report from Shultz. As a result, the Theranos legal attack team descended on Tyler Shultz, and his family. They actually ambushed him at his grandfather's, house, with the support of George. They handed Tyler a restraining order, a letter stating that he had violated his NDA, and a notice to appear in court. After an acrimonious discussion the meeting concluded.

Legal Team Puts Pressure On Tyler Shultz

George Shultz talked with Elizabeth Holmes, and the lawyers set up a meeting for the next day. At that meeting, Tyler Shultz was pressured to provide the names of any Theranos employees who might have talked to the Wall Street Journal. Tyler retained his own lawyers, and the discussion went back and forth for weeks. The Theranos lawyers threatened to bankrupt him and his family if he didn't sign an affidavit stating he had never spoken to a third party about Theranos, and if he did not comply with their other demands. Tyler's parents even had to retain their own lawyers, costing them hundreds of thousands of dollars. Tyler believed he was followed by private investigators and ultimately stopped talking to Carreyrou.

The Theranos legal team tracked down multiple former employees, and threatened them with lawsuits if they spoke to media. They also contacted the

doctors that Carreyrou had found, who had received erroneous lab results from the Theranos testing. Sunny Balwani himself flew out to visit these doctors, and threatened to destroy their reputations if they shared any information with the Wall Street Journal.

Holmes was trying a different avenue to shut down the developing story. Rupert Murdoch, owner of News Corporation, which owned the Wall Street Journal, had invested \$125 million in the latest round of Theranos funding. Holmes asked Murdoch directly to intervene and kill the story, but he declined to do so.

The Theranos lawyers continued to push back, and requested a meeting with the Wall Street Journal's Editor in Chief, Gerry Baker. In the meeting, they offered to show their device in action to Carreyrou, but only if the Journal would delay publishing the article. The publication demurred, and Carreyrou's exposé was published in the Wall Street Journal on October 15, 2015.

Regulatory Agencies Start Cracking Down

Holmes and her legal team tried to rebut the article, but other dominoes were falling. The FDA had conducted a surprise visit to the Theranos lab facilities, and had determined that the nanotainer was an "unapproved medical device" and could not be used. The Centers for Medicare and Medicaid Services started an inspection as well. After an in-depth review of equipment and processes, it cited multiple deficiencies, and even threatened to ban Holmes from blood testing for two years.

Holmes tried hard to re-group, with TV appearances where she promised to do better, and she even went through with a scheduled presentation of the technology at the annual meeting of the American Association of Clinical Chemistry in August, 2016. Still confident and charismatic, she put on a good show but was unable to provide any scientific validation. The scientific community was not impressed.

After that fiasco, even the most ardent supporters lost faith. Investors started filing lawsuits, as did Walgreens, which had been one of Theranos' few customers. So far, as of this book's writing, 10 patients have sued, claiming that the false test results they received led them to suffer health complications. Many are sure to follow. And on March 14, 2018, the SEC laid fraud charges against both Holmes and Balwani.

Conclusion

Some say that where Elizabeth Holmes went wrong was in applying the Silicon Valley culture of secrecy and "fake it 'til you make it" approach to a healthcare company. But while it might be okay to promise more than you deliver in a food

delivery app, or a new social media platform, it's not okay when it comes to promises about health outcomes and lives. As the lawsuits proceed, Theranos has been dissolved. Balwani and Holmes are no longer together. The SEC's criminal investigation is ongoing. And for his investigation into Theranos, John Carreyrou has received multiple journalistic awards.