

# The Theranos Fraud

Sven Niedorf, Loh Aik Hui, Herh Peng Leng

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## **Work distribution**

Loh Aik Hui: Impacts of the Fraud and Factors that Perpetuated the Fraud, Report, Presentation slides

Herh Peng Leng: Takeaways and Regulations, Report, Presentation slides

Sven Niedorf: Basics and History of Theranos, Report, Presentation slides

## **Introduction**

This report presents the case of Theranos, a privately owned healthcare startup, that was primed to take the world by storm by revolutionising blood diagnostics with just a finger prick. At its height, Theranos was valued at a whopping 9 billion and all that value came tumbling down when the company's proprietary technology, the "Edison" and its management malpractices were uncovered. This report seeks to shed light on the timeline of events and its founder, Elizabeth Holmes, the factors that allowed Theranos to defraud investors of millions of dollars, and the key lessons that can be drawn from this incident.

## **Elizabeth Holmes**

The central person of the fraud is the founder and CEO of Theranos Elizabeth Holmes. She was born on February 3, 1984 and studied chemical engineering at Stanford School of engineering from 2002 to 2004 without finishing. She founded Theranos in 2003 and applied for a patent "Medical device for analyte monitoring and drug delivery". The main product that newfound company should commercialize was the so called "Edison Machine".

## **The Edison Machine**

The Edison Machine should do several health tests with a single drop of blood taken from the finger. The machine was supposed to measure specific chemicals in the blood like drugs, hormones and cancer markers. There were two main challenges facing this machine. Firstly, the amount of blood taken using a finger stick was too little to be used for so many tests. The probability of detecting certain diseases and chemicals diminishes with decreasing volume. Secondly, capillary blood, unlike venous blood used traditionally in blood testing, contains other substances such as tissue fluids. This dilutes and contaminates the blood sample used for testing, resulting in further inaccuracy in the tests. In reality, only a few of the tests were performed on the proprietary machine while the rest were given to another company to analyse by stretching the sample. This caused even more inaccuracies. Often Theranos made up excuses why some tests were currently not working.

Normally the progress in the field of blood testing is a steady progress. A company like Theranos would have revolutionised the way humans handle diseases. Previously, blood testing can only be performed in hospitals and laboratories with specialised equipment, leading to inaccessibility of this essential healthcare for the general public. On top of that, blood testing often takes a few days to be performed. A larger amount of blood has to be drawn for each test as well. With the Edison Machine, all these issues can be resolved since the users just need a small blood sample easily drawn using finger stick method and they are able to self run up to 240 tests. This greatly increases the accessibility to blood testing. In addition to the fact that the health sector is a business with high margins, investors hoped that Theranos would be the next unicorn coming from silicon valley like Apple Inc.

## History of Theranos

Theranos was founded 2003 by Elizabeth Holmes with the education trust from her parents right after she left university. To finance its vision the young company focused on collecting venture capital. That money was then invested in human capital and research. One of the investors was the founder and CEO of Oracle, Larry Ellison. In 2009 Sunny Balwani joined Theranos as president and led the operational business. When a startup achieves to be worth 1 billion US-dollars investors call it a "unicorn" because it is that rare. That goal was celebrated by Theranos in the year 2010.

Ten years after founding Theranos had its breakthrough by starting a partnership with Walgreens and offering tests for the first time to the broad public. The peak in valuation was reached in 2014 when Holmes company was worth 9 billion dollars and got in total 724 million dollars of venture capital. One year later the picture of the perfect startup started to crumble. In February 2015 the twice-Nobel prize winning journalist John Carreyrou released a devastating article in "The Wall Street Journal". He noticed that there were no publicly available peer-reviewed studies from Theranos and he doubted that Holmes could invent a machine like the Edison Machine after just two semesters of studying. He got valuable information from whistleblowers who talked about the fraudulent practices. Theranos denied all claims and wanted to sue John Carreyrou.

Nevertheless the Cleveland Clinic started in march a partnership with Theranos to decrease costs of lab tests. But after more and more information were brought to daylight the most important partner Walgreens ended the partnership in 2016 and filed suit against Theranos. In may 2016 Sunny Balwani left the company and in 2018 Holmes resigned as CEO. Four month later Theranos ceased all operations. The aftermath was a year-long legal battle. In january 2022 Holmes was found guilty on charges of defrauding investors. Holmes faces up to 80 years in prison. Sunny Balwani was found guilty to and faces up to 20 years in prison. Both of their final penalties will be announced in september.

## Severity of the hoax

The main issue regarding Theranos was not the fact that it had defrauded investors of millions of dollars (Theranos claimed that they had raised 724 million dollars of venture capital funds and reached valuation of 9 billion dollars at its peak), but rather its impact on patients who received inaccurate blood test results as a result of Theranos incapacibilities, which could lead to further errors in diagnosis and treatments and potentially endangering patient lives. Ultimately, Theranos was forced to void two years of its blood test results given their inaccuracy. There were several such cases, reported by the Wall Street Journal, such as a pregnant mother who received inaccurate results indicating a drop in concentration of a pregnancy hormone, which prompted her practitioner to switch her medication to one that was potentially harmful to the foetus. Such instances of fraudulent healthcare services to patients are particularly unforgiving, especially when a person's wellbeing is at stake and as a result, Theranos faced numerous criminal charges.

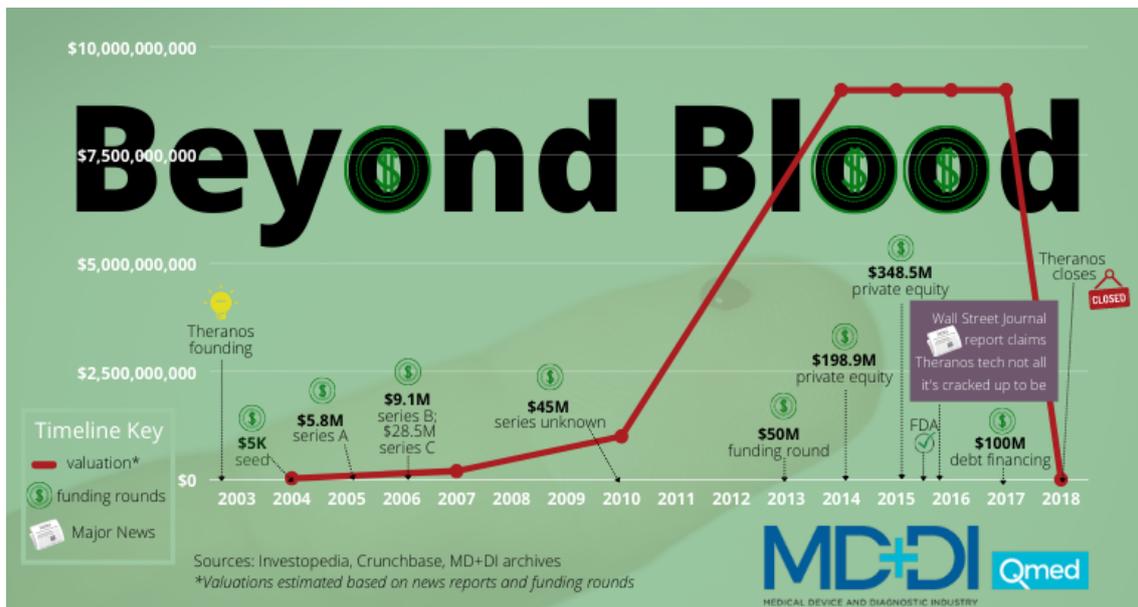


Figure 1: It is visible that Theranos was strongly hyped after 2010. [14]

## Factors that perpetuated the hoax

There were a couple of reasons behind how Theranos was able to deceive numerous high profile investors regarding their proprietary technology.

Firstly, there was a distinct lack of governance and specialised supervision, as most of the board members have backgrounds in fields that do not coincide with biotechnology and medicine. They were mainly politicians and military advisors, for example, George Shultz, former US Secretary of State and Gary Roughead, retired US Navy Admiral. Despite their relatively superior positions, these members had little to no experience in managing and investing in corporations. The lack of supervision is also largely perpetuated by the air-tight, top-down management style of Holmes, who created a highly secretive environment where information is strictly siloed and contained only among highly selective individuals, and it was so extreme that employees were instructed to keep Theranos off their LinkedIn profiles. Lab tests are done in absolute secrecy on the grounds of proprietary technology, meaning that many employees in the company and investors are not aware of the actual processes for the blood tests. Having such a working environment meant that it was difficult for accountability frameworks with regards to lab work, finances and other facets, to be set in place. Furthermore, Holmes was skilled in the way that she established credibility by getting highly influential people onboard, such as media mogul Rupert Murdoch and using logos of well-known pharmaceutical companies like Pfizer on Theranos documents, which further reduced the level of scrutiny.

Secondly, the hype culture that reverberates around Silicon Valley fueled the misguided beliefs of investors, who are deeply driven to make it big by making bets in promising startups that have potential to become global unicorns. The multitude of success stories regarding revolutionary startups have continuously driven this hype culture and this case of Theranos aptly displayed the level of risks that could result if investors are too focused on the potential success of startups and neglect the crucial foundations of a company, such as its management, technology and team. One

term that is well suited to describe this situation of overpromising and undelivering is “vaporware”, which was coined to categorise a product (typically regarding computer products) that is prematurely announced to the public (typically months or years before its purported release) with minimal information about its development to boost publicity, but would ultimately fall very short of what was promised and for some cases, to even not be able to release any product. The fear of missing out on the next big thing was also the main reason why Walgreen was so eager in rolling out their products in their outlets.

Thirdly, Holmes displayed an image that exuded confidence and charisma, which worked thoroughly in her favour. The media was captivated by her story of succeeding in a male-dominated world and strong self-belief to make the world a better place through Theranos blood testing technology, as seen when Forbes named Holmes the youngest and wealthiest self-made billionaire in America by valuing Theranos at a whopping 9 billion despite knowing so little about the company. Another characteristic of Holmes was her consistency of behaviour that greatly inspired confidence among people. She created a strong impression of control, was calm and collected, and often during interviews, displayed great control over her emotions through her body language and baritone voice. All of these behaviours enhanced her credibility as a leader and in so doing, provided her with the tools to influence her staff and potential investors.

## Key takeaways

From this saga, there are a couple of lessons that we can learn to protect ourselves from taking unnecessary risks and differentiate a valuable opportunity from a fraudulent one.

First, it is fundamentally important to ensure that there is good financial governance, which consists of enforcing a lucid system of rules, practices and processes by which a firm is guided, managed and controlled, such that the interests of all stakeholders are taken into account. This includes the effective supervision of the executive-level managers regardless of the level of trust. Holmes utilised celebrity endorsements and exuded unfaltering confidence to convince investors into allowing Holmes to maintain total control in all aspects of Theranos despite the lack of proper corporate governance. As such, investors were ultimately blindsided when the fraudulent activities were unveiled.

Secondly, whilst it is understandable that companies, especially in Silicon Valley, have to keep their secrets close to them, investors need to be able to identify red flags of over-secrecy that signal cover-ups. It should have been suspicious when Theranos refused to allow testing of its proprietary equipment by independent experts despite already having secured patents. In addition, Theranos failed to publish any peer-reviewed papers backing up its technology, despite making claims that their product “Edison” would disrupt medicine. Being an astute investor involves conducting due diligence to understand the product, and the workings of its underlying technology, rather than taking things at face value. This could be achieved by consulting experienced healthcare experts or investors, or to further read up on the topics to bridge the knowledge gap, and understand how this company managed to achieve what others have failed to do so. This is especially pertinent in the field of biotechnology investing, where healthcare published peer-reviewed research is fundamental

to establishing minimum credibility and accountability of work within the scientific community.

Thirdly, investors need to practise prudence and avoid making blind investments for fear of losing out on the next big thing. At its peak, Theranos was valued at 9 billion and this was in hindsight, an obscene over-valuation of the company. Furthermore, it is ingrained in the Silicon Valley culture for founders to be aggressively optimistic of their products, and in many cases, founders make claims and promises that turned out to be well beyond their capabilities. As proclaimed by Warren Buffet, it is extremely important to know what you are investing, who you are investing in, and for the company to have strong earning power.

## **Regulation reforms**

The main reason behind why Theranos was able to pull off its fraudulent lab tests was due to a legal loophole which states that lab-developed tests, which comprise of diagnostics that are designed, developed, and processed in a single laboratory, are not required to be subjected to safety and efficacy trials by the Food and Drug Administration (FDA), unlike drugs. The regulations of such tests are enforced by the administration's own discretion, with no clear guidelines.

After Theranos was exposed, the FDA deliberated about closing this loophole, and published a discussion paper on lab-developed tests in 2017. However, it did not lay out any enforceable regulations and instead, mentioned its support of an oversight approach that is efficient and appropriately balances patient protection with continued access and innovation. On the other hand, congress passed the VALID act which unequivocally gives the FDA authority to regulate laboratory developed tests, in a way similar to in-vitro diagnostic and other medical device manufacturers, by creating an entirely new product category called 'in vitro clinical tests' (IVCTs). Such a move indicated a step towards the right direction of regulating new biotechnology and protecting the interests of the public without stifling innovation.

## **Conclusion**

Despite the wrongdoings of Elizabeth Holmes, it is unfair to state that she set out to deceive investors of their millions of dollars from the beginning. Rather, she was consumed by the fake-it-till-you-make-it culture in Silicon Valley and sold a dream too large that ultimately backfired. In fact, it is common for startups to fail, with many of such companies facing civil lawsuits, except that Theranos faced criminal charges given that they are operating in the healthcare sector. Fraudulent claims will result in misdiagnosis and this will lead to direct and detrimental effects on the health of its users. Investors intentionally put money in these high variance companies knowing the huge risks and rewards, and when these companies fail, the onus is on the investor. Hence, it is exceptionally important to understand the company, its board of executives, and its underlying technology, before making any huge investments.

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