

Theranos: Vision, Effort - No Compliance Ends with DOJ, SEC

Everybody likes the little engine that could. Against all odds it works and works only to overcome all and be a success – the great American story. So it was with a little private company that had a vision of doing more, much more. Laboratory blood tests could be conducted with a small pin prick and a drop of blood analyzed on an amazing new machine right there in the store while the patient shopped – no more tiresome and invasive trips to the clinic. This would be a boon for consumers, physicians, investors and perhaps even the retail industry.

Vice President Joe Biden visited the firm in 2015, surveyed the impressive looking equipment and offered glowing praise for the little company, according to the *New York Times*. Just how the little engine that could, this small private company turned out is the subject of a new book, articles and a new indictment by the U.S. Attorney's Office for the Northern District of California, charging the firm's founder and COO. Those charges follow an earlier Securities and Exchange Commission enforcement action against the company and the two executives. *U.S. v. Holmes*, No. 5:18-cr-00258 (N.D. CA. Unsealed June 15, 2018); *SEC v. Holmes*, Civil Action No. 5:18-cv-01602 (N.D. Calif. Filed March 14, 2018); *SEC v. Balwani*, Civil Action No. 5:18-cv-01603 (N.D. Calif. Filed March 14, 2018).

The charges

Defendant Elizabeth Holmes is the founder of Theranos, Inc., a California company that sought to revolutionize the blood diagnostic industry. Defendant Ramesh Balwani joined the firm as its COO six years after it was founded in 2003. The indictment alleges that the Defendants engaged in two separate schemes conducted from approximately 2009 through 2016. One scheme defrauded doctors and patients. A second defrauded investors.

The schemes were implemented through a series of advertisements and solicitations. Specifically, the indictment alleges that the two defendants used advertisements about

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the blood testing laboratory services of Theranos to encourage and induce doctors and patients to use the services. Those efforts, coupled with others, were used to induce investors to put their money in the enterprise despite the fact that the defendants knew the touted technology was not capable of producing consistent, accurate and reliable results.

Theranos was founded in 2003 by Ms. Holmes. Her vision was to develop new diagnostic technologies, according to the court papers in the criminal and civil actions. The idea was to use small sample testing and ease of access for prevention and early diagnosis. Theranos focused on developing a proprietary analyzer which only needed a small sample of blood to conduct an array of tests.

Mr. Balwani, who joined the firm as COO in 2009, teamed with Ms. Holmes, to try and develop the necessary equipment. In 2010 the two executives began to focus on the retail clinical laboratory market, pursuing contacts with a drug store chain and a national grocery firm. The idea was to place the equipment at designated Patient Service Centers in retail stores. Patients could get their diagnostic tests performed while shopping.

Although the test equipment was not ready at the time the marketing efforts commenced, Ms. Holmes and Mr. Balwani touted the diagnostic machines. Demonstrations were conducted which made it appear the equipment could conduct the tests as claimed, although in fact it could not. Interviews were given to the Wall Street Journal and other media. A series of favorable articles created a wave of positive publicity for the company. The firm, however, was cash short.

From about 2013 through 2015 Ms. Holmes, Mr. Balwani and Theranos raised over \$700 million from investors in two rounds of financing for the privately held company. Investors were lead to believe that the company had successfully developed a proprietary analyzer capable of running a full range of laboratory tests from a small sample of blood. Investors were also told that Theranos would generate over \$100 million in revenues, break even in 2014 and was expected to generate about \$1 billion in 2015. Investors were also told that the company had a profitable relationship with the U.S. Department of Defense and that the wellness centers set up at a drug chain would be expanded. Yet at the time the two executives knew that the firm's actual prospects were dismal with expectations of generating negligible amounts of cash. Just prior to initiating the efforts to secure additional financing Ms. Holmes convinced the board to redo the share classes in a fashion which gave her overwhelming voting control of the company.

By 2016 the company exited the commercial laboratory business. The drug store and food store chains that had been working with Theranos terminated their relationships. By 2017 the firm was on the brink of bankruptcy.

The indictment charges each defendant with two counts of conspiracy to commit wire fraud and nine counts of wire fraud.

Each SEC complaint alleges fraud in violation of Securities Act section 17(a) and Exchange Act section 10(b). The company and Ms. Holmes settled with the Commission.

Ms. Holmes agreed to pay a penalty of \$500,000, to be barred from serving as an officer or director of a public company for 10 years and to return the shares she obtained which gave her control of the company. Mr. Balwani is litigating the action against him.

Comment

To be the little engine that could it is essential to try hard, perhaps harder than most if not all others. At least some success is essential. The path is often long, difficult and seemingly endless, a fact well known to many successful executives.

In the end the little engine that could succeeds on the merits, not by “cutting corners” or “window dressing” the financial statements or the results. In the end whether the firm is a small private company, one that is publically traded or a large enterprise actual success comes to the “engine” that stays on the track. Stated differently, it comes from vision, effort, perhaps a bit of luck and compliance –staying on the track and playing fair and by the rules.

Theranos had by all reports vision. It had years of effort. It might have succeeded if it stayed on the track which, by all accounts it did not -- apparently there was no real compliance. Jumping off the track ends not with a win for consumers, physicians, investors and the company but with charges from the DOJ and the SEC. For the small private firm, the publically traded company or the large enterprise vision, effort and determination needs to be firmly tied to the track – compliance.