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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

SECURITIES AND EXCHANGE COMMISSION, Plaintiff, vs. ELIZABETH HOLMES and THERANOS, INC. Defendants.	Case No. **COMPLAINT**

Plaintiff Securities and Exchange Commission (the "Commission") alleges:

SUMMARY OF THE ACTION

1. This case involves the fraudulent offer and sale of securities by Theranos, Inc. ("Theranos"), a California company that aimed to revolutionize the diagnostics industry, its Chairman and Chief Executive Officer Elizabeth Holmes, and its former President and Chief Operating Officer, Ramesh "Sunny" Balwani. The Commission has filed a separate action against Balwani.

2. Holmes, Balwani, and Theranos raised more than $700 million from late 2013 to 2015 while deceiving investors by making it appear as if Theranos had successfully developed a commercially-ready portable blood analyzer that could perform a full range of laboratory tests from a small sample of blood. They deceived investors by, among other things, making false and misleading statements to the media, hosting misleading technology demonstrations, and overstating the extent of Theranos' relationships with commercial partners and government entities, to whom they had also made misrepresentations.

3. Holmes, Balwani, and Theranos also made false or misleading statements to investors about many aspects of Theranos' business, including the capabilities of its proprietary analyzers, its commercial relationships, its relationship with the Department of Defense ("DOD"), its regulatory status with the U.S. Food and Drug Administration ("FDA"), and its financial condition. These statements were made with the intent to deceive or with reckless disregard for the truth.

4. Investors believed, based on these representations, that Theranos had successfully developed a proprietary analyzer that was capable of conducting a comprehensive set of blood tests from a few drops of blood from a finger. From Holmes' and Balwani's representations, investors understood Theranos offered a suite of technologies to (1) collect and transport a fingerstick sample of blood, (2) place the sample on a special cartridge which could be inserted into (3) Theranos' proprietary analyzer, which would generate the results that Theranos could transmit to the patient or care provider. According to Holmes and Balwani, Theranos' technology could provide blood testing that was faster, cheaper, and more accurate than existing blood testing laboratories, all in one analyzer that could be used outside traditional laboratory settings.

5. At all times, however, Holmes, Balwani, and Theranos were aware that, in its clinical laboratory, Theranos' proprietary analyzer performed only approximately 12 tests of the over 200 tests on Theranos' published patient testing menu, and Theranos used third-party

commercially available analyzers, some of which Theranos had modified to analyze fingerstick samples, to process the remainder of its patient tests.

6. In this action, the Commission seeks an order enjoining Holmes and Theranos from future violations of the securities laws, requiring Holmes to pay a civil monetary penalty, prohibiting Holmes from acting as an officer or director of any publicly-listed company, requiring Holmes to return all of the shares she obtained during this period, requiring Holmes to relinquish super-majority voting shares she obtained during this period, and providing other appropriate relief.

JURISDICTION AND VENUE

7. The Commission brings this action pursuant to Sections 20(b), 20(d), and 22(a) of the Securities Act of 1933 ("Securities Act") [15 U.S.C. §§ 77t(b), 77t(d), and 77v(a)] and Sections 21(d), 21(e), and 27 of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. §§ 78u(d), 78u(e), and 78aa].

8. This Court has jurisdiction over this action pursuant to Sections 20(b), 20(d)(1) and 22(a) of the Securities Act [15 U.S.C. §§ 77t(b), 77t(d)(1), and 77v(a)] and Sections 21(d), 21(e) and 27 of the Exchange Act [15 U.S.C. §§ 78u(d), 78u(e) and 78aa].

9. Defendants, directly or indirectly, made use of the means and instrumentalities of interstate commerce or of the mails in connection with the acts, transactions, practices, and courses of business alleged in this complaint.

10. Venue is proper in this District pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)] and Section 27(a) of the Exchange Act [15 U.S.C. § 78aa(a)]. Theranos is headquartered in Newark, California, and Holmes resides in the District. In addition, acts, transactions, practices, and courses of business that form the basis for the violations alleged in this complaint occurred in this District. Defendants met with and solicited prospective Theranos investors in this District, and the relevant offers or sales of securities took place in this District.

11. Under Civil Local Rule 3-2(d), this civil action should be assigned to the San Jose Division, because a substantial part of the events or omissions which give rise to the claims alleged herein occurred in Santa Clara County.

DEFENDANTS

12. **Elizabeth Holmes**, age 34, of Los Altos Hills, California, is the Chief Executive Officer ("CEO") and Chairman of the Board of Theranos, Inc. Holmes was paid a salary of approximately $200,000 to $390,000 per year between 2013 and 2015. During the same period, she also exercised approximately 53.7 million stock options and received super-majority voting, Class B common shares, which granted her almost complete voting control over the company. Holmes has never sold any of her Theranos stock.

13. **Theranos, Inc.** is a Delaware corporation, established by Holmes in 2003, with its principal place of business in Newark, California. From 2013 through 2015 (the "relevant time period"), Theranos' principal place of business was in Palo Alto, California and its sole managing executives were Holmes and Balwani.

RELEVANT INDIVIDUAL

14. **Ramesh "Sunny" Balwani**, age 52, of Atherton, California, was the President and Chief Operating Officer of Theranos, Inc. from September 2009 to May 2016.

FACTUAL ALLEGATIONS

A. Background

15. Elizabeth Holmes founded Theranos, a diagnostics company, in 2003 after leaving college during her second year. Holmes had a vision of developing new diagnostic technologies, with a focus on small sample testing and easier access to testing results for prevention and earlier diagnosis.

16. For the first five years of its existence, Theranos focused its efforts on developing its proprietary analyzer, the Theranos Sample Processing Unit, or "TSPU," to analyze blood taken from a fingerstick and on assisting pharmaceutical companies with their clinical trials. The earliest generation TSPU was a small point-of-care device that was capable of performing only a

few tests. A point-of-care device can be used to obtain results near where patients provide samples, such as medical offices.

17. In 2009, as Theranos was on the verge of running out of money, Holmes turned to Balwani to guarantee a line of credit for the company. Balwani joined the company and became its President and COO.

18. From the time that Balwani joined Theranos until his departure in 2016, Theranos had no other senior managing executives besides Holmes and Balwani. Holmes generally focused on device innovation, board interaction, and strategic relationships, while Balwani concentrated on developing software for Theranos' technology and managing personnel and operations. Still, they collaborated closely with each other and made decisions about the company together.

B. In 2010, Theranos Decided to Pursue the Retail Clinical Laboratory Space Even Though Its Analyzer Was Not Commercially Ready

19. Theranos spent years in research and development to develop an earlier-generation TSPU. The earlier-generation TSPU was designed to perform only one method of testing – immunochemistries – and could process only one sample at a time. In 2009, Holmes and Balwani turned the company's efforts towards developing a new version of the TSPU, which they hoped would one day be able to perform a broader range of laboratory testing by incorporating additional methods of testing. They later referred to this version of the TSPU as the miniLab.

20. In early 2010, even though the miniLab was not commercially ready, Holmes and Balwani decided to focus on the retail clinical laboratory market by pursuing contracts with a large national pharmacy chain ("Pharmacy A") and a large national grocery chain ("Grocery A"). Their vision was to place miniLabs at designated "Patient Service Centers" in retail stores so that patients could get their diagnostic tests performed while shopping.

21. In connection with discussions about a potential partnership with Pharmacy A, Holmes approved and provided presentations and other written materials to Pharmacy A

executives representing that Theranos had the ability to conduct a broad range of tests on its proprietary analyzer, including general chemistry tests, wellness tests, and some predictive and diagnostic health tests (which involved methods beyond immunochemistries). These materials stated that Theranos would be ready to begin blood testing on its proprietary analyzer at Pharmacy A stores by the fourth quarter of 2010.

22. Holmes also told Pharmacy A executives that Theranos could conduct hundreds of blood tests through fingerstick (or the puncture of a finger), that its testing could be conducted in a rapid timeframe (in less than one hour), and that it could be offered for a reasonable price (much less than Theranos' competitors). Holmes also told Pharmacy A that its analyzer was already deployed on military helicopters.

23. Based on these representations, Pharmacy A executives thought that the miniLab was capable of performing, in a clinical lab setting, a wide range of the tests offered by traditional laboratories. For example, Holmes told Pharmacy A that Theranos could, on its analyzer – the miniLab – perform approximately 90 percent of the tests that a large, traditional central lab could perform. In July 2010, Pharmacy A entered into a contract with Theranos to roll out Theranos' service to Pharmacy A stores.

24. Holmes also made similar statements to Grocery A. She told Grocery A's then-CEO that Theranos had successfully miniaturized the conventional laboratory. Holmes also told him that Theranos' analyzers were being deployed in the battlefield. Based on these representations, in September 2010, Grocery A contracted with Theranos to offer Theranos patient testing in Grocery A stores.

C. In 2013, On the Eve of the Pharmacy A Launch, Theranos Began Modifying Commercially-Available Analyzers and Running Misleading Demonstrations

25. Between 2010 and 2013, Theranos continued to work on developing its miniLab with an eye towards launching its services in Pharmacy A and Grocery A stores.

26. In 2011, Pharmacy A executives raised concerns it had with Theranos' regulatory strategy, and told Holmes and Balwani that Theranos might need to obtain FDA approval for its

miniLab and certify each of its stores as a laboratory in order for the analyzers to be used in Pharmacy A stores.

27. Based on these concerns, in 2012, Theranos and Pharmacy A agreed to modify their original contract to reflect a roll-out of Theranos' service in two phases. In the first phase, before Theranos received regulatory approvals for its analyzers, patient samples would be transported from Pharmacy A stores to centralized laboratories operated by Theranos and tested on Theranos' miniLab there. Theranos opened and operated two centralized laboratories to test patient samples collected from Pharmacy A stores. In the second phase, after Theranos had received the necessary regulatory approvals, Theranos' retail offering at Pharmacy A would be performed on miniLabs placed in Pharmacy A stores.

28. But as September 2013 approached – the date for the launch of the first phase of the roll out of Theranos services in Pharmacy A stores – it became clear to Holmes that the miniLab would not be ready. At the time, Theranos had not fully integrated other testing methods into the miniLab and had not completed the scientific verification steps needed to make any of its blood tests available on the miniLab for patient testing. As a result, Holmes and Balwani made the decision to use Theranos' earlier-generation TSPUs, which could only be used to perform immunochemistries, for patient testing.

29. In order to offer a broader range of fingerstick tests at Pharmacy A, Holmes and Balwani asked Theranos' engineers in July 2013 to modify third-party analyzers from commercial manufacturers so they could analyze fingerstick samples. Theranos scientists spent the two months leading up to the retail launch preparing as many fingerstick tests as possible on the third-party analyzers, which could typically process only venous samples.

30. Holmes and Theranos never told Pharmacy A and Grocery A about Theranos' technological challenges. For instance, in July and August 2013, Theranos coordinated technology demonstrations for various Pharmacy A executives in advance of the retail launch. Holmes instructed Theranos employees to place both earlier generation TSPUs and miniLabs in a demonstration room where Theranos collected fingerstick samples from Pharmacy A

executives. Instead of using these machines to process the tests on these samples, and unbeknownst to the Pharmacy A executives, Theranos used the modified third-party machines to process a portion of the tests.

31. Holmes also instructed Theranos employees to place numerous miniLabs – which could only be used for research and development purposes and could not be used for clinical testing – in a room in Theranos' clinical lab. This made it appear as if Theranos used its miniLab for clinical purposes. Holmes then led a group of Pharmacy A executives on a tour of that room, and those Pharmacy A executives saw rows of miniLabs in Theranos' clinical lab.

32. Based on Holmes' presentation, Pharmacy A executives understood that the blood from their demonstration samples would be tested on Theranos' miniLabs. Holmes never told the executives that Theranos was actually testing some of their blood on modified third-party analyzers.

33. At the end of 2013, Pharmacy A agreed to accelerate a portion of a $100 million "innovation fee" to help Theranos broaden its roll-out of services to Pharmacy A stores. Unbeknownst to Pharmacy A, Theranos was scaling its retail offering by relying on third-party analyzers.

34. Neither Holmes nor Theranos ever told anyone at Pharmacy A that Theranos used third-party analyzers, including those that had been modified to test fingerstick blood. Holmes and Theranos also never told Pharmacy A that Theranos was using third-party analyzers to perform the majority of its testing. If Pharmacy A had known that Theranos was using third-party analyzers for a majority of its patient testing, it would not have accelerated the payment of the innovation fee.

35. Holmes and Balwani also denied there were problems with Theranos' technology in discussions with Grocery A. For example, in response to a question about a rumor that Theranos was facing technological challenges with its proprietary analyzers, Holmes and Balwani assured Grocery A's General Counsel that there was no technological problem with the

analyzers and that the TSPU was capable of performing 90 percent of the blood tests typically requested by doctors for their patients.

36. From its retail launch in September 2013 to the time it closed its clinical laboratories in 2016, Theranos never used its miniLab for patient testing in its clinical laboratory. Theranos conducted – at its height –12 tests using the earlier-generation TSPU, and processed about 50 to 60 tests using the modified third-party analyzers. Theranos processed the remaining 100-plus tests it offered at Pharmacy A using the same types of industry standard technology as other traditional laboratories, or sent tests out to third-party laboratories.

D. Starting in September 2013, Holmes and Theranos Began Publicly Touting Theranos' Proprietary Analyzers in Interviews with the Media, Notwithstanding Theranos' Use of Commercially-Available Analyzers for Patient Testing

37. From 2013 to 2014, Theranos and Holmes emerged into the spotlight by issuing a press release touting the launch of its retail offering with Pharmacy A and granting a number of media interviews for articles that Holmes later used to solicit investors. In September 2013, Theranos announced a partnership with Pharmacy A to offer a "new lab testing service through Pharmacy A pharmacies nationwide." By going to a Pharmacy A store in Palo Alto, California, the first location to offer Theranos testing, consumers could "complete any clinician-directed lab tests with as little as a few drops of blood and results available in a matter of hours."

38. Around the same time, Holmes sat down with a reporter for the *Wall Street Journal* purportedly to discuss the state of Theranos' business. A *Wall Street Journal* article accompanying the Pharmacy A launch announcement stated:

> The secret that hundreds of employees are now refining involves devices that automate and miniaturize more than 1,000 laboratory tests, from routine blood work to advanced genetic analyses. Theranos' processes are faster, cheaper, and more accurate than the conventional methods and require only microscopic blood volumes, not vial after vial of the stuff.

39. Additional articles written after interviews with Holmes continued to raise Theranos' public profile and tout its technological capabilities. An April 2014 *Wired* article

stated that "[i]nstead of vials of blood – one for every test needed – Theranos requires only a pinprick and a drop of blood. With that they can perform hundreds of tests, from standard cholesterol checks to sophisticated genetic analyses."

40. Similarly, a June 2014 *Fortune* article noted that "[Theranos] currently offers more than 200 – and is ramping up to offer more than 1,000 – of the most commonly ordered blood diagnostic tests, all without the need for a syringe." *Fortune* also distinguished Theranos from other blood testing companies because "Theranos [] does not buy any analyzers from third parties." In contrast to the large traditional blood analyzers that occupied whole rooms, Theranos' proprietary analyzers "look[ed] like large desktop computer towers."

41. By the end of 2014, *Forbes* declared that Holmes was "the youngest self-made woman billionaire" whose company could, "[w]ith a painless prick, . . . quickly test a drop of blood at a fraction of the price of commercial labs which need more than one vial."

42. Holmes sat for interviews and communicated with journalists about Theranos and its technology. In email conversations with the *Fortune* reporter, Holmes stated that "it is ok to say the analytical systems are about the size of a desktop computer." Holmes also suggested describing Theranos' miniLab as "much smaller than in conventional laboratories or have a smaller space requirement than conventional laboratories." The *Fortune* reporter used a version of this statement in his article on Theranos. As Holmes knew, or was reckless in not knowing, this was misleading because the device she was describing – the miniLab – was not in use in Theranos' clinical laboratory.

43. Holmes did not correct the false or misleading statements in the articles that were published between 2013 and 2015. In fact, in some instances, she and Theranos provided some of the articles containing untrue or misleading statements to potential investors.

E. Beginning in 2013, Holmes and Theranos Raised Over $700 Million from Investors and Holmes Obtained Super-Voting Control of Theranos While Misleading Investors

44. In late 2013, Theranos had approximately $30 million in cash and short-term securities, which would fund the company's operations for only a few months. As Holmes

knew, Theranos needed cash to continue spending money on research and development to advance the miniLab, which at that time was not ready for commercial use.

45. Holmes anticipated that Theranos would need to raise much more money than it had in its earlier financing rounds and that such fundraising likely would dilute her ownership of the company. In order to retain her control of the company, Holmes in early 2014 convinced Theranos' board and shareholders to pass a resolution creating a new, separate class of shares ("Class B Shares").

46. This resolution (1) split Theranos' stock in a 1 to 5 ratio to allow for future fundraising, and (2) created Class B Shares, which had super-voting (100x) power and would be given only to Holmes. Shareholders were given only a few days to consider and vote on this resolution. Following the resolution's passage, Holmes owned just over half of the company's outstanding shares, but over 99 percent of its voting power. Holmes obtained the Class B Shares during the relevant time period.

47. From late 2013 to 2015, Holmes, Balwani, and Theranos raised over $700 million from investors in two financing rounds. These investors believed – based on false and misleading statements by Holmes – that Theranos had successfully developed a proprietary analyzer that could conduct the full range of laboratory testing from a small sample of blood.

1. The Investor Solicitation Process Generally Included a Face-to-Face Meeting, a Technology Demonstration, and a Binder of Materials

48. After an introduction to Holmes, potential investors would typically meet face-to-face with Holmes, and at times, Balwani. During this meeting, which normally took place at Theranos' headquarters, Holmes described her vision for the company, including her motivation to develop a technology that could perform blood testing on small samples – spurred by her own fear of needles – and her larger desire to provide cheaper, faster, and more accurate laboratory testing so that diagnoses of serious conditions and diseases could take place sooner.

49. This initial meeting was often followed by a purported demonstration of Theranos' proprietary analyzers, the TSPU, and the miniLab. In several instances, potential

investors would be taken by Holmes and Balwani to a different room to view Theranos' desktop computer-like analyzers. A phlebotomist would arrive to draw their blood through fingerstick, using a nanotainer, a Theranos-developed collection device. Then the sample was either inserted into the TSPU or taken away for processing. Based on what they saw, potential investors believed that Theranos had tested their blood on either an earlier-generation TSPU or the miniLab. As Holmes knew, or was reckless in not knowing, however, Theranos often actually tested their blood on third-party analyzers, because Theranos could not conduct all of the tests it offered prospective investors on its proprietary analyzers.

50. Theranos also sent investors a binder of background materials, which Holmes instructed employees to compile. In addition to incorporation documents and shareholder agreements, the typical investor binder included (1) a cover letter drafted and signed by Holmes; (2) a company overview slide deck presentation; (3) reports of clinical trials work Theranos performed with its pharmaceutical companies; (4) financial projections; and (5) articles and profiles about Theranos, including the 2013 and 2014 articles from *The Wall Street Journal*, *Wired*, and *Fortune* that were written after Holmes provided them with interviews. These materials were important to investors in considering whether to invest in Theranos.

51. One section of the investor binders touted Theranos' work with pharmaceutical companies and contained a number of reports purportedly related to the clinical trials work Theranos had performed with those pharmaceutical companies. The reports prominently featured the company logos of well-known pharmaceutical companies, suggesting that the reports were drafted by these pharmaceutical companies. However, as Holmes knew, only one report in the investor binder was co-written by a pharmaceutical client. The other two reports were drafted by Theranos employees, despite displaying the logos of pharmaceutical companies. Investors believed that pharmaceutical companies had written their own endorsements of Theranos' technology, when the pharmaceutical companies had not.

2. Holmes and Theranos Made a Series of False or Misleading Statements to Investors That Confirmed the Company's Public Narrative

52. Holmes made statements to investors about the status of Theranos' technology, historical contracts, commercial relationships, regulatory strategy, and financial performance that were consistent with the public image she and Theranos were promoting of Theranos as a company that was revolutionizing the diagnostics industry.

a. Holmes and Theranos Represented That Theranos' Proprietary Analyzer Was Capable of Conducting the Full Range of Testing When It Could Not

53. Holmes represented to investors that Theranos' miniLab was capable of processing a full range of laboratory tests. For instance, Holmes and Balwani told one investor that Theranos' proprietary analyzer could process over 1,000 Current Procedural Terminology ("CPT") codes and that Theranos had developed a technological solution for an additional 300 CPT codes. She made similar representations to other investors, claiming that Theranos could run all of its blood tests on one analyzer using chemicals from one consumable cartridge.

54. Theranos' company overview presentation that Theranos included in investor binders also echoed these same statements. The presentation noted, among other things, that "Theranos' proprietary, patented technology runs comprehensive blood tests from a finger-stick and tests from micro-samples of other matrices, and generates significantly higher integrity data than currently possible."

55. But Theranos' analyzers never performed comprehensive testing or processed 1,000 CPT codes in its clinical lab. In fact, as Holmes knew, or was reckless in not knowing, Theranos' clinical lab used the TSPU only to perform 12 of the tests offered to patients.

56. In addition to not disclosing the use of third-party analyzers to conduct the demonstrations, Holmes' and Theranos' actions made it appear as if Theranos' proprietary analyzer had more extensive capabilities than it actually did. When potential investors tried out Theranos' services by bringing a physician's laboratory requisition to a Pharmacy A store,

Holmes instructed Theranos employees to remove certain tests from the order if Theranos was unable to perform those tests using a fingerstick collection.

57. This conduct led investors to believe that Theranos' proprietary analyzers were broadly in use by Theranos and that they produced results on a broader range of tests than they actually did. Investors would not have invested had they known Theranos' promises about its ability to run a broad range of tests were untrue and that the TSPU was being used to run only a limited number of tests in its lab. When presenting to investors, Holmes knew, or was reckless in not knowing, that the miniLab was not presently capable of processing a full range of laboratory tests.

58. Holmes' statements about the capabilities of Theranos' proprietary analyzer were important to many potential investors because the technology was a basis of their investments.

b. Holmes and Theranos Stated That Theranos Manufactured All of Its Own Analyzers When It Actually Used Third-Party Analyzers to Run the Majority of Its Tests

59. Holmes also represented to investors that Theranos manufactured all of its own analyzers, when Theranos had in fact only manufactured its own TSPUs. For instance, Holmes told one investor that Theranos used its own analyzer equipment and did not buy analyzer equipment from third parties. She and Balwani explained to another investor that 100 percent of Theranos' analyzers were manufactured in Theranos' facility in Newark, California.

60. The company overview presentation in some investor binders also showed pictures of the TSPU and miniLab under the heading "Theranos Systems," but excluded pictures of the third-party analyzers Theranos was using.

61. Finally, the *Fortune* article – for which Holmes was extensively interviewed and which she included in materials sent to investors – stated that "Theranos [] does not buy any analyzers from third parties."

62. These statements gave potential investors the impression that Theranos was only using its own TSPUs and miniLabs for patient testing.

63. As Holmes knew, or was reckless in not knowing, statements that Theranos manufactured all of its analyzers were false or misleading in light of Theranos' broad use of third-party analyzers. Theranos conducted the majority of its testing using third-party analyzers.

64. Theranos' capability to run the full range of laboratory testing on its proprietary analyzer was a key competitive advantage potential investors considered when deciding whether to invest in the company.

c. Holmes and Theranos Made False or Misleading Statements About Theranos' Historical Contracts with the DOD

65. Holmes also made false or misleading statements concerning Theranos' historical business contracts with the DOD. In Holmes' cover letter, which she included in investor binders, she highlighted the company's "historical" work with "military clients." The third page of the company overview presentation introduces the company with the following statement, "[c]urrent and past clients include . . . U.S. and foreign government health and military organizations."

66. Holmes also made other statements that gave potential investors the impression that these historical relationships were meaningful. Holmes told multiple investors that Theranos' technology had been deployed by the DOD in the battlefield and in Afghanistan. Holmes told investors that the DOD had deployed Theranos' miniLab on medevac helicopters.

67. Holmes also included a comment in her cover letter that "Theranos has grown from cash from its contracts for some time," which misled investors into believing that these contracts funded Theranos' operations. She made the same comment verbally to other potential investors. Although Theranos had discussions with different military and government entities, the company earned limited revenues from those efforts, and Theranos primarily grew from investor capital raises.

68. Holmes knew, or was reckless in not knowing, that these statements were false and misleading. While Theranos' technology was used in a DOD burn study, it was never deployed by the DOD in the battlefield, in Afghanistan, or on medevac helicopters. From 2011

to 2014, Holmes had discussions with multiple divisions of the DOD. However, Theranos generated only approximately $300,000 from three DOD contracts.

69. Holmes' statements about Theranos' history with the DOD were important to potential investors because these relationships lent legitimacy to Theranos' business and its proprietary analyzer.

d. Holmes and Theranos Told Investors That Theranos' Relationships with Pharmacy A and Grocery A Were Thriving When They Were Stalled

70. During meetings and in investor binders, Holmes described Theranos' thriving relationships with Pharmacy A and Grocery A. Much of the company overview presentation was dedicated to Theranos' relationship with Pharmacy A, showing pictures of the patient service centers where patients would get their fingers pricked, and a map of the number of Pharmacy A stores across the country that would soon be offering Theranos' blood testing.

71. Holmes also noted, in her cover letter, that since the launch of Theranos' roll-out in Pharmacy A stores, the company had also begun "operating in the consumer, physician, and hospital laboratory testing business," highlighting the importance of the Pharmacy A relationship in paving the way for these other lines of business.

72. Most importantly, Holmes represented to numerous investors in late 2014 that Theranos was expected to roll out its retail services to hundreds of Pharmacy A stores in 2015. This information was also included in financial projections that Theranos sent to investors that were based on the assumption that Theranos would be rolling out to 800 or 900 stores by year-end 2015.

73. However, by late 2014, while Theranos was raising the bulk of the over $700 million it raised during the relevant time period, Holmes was aware that Theranos' retail roll out with Pharmacy A was stalled due to, among other issues, some concerns Pharmacy A executives had with regard to Theranos' performance.

74. Holmes knew that patient traffic and the percentage of collections being performed by fingerstick were important metrics for Pharmacy A and also knew that Pharmacy

A had concerns regarding the lower than expected number of fingerstick collections being performed in its stores.

75. In December 2014, Holmes met with Pharmacy A executives to discuss potentially modifying the parties' relationship to a landlord and tenant model, whereby Theranos would rent space in Pharmacy A stores. Holmes did not share any of these developments with investors. Holmes knew, or was reckless in not knowing, that Theranos would not be expanding into Pharmacy A as quickly as she represented it would.

76. Holmes also told investors in late 2014 that Theranos services would be rolled out in more than 100 Grocery A stores in January 2015. But the relationship with Grocery A had already begun to stall in 2013, during which the parties had started discussing the possibility of modifying the contract so that Theranos would rent space in individual supermarkets. The parties were still engaged in these discussions in 2014.

77. By June 2014, Holmes told a Theranos board member that she was contemplating terminating Theranos' relationship with Grocery A. By August 2014, the parties ceased to be in communication with one another. Nevertheless, when meeting with investors in the fall of 2014, Holmes continued to discuss Theranos' relationship with Grocery A to investors. Holmes knew, or was reckless in not knowing, that her statements about Theranos' relationship with Grocery A were false or misleading.

78. The statements made by Holmes about the status of the Pharmacy A and Grocery A relationships were important to investors because these contracts gave potential investors confidence that Theranos' technologies were commercially ready. Pharmacy A and Grocery A were also the major drivers of future revenues for the company. In reality, Holmes and Theranos were attempting to renegotiate Theranos' agreements with these retail businesses in light of the delays in rolling out.

e. Holmes Claimed That Theranos Was Not Required to Seek FDA Approval Despite Repeatedly Being Told That Approval Was Necessary for Its Analyzers and Tests

79. When speaking to potential investors in late 2013 through 2015, Holmes consistently stated that Theranos did not need to obtain approval from the FDA for its miniLab and tests, and instead said that Theranos was applying for FDA approval voluntarily because it was the "gold standard." For instance, Holmes told multiple investors that approval was not required for the miniLab because Theranos was not selling its devices to other companies.

80. Holmes represented to business partners and investors that FDA approval was not necessary because she believed that Theranos' tests were laboratory developed tests ("LDTs"), or tests developed and used inside a clinical laboratory, over which the FDA had historically exercised its enforcement discretion to not require FDA clearance. However, she and Balwani were told by multiple parties, including Pharmacy A, that the FDA might reject this regulatory strategy because Theranos' miniLab had not previously obtained approval from the FDA. Holmes and FDA representatives discussed Theranos' regulatory strategy in late 2013 through 2014 while Theranos continued to offer LDTs to retail patients.

81. By the time of Theranos' financing round in 2014, FDA representatives told Holmes that clearance or approval would be necessary for Theranos' analyzer and tests. In late 2013 and throughout 2014, FDA representatives met with Holmes and sent letters to Theranos stating that they did not believe Theranos was offering LDTs, and that even if Theranos was not selling its miniLab or tests, FDA clearance or approval was necessary. Based on these communications, Holmes agreed to submit all components of Theranos' testing technology to the FDA for clearance or approval. However, Holmes continued to raise additional funds while telling investors Theranos was seeking FDA approval voluntarily. But Holmes knew, or was reckless in not knowing, that FDA approval was necessary for Theranos' analyzer and tests.

82. Holmes' statements that Theranos did not need FDA approval or clearance were important to investors because approval or clearance would have been an obstacle in the company's path to realizing full commercialization.

f. Holmes Told Investors That Theranos Had Generated or Would Generate Over $100 Million in Revenues in 2014 and That It Was On Track to Make $1 Billion in Revenues in 2015, But This Information Had No Basis

83. Theranos included financial information in the investor binders that projected that Theranos would generate over $100 million in revenues and break even in 2014. These documents, which were drafted by Balwani, and which Holmes reviewed and shared with potential investors, also represented that Theranos expected to generate approximately $1 billion in revenues in 2015.

84. The projections further indicated that Theranos would obtain revenue from several lines of business, including retail pharmacies (Pharmacy A and Grocery A), samples collected from physicians' offices, samples collected from hospitals, and pharmaceutical services.

85. Holmes also provided historical financial information to one potential investor. In August 2015, Holmes met with a potential investor, during which she provided Theranos' financial results for fiscal year 2014. These financials showed 2014 net revenues of $108 million, and 2015 and 2016 net revenue projections of $240 million and $750 million, respectively.

86. But Theranos' actual financial performance bore no resemblance to the financial information Holmes shared with investors. Theranos recorded little more than $100,000 in revenue in 2014 and was nowhere near generating $100 million in revenue by the end of 2014.

87. Holmes knew, or was reckless in not knowing, that Theranos sent different financial information containing Theranos' actual revenue numbers (a little over $100,000) to a third-party valuation firm that it had retained to value the company's common stock. Some of Theranos' projections, provided to potential investors in October 2014, stated Theranos would earn $40 million from pharmaceutical services, $46 million from lab services provided to hospitals, and $9 million from lab services provided to physicians' offices, all by the end of 2014. In reality, Theranos had no revenues from any of those lines of business.

88. Holmes also knew, or was reckless in not knowing, that the 2015 $1 billion revenue projections were unreasonable. By late 2014, Holmes knew Theranos' roll outs in Pharmacy A and Grocery A stores were not going as planned. Theranos and Holmes also knew the company had made limited progress in advancing the other lines of business reflected in the projections. Holmes knew that Theranos had no active discussions with pharmaceutical companies, had partnered with only a handful of hospitals, and had no knowledge of any contracts between Theranos and physicians' offices.

89. These financial projections were important to investors because they gave the impression that Theranos had already secured contracts to deliver these revenues and that the company's business was growing rapidly.

F. Theranos Exited the Commercial Laboratory Business in 2016, and By the End of 2017, Was On the Verge of Bankruptcy

90. In 2016, after regulatory inspections of Theranos' clinical laboratories and manufacturing facility, Theranos and Holmes exited the retail laboratory business and shifted the company's focus away from retail clinical testing and back to developing the miniLab. Additionally, Grocery A and Pharmacy A terminated their relationships with Theranos.

91. In 2017, Theranos and Holmes settled a lawsuit with an investor that alleged it was defrauded by Theranos. Theranos also settled a lawsuit with Pharmacy A, which brought an action for breach of contract against the company.

92. In 2017, Theranos conducted a tender offer to recapitalize certain investors from its later fundraising rounds. As part of that recapitalization, Holmes returned approximately 34 million of her shares to Theranos to prevent other investors from being diluted as a result of the tender offer. As part of the tender offer, Theranos agreed not to take certain corporate actions – including the decisions to issue new equity or amend the company's bylaws – without a vote of the majority of shareholders who invested during the relevant time period.

93. Due to the company's liquidation preference, if Theranos is acquired or is otherwise liquidated, Holmes would not profit from her ownership until – assuming redemption

of certain warrants – over $750 million is returned to defrauded investors and other preferred shareholders.

94. In late 2017, on the verge of bankruptcy, Theranos obtained a term loan, secured on the value of Theranos' patent portfolio, that it anticipated would allow the company to continue work on the miniLab for approximately one year.

FIRST CLAIM FOR RELIEF

Violations of Section 10(b) of the Exchange Act and Rule 10b-5

By Both Defendants

95. The Commission re-alleges and incorporates by reference Paragraph Nos. 1 through 94.

96. By engaging in the conduct described above, Defendants Holmes and Theranos, directly or indirectly, in connection with the purchase or sale of securities, by the use of means or instrumentalities of interstate commerce, or the mails, with scienter:

(a) Employed devices, schemes, or artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; and

(c) Engaged in acts, practices, or courses of business which operated or would operate as a fraud or deceit upon other persons, including purchasers and sellers of securities.

97. By reason of the foregoing, Defendants violated, and unless restrained and enjoined will continue to violate, Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §§ 240.10b-5].

SECOND CLAIM FOR RELIEF

Violations of Sections 17(a)(1), (2), and (3) of the Securities Act

By Both Defendants

98. The Commission re-alleges and incorporates by reference Paragraph Nos. 1 through 94.

99. By engaging in the conduct described above, Defendants Holmes and Theranos, directly or indirectly, in the offer or sale of securities, by use of the means or instruments of transportation or communication in interstate commerce or by use of the mails,

(1) with scienter, employed devices, schemes, or artifices to defraud;

(2) obtained money or property by means of untrue statements of material fact or by omitting to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and

(3) engaged in transactions, practices, or courses of business which operated or would operate as a fraud or deceit upon purchasers.

100. By reason of the foregoing, Defendants violated, and unless restrained and enjoined will continue to violate, Section 17(a) of the Securities Act [15 U.S.C. §§ 77q(a)].

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests that this Court:

I.

Permanently enjoin Defendants Holmes and Theranos from directly or indirectly violating Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)], and Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)], and Rule 10b-5 [17 C.F.R. § 240.10b-5] thereunder.

II.

Issue an order requiring Defendant Holmes to pay a civil monetary penalty pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)] and Section 21(d) of the Exchange Act [15 U.S.C. § 78u(d)(3)].

III.

Issue an order requiring Defendant Holmes to return 18,897,137 Class B common stock shares in Theranos to Theranos within 14 days of entry of judgment pursuant to the Court's equitable powers.

IV.

Issue an order requiring Defendant Holmes to provide written notice to Theranos that she elects to convert all shares of Class B common stock shares in Theranos to Class A common stock shares, and take all necessary administrative actions to effectuate the conversion of these Class B common stock shares to Class A common stock shares within 28 days of entry of judgment pursuant to the Court's equitable powers.

V.

Prohibit Defendant Holmes from serving as an officer or director of any entity having a class of securities registered with the Commission pursuant to Section 12 of the Exchange Act [15 U.S.C. § 78*l*] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78o(d)], pursuant to Section 20(e) of the Securities Act [15 U.S.C. § 77t(e)] and Section 21(d)(2) of the Exchange Act [15 U.S.C. § 78u(d)(2)].

VI.

Retain jurisdiction of this action in accordance with the principles of equity and the Federal Rules of Civil Procedure in order to implement and carry out the terms of all orders and decrees that may be entered, or to entertain any suitable application or motion for additional relief within the jurisdiction of this Court.

VII.

Grant such other and further relief as this Court may determine to be just and necessary.

Dated: March 14, 2018

Respectfully submitted,

/s/ Jessica W. Chan
JESSICA W. CHAN
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SECURITIES AND EXCHANGE COMMISSION