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11 **UNITED STATES DISTRICT COURT**
 12 **NORTHERN DISTRICT OF CALIFORNIA**
 13 **SAN JOSE DIVISION**

15 SECURITIES AND EXCHANGE COMMISSION,
 16 Plaintiff,
 17 vs.
 18 ELIZABETH HOLMES and THERANOS, INC.
 19 Defendants.

Case No.

COMPLAINT

20
21
22 Plaintiff Securities and Exchange Commission (the “Commission”) alleges:

23 **SUMMARY OF THE ACTION**

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

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

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

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

24 5. At all times, however, Holmes, Balwani, and Theranos were aware that, in its
25 clinical laboratory, Theranos' proprietary analyzer performed only approximately 12 tests of the
26 over 200 tests on Theranos' published patient testing menu, and Theranos used third-party
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1 few tests. A point-of-care device can be used to obtain results near where patients provide
2 samples, such as medical offices.

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

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

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

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

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

26 21. In connection with discussions about a potential partnership with Pharmacy A,
27 Holmes approved and provided presentations and other written materials to Pharmacy A
28

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

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

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

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

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

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

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

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

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

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

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

23 30. Holmes and Theranos never told Pharmacy A and Grocery A about Theranos'
24 technological challenges. For instance, in July and August 2013, Theranos coordinated
25 technology demonstrations for various Pharmacy A executives in advance of the retail launch.
26 Holmes instructed Theranos employees to place both earlier generation TSPUs and miniLabs in
27 a demonstration room where Theranos collected fingerstick samples from Pharmacy A
28

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

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

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

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

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

23 35. Holmes and Balwani also denied there were problems with Theranos’ technology
24 in discussions with Grocery A. For example, in response to a question about a rumor that
25 Theranos was facing technological challenges with its proprietary analyzers, Holmes and
26 Balwani assured Grocery A’s General Counsel that there was no technological problem with the
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1 analyzers and that the TSPU was capable of performing 90 percent of the blood tests typically
2 requested by doctors for their patients.

3 36. From its retail launch in September 2013 to the time it closed its clinical
4 laboratories in 2016, Theranos never used its miniLab for patient testing in its clinical laboratory.
5 Theranos conducted – at its height – 12 tests using the earlier-generation TSPU, and processed
6 about 50 to 60 tests using the modified third-party analyzers. Theranos processed the remaining
7 100-plus tests it offered at Pharmacy A using the same types of industry standard technology as
8 other traditional laboratories, or sent tests out to third-party laboratories.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

26 49. This initial meeting was often followed by a purported demonstration of
27 Theranos' proprietary analyzers, the TSPU, and the miniLab. In several instances, potential
28

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

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

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

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

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

8 **a. Holmes and Theranos Represented That Theranos’**
9 **Proprietary Analyzer Was Capable of Conducting the Full**
10 **Range of Testing When It Could Not**

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

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

22 55. But Theranos’ analyzers never performed comprehensive testing or processed
23 1,000 CPT codes in its clinical lab. In fact, as Holmes knew, or was reckless in not knowing,
24 Theranos’ clinical lab used the TSPU only to perform 12 of the tests offered to patients.

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

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

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

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

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

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

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

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

26 62. These statements gave potential investors the impression that Theranos was only
27 using its own TSPUs and miniLabs for patient testing.
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1 63. As Holmes knew, or was reckless in not knowing, statements that Theranos
2 manufactured all of its analyzers were false or misleading in light of Theranos' broad use of
3 third-party analyzers. Theranos conducted the majority of its testing using third-party analyzers.

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

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

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

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

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

25 68. Holmes knew, or was reckless in not knowing, that these statements were false
26 and misleading. While Theranos' technology was used in a DOD burn study, it was never
27 deployed by the DOD in the battlefield, in Afghanistan, or on medevac helicopters. From 2011
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1 to 2014, Holmes had discussions with multiple divisions of the DOD. However, Theranos
2 generated only approximately \$300,000 from three DOD contracts.

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

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

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

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

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

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

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

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

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

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

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

19 78. The statements made by Holmes about the status of the Pharmacy A and Grocery
20 A relationships were important to investors because these contracts gave potential investors
21 confidence that Theranos' technologies were commercially ready. Pharmacy A and Grocery A
22 were also the major drivers of future revenues for the company. In reality, Holmes and Theranos
23 were attempting to renegotiate Theranos' agreements with these retail businesses in light of the
24 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

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

8 80. Holmes represented to business partners and investors that FDA approval was not
9 necessary because she believed that Theranos’ tests were laboratory developed tests (“LDTs”),
10 or tests developed and used inside a clinical laboratory, over which the FDA had historically
11 exercised its enforcement discretion to not require FDA clearance. However, she and Balwani
12 were told by multiple parties, including Pharmacy A, that the FDA might reject this regulatory
13 strategy because Theranos’ miniLab had not previously obtained approval from the FDA.
14 Holmes and FDA representatives discussed Theranos’ regulatory strategy in late 2013 through
15 2014 while Theranos continued to offer LDTs to retail patients.

16 81. By the time of Theranos’ financing round in 2014, FDA representatives told
17 Holmes that clearance or approval would be necessary for Theranos’ analyzer and tests. In late
18 2013 and throughout 2014, FDA representatives met with Holmes and sent letters to Theranos
19 stating that they did not believe Theranos was offering LDTs, and that even if Theranos was not
20 selling its miniLab or tests, FDA clearance or approval was necessary. Based on these
21 communications, Holmes agreed to submit all components of Theranos’ testing technology to
22 the FDA for clearance or approval. However, Holmes continued to raise additional funds while
23 telling investors Theranos was seeking FDA approval voluntarily. But Holmes knew, or was
24 reckless in not knowing, that FDA approval was necessary for Theranos’ analyzer and tests.

25 82. Holmes’ statements that Theranos did not need FDA approval or clearance were
26 important to investors because approval or clearance would have been an obstacle in the
27 company’s path to realizing full commercialization.
28

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.

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

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

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

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

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

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

26 93. Due to the company's liquidation preference, if Theranos is acquired or is
27 otherwise liquidated, Holmes would not profit from her ownership until – assuming redemption
28

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

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

6 **FIRST CLAIM FOR RELIEF**

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

8 *By Both Defendants*

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

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

- 14 (a) Employed devices, schemes, or artifices to defraud;
15 (b) Made untrue statements of material facts or omitted to state material facts
16 necessary in order to make the statements made, in the light of the circumstances
17 under which they were made, not misleading; and
18 (c) Engaged in acts, practices, or courses of business which operated or would
19 operate as a fraud or deceit upon other persons, including purchasers and sellers
20 of securities.

21 97. By reason of the foregoing, Defendants violated, and unless restrained and
22 enjoined will continue to violate, Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and
23 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)].

1 **III.**

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

5 **IV.**

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

11 **V.**

12 Prohibit Defendant Holmes from serving as an officer or director of any entity having a
13 class of securities registered with the Commission pursuant to Section 12 of the Exchange Act
14 [15 U.S.C. § 78l] or that is required to file reports pursuant to Section 15(d) of the Exchange Act
15 [15 U.S.C. § 78o(d)], pursuant to Section 20(e) of the Securities Act [15 U.S.C. § 77t(e)] and
16 Section 21(d)(2) of the Exchange Act [15 U.S.C. § 78u(d)(2)].

17 **VI.**

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