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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 RAMESH “SUNNY” BALWANI,
19 Defendant.

Case No.

COMPLAINT

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 Holmes and Theranos.

1 2. Balwani, Holmes, 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. Balwani, Holmes, 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 Balwani's and Holmes' representations,
17 investors understood that 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 Balwani and Holmes, 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, Balwani, Holmes, 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
27
28

1 | **DEFENDANT**

2 | 12. Ramesh “Sunny” Balwani, age 52, of Atherton, California, was the President and
3 | Chief Operating Officer of Theranos, Inc. from September 2009 to May 2016. From 2013
4 | through 2015 (the “relevant time period”), Balwani received a salary of between approximately
5 | \$99,000 and \$200,000.

6 | **OTHER RELEVANT INDIVIDUAL AND ENTITY**

7 | 13. Elizabeth Holmes, age 34, of Los Altos Hills, California, is the Chief Executive
8 | Officer (“CEO”) and Chairman of the Board of Theranos, Inc.

9 | 14. Theranos, Inc. is a Delaware corporation, with its principal place of business in
10 | Newark, California. During the relevant time period, Theranos’ principal place of business was
11 | in Palo Alto, California and its sole managing executives were Holmes and Balwani.

12 | **FACTUAL ALLEGATIONS**

13 | **A. Background**

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

18 | 16. For the first five years of its existence, before Balwani joined Theranos, Theranos
19 | focused its efforts on developing its proprietary analyzer, the Theranos Sample Processing Unit,
20 | or “TSPU,” to analyze blood taken from a fingerstick and on assisting pharmaceutical companies
21 | with their clinical trials. The earliest generation TSPU was a small point-of-care device that was
22 | capable of performing only a few tests. A point-of-care device can be used to obtain results near
23 | where patients provide samples, such as medical offices.

24 | 17. In 2009, as Theranos was on the verge of running out of money, Holmes turned
25 | to her then-boyfriend Balwani, who guaranteed a line of credit for the company. Balwani joined
26 | the company and became its President and COO that same year.

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

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

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

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

21 21. In connection with discussions about a potential partnership with Pharmacy A,
22 Holmes approved and, copying Balwani, provided presentations and other written materials to
23 Pharmacy A executives representing that Theranos had the ability to conduct a broad range of
24 tests on its proprietary analyzer, including general chemistry tests, wellness tests, and some
25 predictive and diagnostic health tests (which involved methods beyond immunochemistries).
26 These materials stated that Theranos would be ready to begin blood testing on its proprietary
27 analyzer at Pharmacy A stores by the fourth quarter of 2010.

1 22. Balwani and Holmes also told Pharmacy A executives that Theranos could
2 conduct hundreds of blood tests through fingerstick (or the puncture of a finger), that its testing
3 could be conducted in a rapid timeframe (in less than one hour), and that it could be offered for a
4 reasonable price (much less than Theranos’ competitors). Balwani also showed a Pharmacy A
5 executive a prototype of one of Theranos’ analyzers, which he represented was being used on
6 military helicopters.

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

13 24. Balwani and Holmes also made similar statements to Grocery A. They told
14 Grocery A’s then-CEO that Theranos had successfully miniaturized the conventional laboratory.
15 Balwani also was present when Holmes told Grocery A’s then-CEO that Theranos’ analyzers
16 were being deployed in the battlefield. Based on these representations, in September 2010,
17 Grocery A contracted with Theranos to offer Theranos patient testing in Grocery A stores.

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

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

23 26. In 2011, Pharmacy A executives raised concerns it had with Theranos’ regulatory
24 strategy, and told Balwani and Holmes that Theranos might need to obtain FDA approval for its
25 miniLab and certify each of its stores as a laboratory in order for the analyzers to be used in
26 Pharmacy A stores.

27 27. Based on these concerns, in 2012, Theranos and Pharmacy A agreed to modify
28 their original contract to reflect a roll-out of Theranos’ service in two phases. In the first phase,

1 before Theranos received regulatory approvals for its analyzers, patient samples would be
2 transported from Pharmacy A stores to centralized laboratories operated by Theranos and tested
3 on Theranos' miniLab there. Theranos opened and operated two centralized laboratories to test
4 patient samples collected from Pharmacy A stores. In the second phase, after Theranos had
5 received the necessary regulatory approvals, Theranos' retail offering at Pharmacy A would be
6 performed on miniLabs placed in Pharmacy A stores.

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

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

19 30. Balwani and Holmes never told Pharmacy A and Grocery A about Theranos'
20 technological challenges. For instance, in July and August 2013, Theranos coordinated
21 technology demonstrations for various Pharmacy A executives in advance of the retail launch.
22 Holmes, with Balwani's knowledge, instructed Theranos employees to place both earlier
23 generation TSPUs and miniLabs in a demonstration room where Theranos collected fingerstick
24 samples from Pharmacy A executives. Instead of using these machines to process the tests on
25 these samples, and unbeknownst to the Pharmacy A executives, Theranos used the modified
26 third-party machines to process a portion of the tests.

1 31. Based on Balwani’s and Holmes’ presentations, Pharmacy A executives
2 understood that the blood from their demonstration samples would be tested on Theranos’
3 miniLabs. Balwani never told the executives that Theranos was actually testing some of their
4 blood on modified third-party analyzers.

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

9 33. Balwani never told anyone at Pharmacy A that Theranos used third-party
10 analyzers, including those that had been modified to test fingerstick blood. He also never told
11 Pharmacy A that Theranos was using third-party analyzers to perform the majority of its testing.
12 If Pharmacy A had known that Theranos was using third-party analyzers for a majority of its
13 patient testing, it would not have accelerated the payment of the innovation fee.

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

20 35. Balwani also instructed Theranos’ laboratory employees to use code names to
21 refer to third-party analyzers in its laboratory information systems, ensuring that even other
22 Theranos employees would not know that Theranos was using third-party analyzers to conduct a
23 portion of its patient testing.

24 36. From its retail launch in September 2013 to the time it closed its clinical
25 laboratories in 2016, Theranos never used its miniLab for patient testing in its clinical laboratory.
26 Theranos conducted – at its height –12 tests using the earlier-generation TSPU, and processed
27 about 50 to 60 tests using the modified third-party analyzers. Theranos processed the remaining
28

1 100-plus tests it offered at Pharmacy A using the same types of industry standard technology as
2 other traditional laboratories, or sent tests out to third-party laboratories.

3 **D. Starting in September 2013, Theranos Began Publicly Touting Theranos’**
4 **Proprietary Analyzers in Interviews with the Media, Notwithstanding**
5 **Theranos’ Use of Commercially-Available Analyzers for Patient Testing**

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

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

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

21 39. Additional articles written after interviews with Holmes continued to raise
22 Theranos’ public profile and tout its technological capabilities. An April 2014 *Wired* article
23 stated that “[i]nstead of vials of blood – one for every test needed – Theranos requires only a
24 pinprick and a drop of blood. With that they can perform hundreds of tests, from standard
25 cholesterol checks to sophisticated genetic analyses.”

26 40. Similarly, a June 2014 *Fortune* article noted that “[Theranos] currently offers
27 more than 200 – and is ramping up to offer more than 1,000 – of the most commonly ordered
28 blood diagnostic tests, all without the need for a syringe.” *Fortune* also distinguished Theranos

1 from other blood testing companies because “Theranos [] does not buy any analyzers from third
2 parties.” In contrast to the large traditional blood analyzers that occupied whole rooms,
3 Theranos’ proprietary analyzers “look[ed] like large desktop computer towers.”

4 41. Balwani knew, or was reckless in not knowing, that the *Fortune* article contained
5 misstatements about Theranos’ technology. Nevertheless, Balwani discussed the *Fortune* article
6 with investors but failed to correct the misstatements, instead commenting that the article
7 provided a favorable boost to Theranos’ public image.

8 42. Balwani did not correct the false or misleading statements in the articles that were
9 published between 2013 and 2015. In fact, in some instances, as Balwani knew, or was reckless
10 in not knowing, Theranos provided to potential investors some of the articles containing untrue
11 or misleading statements.

12 **E. Beginning in 2013, Balwani, Holmes, and Theranos Raised Over \$700**
13 **Million from Investors**

14 43. In late 2013, Theranos had approximately \$30 million in cash and short-term
15 securities, which would fund the company’s operations for only a few months. As Balwani and
16 Holmes knew, Theranos needed cash to continue spending money on research and development
17 to advance the miniLab, which at that time was not ready for commercial use.

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

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

25 45. After an introduction to Holmes, potential investors would typically meet face-to-
26 face with Holmes, and at times, Balwani. During this meeting, which normally took place at
27 Theranos’ headquarters, Holmes described her vision for the company, including her motivation
28

1 to develop a technology that could perform blood testing on small samples – spurred by her own
2 fear of needles – and her larger desire to provide cheaper, faster, and more accurate laboratory
3 testing so that diagnoses of serious conditions and diseases could take place sooner.

4 46. This initial meeting was often followed by a purported demonstration of
5 Theranos’ proprietary analyzers, the TSPU, and the miniLab. In several instances, potential
6 investors would be taken by Balwani and Holmes to a different room to view Theranos’ desktop
7 computer-like analyzers. A phlebotomist would arrive to draw their blood through fingerstick,
8 using a nanotainer, a Theranos-developed collection device. Then the sample was either inserted
9 into the TSPU or taken away for processing. Based on what they saw, potential investors
10 believed that Theranos had tested their blood on either an earlier-generation TSPU or the
11 miniLab. As Balwani knew, however, Theranos often actually tested their blood on third-party
12 analyzers, because Theranos could not conduct all of the tests it offered prospective investors on
13 its proprietary analyzers.

14 47. As Balwani knew, or was reckless in not knowing, Theranos also sent investors a
15 binder of background materials, which Holmes instructed employees to compile. In addition to
16 incorporation documents and shareholder agreements, the typical investor binder included (1) a
17 cover letter drafted and signed by Holmes; (2) a company overview slide deck presentation;
18 (3) reports of clinical trials work Theranos performed with its pharmaceutical companies;
19 (4) financial projections; and (5) articles and profiles about Theranos, including the 2013 and
20 2014 articles from *The Wall Street Journal*, *Wired*, and *Fortune* that were written after Holmes
21 provided them with interviews. These materials were important to investors in considering
22 whether to invest in Theranos.

23 **2. Balwani and Holmes Made a Series of False or Misleading**
24 **Statements to Investors That Confirmed the Company’s Public**
25 **Narrative**

26 48. Balwani and Holmes made statements to investors about the status of Theranos’
27 technology, historical contracts, commercial relationships, regulatory strategy, and financial
28

1 performance that were consistent with the public image they were promoting of Theranos as a
2 company that was revolutionizing the diagnostics industry.

3 **a. Balwani and Holmes Represented That Theranos’**
4 **Proprietary Analyzer Was Capable of Conducting the Full**
5 **Range of Testing When It Could Not**

6 49. Balwani and Holmes represented to investors that Theranos’ miniLab was
7 capable of processing a full range of laboratory tests. For instance, they told one investor that
8 Theranos’ proprietary analyzer could process over 1,000 Current Procedural Terminology
9 (“CPT”) codes and that Theranos had developed a technological solution for an additional 300
10 CPT codes. In 2014, Balwani told an investor that Theranos had between 150 and 200
11 fingerstick tests operating in its clinical lab.

12 50. Theranos’ company overview presentation, which Balwani sent to a potential
13 investor, also echoed these same statements. Under a slide titled “Same Tests, A Whole New
14 approach” and featuring a picture of a fingerprick and Theranos collection device, the
15 presentation included the statement “Theranos runs any test available in central laboratories, and
16 processes all sample types.”

17 51. But Theranos’ analyzers never performed comprehensive testing or processed
18 1,000 CPT codes, nor did Theranos ever offer between 150 and 200 fingerstick tests in its
19 clinical lab. In fact, as Balwani knew, or was reckless in not knowing, Theranos’ clinical lab
20 used the TSPU only to perform 12 of the tests offered to patients.

21 52. In addition to not disclosing the use of third-party analyzers to conduct the
22 demonstrations, Balwani’s and Holmes’ actions made it appear as if Theranos’ proprietary
23 analyzer had more extensive capabilities than it actually did. When potential investors tried out
24 Theranos’ services by bringing a physician’s laboratory requisition to a Pharmacy A store,
25 Holmes, with Balwani’s knowledge, instructed Theranos employees to remove certain tests from
26 the order if Theranos was unable to perform those tests using a fingerstick collection.

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

8 54. Balwani’s statements about the capabilities of Theranos’ proprietary analyzer
9 were important to potential investors because the technology was a basis of their investments.

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

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

19 56. The company overview presentation, which Balwani provided to at least one
20 investor, also showed pictures of the TSPU and miniLab under the heading “Theranos Systems,”
21 but excluded pictures of the third-party analyzers Theranos was using.

22 57. Finally, the *Fortune* article – which Balwani received and discussed with an
23 investor – stated that “Theranos [] does not buy any analyzers from third parties.”

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

26 59. As Balwani knew, or was reckless in not knowing, statements that Theranos
27 manufactured all of its analyzers were false or misleading in light of Theranos’ broad use of
28 third-party analyzers. Theranos conducted the majority of its testing using third-party analyzers.

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

4 **c. Balwani and Holmes Made False or Misleading Statements**
5 **About Theranos’ Historical Contracts with the DOD**

6 61. Balwani and Holmes also made false or misleading statements concerning
7 Theranos’ historical business contracts with the DOD. For instance, Balwani provided a
8 presentation to a potential investor that listed the DOD as a “[k]ey deployment” for Theranos.

9 62. Balwani and Holmes also made other statements that gave potential investors the
10 impression that these historical relationships were meaningful. Balwani and Holmes told
11 multiple investors that Theranos’ technology had been deployed by the DOD in the battlefield
12 and in Afghanistan. They also told investors that the DOD had deployed Theranos’ miniLab on
13 medevac helicopters.

14 63. Balwani told one potential investor in late 2013 that 75 percent of Theranos’
15 current revenues were from the military. Balwani told another potential investor in late 2014 that
16 the company had long-dated contracts with the DOD that would provide future revenue to
17 Theranos.

18 64. Balwani knew, or was reckless in not knowing, that these statements were false
19 and misleading. While Theranos’ technology was used in a DOD burn study, it was never
20 deployed by the DOD in the battlefield, in Afghanistan, or on medevac helicopters. From 2011
21 to 2014, Theranos had discussions with multiple divisions of the DOD. However, Theranos
22 generated only approximately \$300,000 from three DOD contracts.

23 65. Balwani’s statements about Theranos’ history with the DOD were important to
24 potential investors because these relationships lent legitimacy to Theranos’ business and its
25 proprietary analyzer.

1 **d. Balwani and Holmes Told Investors That Theranos’**
2 **Relationships with Pharmacy A and Grocery A Were**
3 **Thriving When They Were Stalled**

4 66. During meetings and in investor binders, Balwani and Holmes described
5 Theranos’ thriving relationships with Pharmacy A and Grocery A. Much of the company
6 overview presentation was dedicated to Theranos’ relationship with Pharmacy A, showing
7 pictures of the patient service centers where patients would get their fingers pricked, and a map
8 of the number of Pharmacy A stores across the country that would soon be offering Theranos’
9 blood testing. Notwithstanding that Balwani managed the Pharmacy A relationship, Balwani
10 represented to numerous investors in late 2014 that Theranos was expected to roll out its retail
11 services to hundreds of Pharmacy A stores in 2015. This information was also included in
12 financial projections that Balwani drafted for investors that were based on the assumption that
13 Theranos would be rolling out to 800 or 900 stores by year-end 2015.

14 67. However, by late 2014, while Theranos was raising the bulk of the over \$700
15 million it raised during the relevant time period, Balwani was aware that Theranos’ retail roll out
16 with Pharmacy A was stalled due to, among other issues, some concerns Pharmacy A executives
17 had with regard to Theranos’ performance.

18 68. In August 2014, a senior Pharmacy A executive told Balwani that patient traffic
19 and fingerstick draw percentages would need to increase in order for the executive to convince
20 Pharmacy A management to roll out Theranos services to more stores. At a partnership meeting
21 later that month, which Balwani attended, Theranos and Pharmacy A discussed reducing the
22 number of Pharmacy A stores that Theranos services would be rolled out to in 2015 from 500
23 stores to 200.

24 69. In December 2014, Balwani met with Pharmacy A executives to discuss
25 potentially modifying the parties’ relationship to a landlord and tenant model, whereby Theranos
26 would rent space in Pharmacy A stores. Balwani did not share any of these developments with
27 investors. Balwani knew, or was reckless in not knowing, that Theranos would not be expanding
28 into Pharmacy A as quickly as he represented it would.

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

6 71. By August 2014, Grocery A and Theranos ceased to be in communication with
7 one another. Nevertheless, when meeting with investors in the fall of 2014, Balwani continued
8 to discuss Theranos' relationship with Grocery A to investors. Balwani knew, or was reckless in
9 not knowing, that his statements about Theranos' relationship with Grocery A were false or
10 misleading.

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

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

20 73. When speaking to potential investors in late 2013 through 2015, Balwani and
21 Holmes consistently stated that Theranos did not need to obtain approval from the FDA for its
22 miniLab and tests, and instead said that Theranos was applying for FDA approval voluntarily.
23 For instance, Balwani told a potential investor that approval was not required for the miniLab
24 because Theranos was not selling its devices to other companies.

25 74. Balwani and Holmes represented to business partners and investors that FDA
26 approval was not necessary because they believed that Theranos' tests were laboratory developed
27 tests ("LDTs"), or tests developed and used inside a clinical laboratory, over which the FDA had
28

1 | historically exercised its enforcement discretion to not require FDA clearance. However,
2 | Balwani and Holmes were told by multiple parties, including Pharmacy A, that the FDA might
3 | reject this regulatory strategy because Theranos' miniLab had not previously obtained approval
4 | from the FDA.

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

15 | 76. Balwani's statements that Theranos did not need FDA approval or clearance were
16 | important to investors because approval or clearance would have been an obstacle in the
17 | company's path to realizing full commercialization.

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

22 | 77. Balwani drafted the financial information that Theranos included in the investor
23 | binders that projected that Theranos would generate over \$100 million in revenues and break
24 | even in 2014. These documents also represented that Theranos expected to generate
25 | approximately \$1 billion in revenues in 2015. Balwani told potential investors in October 2014
26 | that he had confidence in the year-end 2014 projections, in part because they were already more
27 | than nine months into the calendar year.
28 |

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

5 79. Some of Theranos' projections, which Balwani provided to potential investors in
6 October 2014, stated Theranos would earn \$40 million from pharmaceutical services, \$46
7 million from lab services provided to hospitals, and \$9 million from lab services provided to
8 physicians' offices, all by the end of 2014. In reality, Theranos had no revenues from any of
9 those lines of business. And Balwani knew that Theranos was not on track to break even in
10 2014.

11 80. Theranos' actual financial performance bore no resemblance to the financial
12 information Balwani shared with investors. Theranos recorded little more than \$100,000 in
13 revenue in 2014 and was nowhere near generating \$100 million in revenue by the end of 2014.

14 81. Balwani knew, or was reckless in not knowing, the 2014 revenue projection was
15 baseless. In October 2014, the same month he was providing year-end projected revenue figures
16 between \$120 and \$140 million to potential investors, Balwani told Theranos' potential insurers
17 that Theranos was operating at an \$8 million to \$9 million monthly net loss.

18 82. Balwani also knew, or was reckless in not knowing, that Theranos was using
19 different projections with the third-party valuation firm that Theranos had retained to value the
20 company's common stock. The valuation firm prepared a report dated October 2014, which
21 Balwani received, that analyzed the value of Theranos' common stock based on an assumption
22 that it would recognize approximately \$1 million in revenue for 2014 and \$110 million for 2015.

23 83. By late 2014, Balwani knew Theranos' roll-outs in Pharmacy A and Grocery A
24 stores were not going as planned. Balwani also knew the company had made limited progress in
25 advancing the other lines of business reflected in the projections. Balwani knew that Theranos
26 had no active discussions with pharmaceutical companies, had partnered with only a handful of
27 hospitals, and had no knowledge of any contracts between Theranos and physicians' offices.

28

1 Balwani thus also knew, or was reckless in not knowing, that the 2015 \$1 billion revenue
2 projections were unreasonable.

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

6 **F. Balwani Left Theranos in 2016**

7 85. In May 2016, after regulatory inspections of Theranos' clinical laboratories and
8 its manufacturing facility, Balwani left Theranos.

9 86. In 2017, Balwani, Holmes, and Theranos settled a lawsuit with an investor that
10 alleged they had committed securities fraud.

11 **FIRST CLAIM FOR RELIEF**

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

13 87. The Commission re-alleges and incorporates by reference Paragraph Nos. 1
14 through 86.

15 88. By engaging in the conduct described above, Defendant, directly or indirectly, in
16 connection with the purchase or sale of securities, by the use of means or instrumentalities of
17 interstate commerce, or the mails, with scienter:

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

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

1 **SECOND CLAIM FOR RELIEF**

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

3 90. The Commission re-alleges and incorporates by reference Paragraph Nos. 1
4 through 86.

5 91. By engaging in the conduct described above, Defendant directly or indirectly, in
6 the offer or sale of securities, by use of the means or instruments of transportation or
7 communication in interstate commerce or by use of the mails,

- 8 (a) with scienter, employed devices, schemes, or artifices to defraud;
- 9 (b) obtained money or property by means of untrue statements of material
10 fact or by omitting to state a material fact necessary in order to make the
11 statements made, in light of the circumstances under which they were
12 made, not misleading; and
- 13 (c) engaged in transactions, practices, or courses of business which operated
14 or would operate as a fraud or deceit upon purchasers.

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

17 **THIRD CLAIM FOR RELIEF**

18 *Aiding and Abetting Violations of Section 10(b) of the Exchange Act and Rule 10b-5*
19 *Thereunder*

20 93. The Commission realleges and incorporates by reference paragraphs 1 through
21 86.

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

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

- 1 (b) Made untrue statements of material facts or omitted to state material facts
2 necessary in order to make the statements made, in the light of the
3 circumstances under which they were made, not misleading; and
4 (c) Engaged in acts, practices, or courses of business which operated or
5 would operate as a fraud or deceit upon other persons, including
6 purchasers and sellers of securities.

7 95. By engaging in the acts and conduct alleged above, Defendant knowingly or
8 recklessly provided substantial assistance to Holmes' or Theranos' violations of Section 10(b) of
9 the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §§ 240.10b-5], and
10 thereby aided and abetted such violations, and unless restrained and enjoined, will continue to
11 violate these provisions.

12
13 **FOURTH CLAIM FOR RELIEF**

14 *Aiding and Abetting Violations of Section 17(a) of the Securities Act*

15 96. The Commission realleges and incorporates by reference paragraphs 1 through
16 86.

17 97. By engaging in the conduct described above, Holmes or Theranos directly or
18 indirectly, in the offer or sale of securities, by use of the means or instruments of transportation
19 or communication in interstate commerce or by use of the mails,

- 20 (a) with scienter, employed devices, schemes, or artifices to defraud;
21 (b) obtained money or property by means of untrue statements of material
22 fact or by omitting to state a material fact necessary in order to make the
23 statements made, in light of the circumstances under which they were
24 made, not misleading; and
25 (c) engaged in transactions, practices, or courses of business which operated
26 or would operate as a fraud or deceit upon purchasers.

1 98. By engaging in the acts and conduct alleged above, Defendant knowingly or
2 recklessly provided substantial assistance to Holmes' or Theranos' violations of Section 17(a) of
3 the Securities Act [15 U.S.C. §§ 77q(a)], and thereby aided and abetted such violations, and
4 unless restrained and enjoined, will continue to violate these provisions.

5 **PRAYER FOR RELIEF**

6 WHEREFORE, the Commission respectfully requests that this Court:

7 **I.**

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

11 **II.**

12 Issue an order requiring Defendant to pay a civil monetary penalty pursuant to
13 Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)] and Section 21(d) of the Exchange Act
14 [15 U.S.C. § 78u(d)(3)].

15 **III.**

16 Prohibit Defendant from serving as an officer or director of any entity having a class of
17 securities registered with the Commission pursuant to Section 12 of the Exchange Act [15 U.S.C.
18 § 78l] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C.
19 § 78o(d)], pursuant to Section 20(e) of the Securities Act [15 U.S.C. § 77t(e)] and
20 Section 21(d)(2) of the Exchange Act [15 U.S.C. § 78u(d)(2)].

21 **IV.**

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

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