

1 Reed R. Kathrein (139304)
Peter E. Borkon (212596)
2 Nicholas S. Singer (306098)
HAGENS BERMAN SOBOL SHAPIRO LLP
3 715 Hearst Avenue, Suite 202
Berkeley, CA 94710
4 Telephone: (510) 725-3000
Facsimile: (510) 725-3001
5 reed@hbsslaw.com
peterb@hbsslaw.com
6 nsinger@hbsslaw.com

7 Steve W. Berman (*pro hac vice* applied for)
HAGENS BERMAN SOBOL SHAPIRO LLP
8 1918 Eighth Avenue, Suite 3300
Seattle, WA 98101
9 Telephone: (206) 623-7292
Facsimile: (206) 623-0594
10 steve@hbsslaw.com

11 *Attorneys for Plaintiffs and Proposed Lead*
Counsel for the Class

12 UNITED STATES DISTRICT COURT
13
14 NORTHERN DISTRICT OF CALIFORNIA

15 ROBERT COLMAN and HILARY
TAUBMAN-DYE, Individually and on Behalf
16 of All Others Similarly Situated,

17 Plaintiffs,

18 v.

19 THERANOS, INC., ELIZABETH HOLMES,
and RAMESH BALWANI,

20 Defendants.

No.

CLASS ACTION COMPLAINT FOR
VIOLATIONS OF CALIFORNIA'S
SECURITIES, UNFAIR COMPETITION,
AND COMMON LAWS

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. SUMMARY OF ACTION	1
III. PARTIES	4
IV. JURISDICTION AND VENUE.....	5
V. FACTUAL BACKGROUND	6
A. Theranos Builds up Publicity to Raise New Money from Investors	6
B. Defendants Court New Investors.....	9
C. Defendants Continue to Barrage the Media with Their False Narrative to Attract Investors	11
D. Promises on Theranos' Website and in Walgreens' Stores, and an Advertisement Were Also Used to Court Investors and Promote the "Narrative"	28
E. Plaintiffs and Class Invest Hundreds of Millions of Dollars in Theranos.....	32
F. Defendants' Private Solicitations are Consistently Misleading and Demonstrate Intent to Mislead	33
G. Defendants Attack Their Critics	35
H. Defendants' Theranos Story Unravels.....	39
1. Defendants Misrepresented the Extent to Which Theranos Tested Blood Samples Using Its Own Proprietary Analyzers	39
2. Defendants Misrepresented the Reason Theranos Stopped Using Its Finger-Stick and Nanotainer Collection Method for All but One Test	40
3. Theranos Labs Get Shut Down As Non-Compliant with Federal Regulations and Federal Agencies Begin to Investigate Theranos	41
I. Plaintiffs Have Been Damaged As Theranos' Value Has Plummeted by Over Ninety Percent	46
VI. CLASS ALLEGATIONS	46
VII. CAUSES OF ACTION.....	48
COUNT I SECURITIES FRAUD IN VIOLATION OF CAL. CORP. CODE §§ 25400(D) & 25500 (AGAINST ALL DEFENDANTS)	48
COUNT II SECURITIES FRAUD IN VIOLATION OF CAL. CORP. CODE §§ 25401, 25501 & 25504 (AGAINST ALL DEFENDANTS).....	49

COUNT III VIOLATION OF CALIFORNIA’S UNFAIR COMPETITION LAW (CAL. BUS. & PROF. CODE § 17200 ET SEQ.) (AGAINST ALL DEFENDANTS)	50
COUNT IV FRAUD AND DECEIT (CAL. CIV. CODE §§ 1709 & 1710 AND COMMON LAW) (AGAINST ALL DEFENDANTS)	51
COUNT V FRAUDULENT CONCEALMENT (CAL. CIV. CODE § 1710 AND COMMON LAW) (AGAINST ALL DEFENDANTS)	51
COUNT VI CONSTRUCTIVE FRAUD (CAL. CIV. CODE § 1573 AND COMMON LAW) (AGAINST ALL DEFENDANTS)	52
COUNT VII NEGLIGENT MISREPRESENTATION (CAL. CIV. CODE § 1710 AND COMMON LAW) (AGAINST ALL DEFENDANTS)	53
DEMAND FOR RELIEF	53
JURY DEMAND	54

I. INTRODUCTION

Robert Colman and Hilary Taubman-Dye, individually and on behalf of all others similarly situated (Plaintiffs), by and through their attorneys, allege upon knowledge as to themselves and their own conduct, and otherwise upon information and belief, including based on investigation of counsel, the facts stated in the public record, press releases, media reports and articles, court documents, regulatory filings, and online interviews and videos, as follows.

II. SUMMARY OF ACTION

1. Companies owe a duty to potential investors to be open and honest. Even non-public companies are bound by this principle of frankness no matter how sophisticated their potential investors might be. Specifically, those who solicit investments for a company should not make statements that are designed to reach potential investors that are materially false, misleading or incomplete. Those who make statements to investors must believe them to be true and complete, have a reasonable basis for their belief, and exercise reasonable care and not know of any untruth or omission.

2. Plaintiffs bring this action because Theranos, Inc. (“Theranos”), Chief Executive Officer Elizabeth Holmes (“Holmes”), and former President and Chief Operating Officer Ramesh “Sunny” Balwani (“Balwani”) flaunted these simple rules. To them, being honest and forthright was an obstacle to their goals. Instead, beginning in July 2013, Theranos, Holmes and Balwani set in motion a widespread publicity campaign whose purpose was raising billions for Theranos and themselves and to induce investors to invest in Theranos. They told the public, knowing and intending that their statements would reach potential investors, that they had perfected “a proprietary” and “revolutionary technology” over the past ten years that would change the world of laboratory testing.

3. Holmes claimed that Theranos’ proprietary technology could take a pinprick’s worth of blood, extracted from the tip of a finger instead of intravenously, and test for hundreds of diseases—a remarkable innovation that was going to save millions of lives and, in a phrase that Holmes often repeated, “Change the world.” Based on this story, Defendant also claimed that this technology had been vetted or was being vouched for by clinics, pharmaceutical companies, experts,

1 regulators and an all-star board of directors. And they announced that the technology was
2 immediately being rolled-out by one of the nation's largest drug store chains, Walgreens.

3 4. Holmes honed her story to near perfection. She gave hundreds of interviews in which
4 she promoted her narrative about Theranos' revolutionary technology. She bolstered that story by
5 attracting to the Theranos Board of Directors luminaries like Henry Kissinger and George Schultz.
6 Holmes adorned the covers of *Fortune*, *Forbes* and other publications and promoted her message
7 there and elsewhere. She also amassed a net worth of around \$9 billion.

8 5. The truth—there was no revolutionary technology. On October 15, 2015, the Wall
9 Street Journal (WSJ) shocked the investing world with a story that Theranos was “struggling” with
10 turning this technology into a reality. According to the WSJ, Theranos' employees were “leery about
11 the machine's accuracy” and the machine was being used for a tiny number of tests. The article also
12 reported that some doctors didn't trust the test results they were receiving. While Theranos
13 vigorously attacked and denied the WSJ article and follow-on media reports—calling them “factually
14 and scientifically erroneous and grounded in baseless assertions by inexperienced and disgruntled
15 former employees and industry incumbents”—those reports have turned out to be largely true.
16 Reportedly, Theranos is under investigation by the United States Department of Justice (U.S. DOJ)
17 and the Securities and Exchange Commission (SEC).

18 6. Even worse, findings by regulators have forced Theranos to void tens of thousands of
19 customers' blood test results, raising the specter of patient harm. In July 2016, the Center for
20 Medicare and Medicaid Services imposed significant sanctions on Theranos, including revoking the
21 Company's Clinical Laboratory Improvement Amendments (CLIA) certification, imposing a
22 monetary penalty of \$10,000 per day for each day of non-compliance with the conditions necessary
23 for CLIA certification, and banning Holmes and Balwani, and thereby Theranos itself, from owning
24 or operating a laboratory for at least two years.

25 7. And yet another hammer fell on the story when Theranos' commercial partner,
26 Walgreens, sued Theranos in November 2016 for breach of contract. Walgreens alleges that
27 Theranos made the following promises to Walgreens, which are virtually identical to the
28 representations Theranos made to investors which Theranos breached:

- a. Theranos had developed a “proprietary, patented technology” capable of running “comprehensive blood tests from a fingerstick, in real-time at the point of care, outside of traditional lab settings”;
- b. The blood tests would be run on a proprietary device they called “Theranos Systems”;
- c. The proprietary technology had been “comprehensively validated over the course of the last seven years by ten of the fifteen largest pharmaceutical companies”;
- d. The technology already had been used by numerous current and past clients, including these same pharmaceutical companies, midsize bio-pharma companies, prominent research institutions, and U.S. and foreign government health and military organizations; and
- e. The Theranos Systems were validated under FDA guidelines and “classified as nonsignificant risk devices.”¹

8. While Walgreens avoids alleging these claims were false or fraudulent, it alleges that these promises were inconsistent with reality. For example, Walgreens claims that based on negotiations and representations, it was the expectation of the parties “that the blood would be collected using Theranos’ finger-stick technology. . . . Theranos did not deliver on that expectation.”

9. The once-vaunted company is in disarray and the value of its securities are in a freefall.

10. Accordingly, Plaintiffs bring this complaint, on behalf a class consisting of all persons or entities who, directly or indirectly purchased or committed to purchase Theranos securities from July 29, 2013, through October 5, 2016. Plaintiffs bring these claims and seek recovery under the California Securities Statutes (Cal. Corp. Code §§ 25400(d), 25401, 25500, 25501 and 25504), California’s Unfair Competition Law (Cal. Bus. & Prof. Code § 17200 *et seq.*), California statutory and common law governing fraud and deceit (Cal. Civ. Code §§ 1709, 1710), fraudulent concealment (Cal. Civ. Code § 1710), constructive fraud (Cal. Civ. Code § 1573), and Negligent Misrepresentation (Cal. Civ. Code § 1710).

¹ *Walgreen Co. v. Theranos, Inc.*, No. 1:16-cv-01040-SLR (redacted version filed Nov. 15, 2016), filed in the United States District Court for the District of Delaware.

III. PARTIES

11. Plaintiff Robert Colman (Mr. Colman) is an Idaho resident. Mr. Colman purchased Theranos securities in September 2013 through a member interest in Lucas Venture Group XI, LLC (LVG XI), a California LLC whose principal place of business is Menlo Park, California. The sole purpose of LVG XI was to purchase Series G Theranos shares. LVG XI is managed by LVG GP IV, LLC, a Delaware corporation whose managing member is Donald A. Lucas (Lucas), a California resident. Lucas directly solicited Mr. Colman's investment, at the invitation of Theranos and Holmes. Defendants' invitation was purportedly a favor to Lucas, whose father, Donald L. Lucas, originally funded Theranos and "mentored" Holmes. Donald A. Lucas claims to serve as a strategic advisor to Theranos. The offer to sell Theranos stock and Mr. Colman's Theranos stock purchase took place in California. Mr. Colman relied, at least in part, on Theranos' representations herein, including that Theranos had developed a Commercially ready groundbreaking blood test technology that was highly accurate, that involved drawing only a few droplets of blood, and was being rolled out by Walgreens. Mr. Colman was not aware of the material omissions alleged herein.

12. Plaintiff Hilary Taubman-Dye (Ms. Taubman-Dye) is a California resident. She purchased Theranos securities in August 2015 at \$19.00 per share as Series B units of a SharePost affiliated fund, Celadon Technology Fund VII, LLC, whose purpose was to acquire Theranos shares of other investors or current or former personnel who held Series C Preferred shares, and hold Theranos stock. This transaction was managed and conducted by SharePost Financial Corporation (SharePost.com); a subsidiary of SharePost Inc. located in San Bruno, California, and was controlled by and occurred with the knowledge and consent of Defendants. Ms. Taubman-Dye's August purchase did not finalize until December 7, 2015, as Defendants imposed three separate rights of refusal on the sale. The first allowed Theranos to purchase Company stock on the same terms offered to SharePost; the second offered the same terms to Holmes; the third allowed Theranos to assign their right of first refusal to an undisclosed third party (an "Assignee"), pursuant to which such Assignee could purchase Theranos securities on the same terms previously offered to Theranos and Holmes. On August 19, 2015, SharePost successfully entered into a binding purchase agreement with a seller of Theranos securities. On August 21, 2015, the unidentified seller provided notice to

Theranos of the proposed sale, triggering the relevant rights of refusal to Theranos Securities. On October 19, 2015, after the WSJ's Theranos exposé, Ms. Taubman-Dye attempted to cancel the transaction (as did others); but SharePost informed investors that Theranos waived its right of first refusal, thereby triggering the rights of Holmes and, potentially, the Assignee. Neither Holmes nor any third party exercised their rights. Ms. Taubman-Dye's purchase became final on or about December 1, 2015. All aspects of this transaction took place in California as the offer to sell took place in California, and all documents were sent from and delivered in California. Ms. Taubman-Dye relied, at least in part, on Theranos' representations herein, including that Theranos had developed a commercially ready groundbreaking blood test technology that was highly accurate, that involved drawing only a few droplets of blood, and was being successfully rolled out by Walgreens. Ms. Taubman-Dye was not aware of the material omissions alleged herein.

13. Defendant Theranos, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business in Palo Alto, California.

14. Defendant Holmes is the founder, Chief Executive Officer, and Chairman of the Board of Directors of Theranos. Holmes is also the controlling stockholder of Theranos, holding over 50% of the stock.² Holmes resides in California.

15. Defendant Balwani is the former President, Chief Operating Officer, and board member of Theranos. Balwani left the Company in or about May 2016 and resides in California.

16. Plaintiffs allege and believe that others may have aided and abetted Defendants' actions and reserve the right to name additional defendants.

IV. JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332(d)(2) as this is a class action where at least one of the members of the class is a citizen of a State different from any defendant, and the controversy exceeds the sum or value of \$5,000,000.

² Holmes has stated that she retains control of over 50% of the shares of Theranos. Roger Parloff, *This CEO is out for blood*, Fortune (June 12, 2014), available at <http://fortune.com/2014/06/12/theranos-blood-holmes/> (last accessed Nov. 25, 2016).

18. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(a) & (b) because (1) one or more defendants reside in this district and all the defendants are residents of this State, and (2) a substantial part of the events or omissions giving rise to the claims occurred in this district.

V. FACTUAL BACKGROUND

A. Theranos Builds up Publicity to Raise New Money from Investors

19. Founded by Defendant Holmes in 2003, Theranos is a private life-sciences company that claimed to “revolutionize” the laboratory testing industry with innovative methods for drawing and testing blood and interpreting patient data to improve outcomes and lower health care costs. According to press reports in December 2004, Holmes had raised \$6 million to fund Theranos.³ By the end of 2010, Holmes had raised more than \$92 million in venture capital for Theranos.⁴

20. In July 2013, Defendants, and others, began to implement a strategy to pull in new investors. Defendants had approached Walgreens in 2010 with “the promise of an innovative technology that would revolutionize blood testing.” The next step was to launch the finger-stick technology to consumers, which Theranos stated it would be ready to do as early as later that year. In June 2012, Theranos and Walgreens entered into an agreement that provided a framework pursuant to which “Theranos Wellness Centers” could operate inside Walgreens stores, in which technicians would collect blood samples. Theranos represented to Walgreens that blood would be collected using Theranos’ finger-stick technology and would then be sent to a Theranos CLIA-certified laboratory for testing. On March 20, 2013, Walgreens began a controlled soft launch of Theranos Wellness Centers at a single store in Phoenix, Arizona. By late summer 2013, Walgreens was ready to publicly announce the relationship.

21. In preparation for the solicitation and sale of Theranos shares to new investors, Defendants began courting press attention with the announcement of a luminary Board of Directors. Theranos, Holmes, and Balwani opened Twitter accounts in July 2013 and began granting interviews

³ Ken Auletta, *Blood, Simpler: One Woman’s Drive to Revolutionize Medical Testing*, The New Yorker (Dec. 15, 2014), available at <http://www.newyorker.com/magazine/2014/12/15/blood-simpler> (last accessed Nov. 25, 2016).

⁴ Kimberly Weisul, *How Playing the Long Game Made Elizabeth Holmes a Billionaire*, Inc. (Oct. 2015), available at <http://www.inc.com/magazine/201510/kimberly-weisul/the-longest-game.html> (last accessed Nov. 25, 2016).

1 and sending out tweets and retweets regarding Theranos' technology. On July 29, 2013, Theranos
 2 posted its first press release on its website announcing that Wells Fargo & Co. Chairman and CEO
 3 Richard Kovacevich and retired four-star Marine General James "Mad Dog" Mattis were appointed
 4 to the Board of Directors.⁵ The Company also highlighted that these luminaries joined other
 5 luminaries on the board, including former Secretary of State Henry A. Kissinger, former Senator
 6 Samuel Nunn, William J. Perry, former Admiral Gary Roughead, and former Secretary of State,
 7 Treasury and Labor George P. Shultz.

8 22. In August 2013, Defendants courted WSJ writer Joseph Rago with an exclusive
 9 interview that would bring Theranos' story out to the world. Theranos claimed to the WSJ that it had
 10 developed proprietary equipment capable of running comprehensive blood tests from as little as a
 11 few drops of blood, which are approximately 1/100th to 1/1000th the size of a typical venous blood
 12 draw (or "venipuncture"). Theranos also claimed to have developed a proprietary method to draw
 13 drops of blood from a patient's finger using a finger stick and to collect and store that blood (a
 14 "capillary sample") in a proprietary device called a "nanotainer." The blood stored in the nanotainer
 15 would then be tested using Theranos' proprietary laboratory equipment, or "analyzers," which would
 16 provide accurate results to customers in a matter of hours.

17 23. Echoing the Company's statements made in his exclusive interview, Joseph Rago
 18 published a WSJ article on September 8, 2013, in which Holmes claimed that Theranos could "run
 19 any combination of tests, including sets of follow-on tests" at once, very quickly, all from a single
 20 small blood sample.⁶ Theranos' website prominently featured a nanotainer balanced on the tip of a
 21 finger and the slogan: "one tiny drop changes everything." "Now, for the first time," the website
 22
 23

24 ⁵ Theranos press release, *Theranos Announces New Members of its Board of Directors* (July 29,
 25 2013), available at [https://news.theranos.com/2013/07/29/theranos-announces-new-members-of-its-](https://news.theranos.com/2013/07/29/theranos-announces-new-members-of-its-board-of-directors)
 26 [board-of-directors](https://news.theranos.com/2013/07/29/theranos-announces-new-members-of-its-board-of-directors) (last accessed Nov. 25, 2016); Ron Leuty, *Theranos adds Kovacevich to all-star*
board, San Francisco Business Times (Aug. 2, 2013), available at
[http://www.bizjournals.com/sanfrancisco/print-edition/2013/08/02/theranos-adds-kovacevich-to-all-](http://www.bizjournals.com/sanfrancisco/print-edition/2013/08/02/theranos-adds-kovacevich-to-all-star.html)
[star.html](http://www.bizjournals.com/sanfrancisco/print-edition/2013/08/02/theranos-adds-kovacevich-to-all-star.html) (last accessed Nov. 25, 2016).

27 ⁶ Joseph Rago, *Elizabeth Holmes: The Breakthrough of Instant Diagnosis*, The Wall Street
 28 Journal (Sept. 8, 2013), available at [http://www.wsj.com/articles/SB1000142412788732412300457](http://www.wsj.com/articles/SB10001424127887324123004579055003869574012)
[9055003869574012](http://www.wsj.com/articles/SB10001424127887324123004579055003869574012) (last accessed Nov. 23, 2016).

1 claimed, Theranos' "laboratory can perform your tests quickly and accurately on samples as small as
2 a single drop."

3 24. On September 9, 2013, Theranos and Walgreens announced in a press release, timed
4 to follow the WSJ article, plans to roll out Theranos "wellness centers" inside retail locations of
5 Walgreens—one of the most well-known and successful pharmacy chains in the United States.
6 Theranos and Walgreens claimed in a press release the same day that with its first Walgreens
7 pharmacy chain location launching in Silicon Valley, "consumers *can now* complete any clinician-
8 directed lab test with as little as a few drops of blood and results available in a matter of hours." It
9 also stated, "For the first time, Theranos is introducing CLIA-certified laboratory services with the
10 ability to run its tests on micro-samples." The press release states in relevant part:

11 Theranos, Inc. and Walgreens (NYSE: WAG) (NASDAQ: WAG)
12 today announced a long-term partnership to bring access to Theranos'
new lab testing service through Walgreens pharmacies nationwide. . . .

13 For the first time, Theranos is introducing CLIA-certified laboratory
14 services with the ability to run its tests on micro-samples. Theranos'
15 proprietary laboratory infrastructure minimizes human error through
16 extensive automation to produce high quality results. Test results are
available to physicians in a matter of hours, enabling fast diagnoses to
help informed treatment choices. . . .

17 "For the past 10 years, Theranos has worked relentlessly to reach a
18 point at which we could help make actionable information accessible
19 to physicians and patients at the time it matters most. Clinicians can
now see their patients having received lab results from fresh samples in
a matter of hours," said Elizabeth Holmes, Chairman, CEO and
Founder of Theranos. . . .

20 By minimizing the volume of blood required from patient draws,
21 Theranos helps clinicians provide a new standard of care across all
specialties and treatment areas. . . .

22 "Theranos' service offers affordable certified lab testing with quicker
23 response times, and furthers our mission to provide a differentiated
24 patient experience," said Kermit Crawford, Walgreens president of
pharmacy, health and wellness. . . .⁷

25
26
27 ⁷ Theranos press release, *Theranos Selects Walgreens as a Long-Term Partner Through Which to*
28 *Offer Its New Clinical Laboratory Service* (Sept. 9, 2013), available at <https://news.theranos.com/2013/09/09/theranos-selects-walgreens-as-a-long-term-partner-through-which-to-offer-its-new-clinical-laboratory-service> (last accessed Nov. 25, 2016).

25. This web page, WSJ article and press release were false and misleading in that

- (1) Theranos was not “now” (or ever) capable of performing its agreement with Walgreens;
- (2) Theranos did not have necessary regulatory approval to use its “tests using micro-samples” on its proprietary device --- the nanotainer; (3) Theranos’ labs were not in compliance with CLIA standards; (4) Theranos proprietary technology had not “reached a point at which [it] could make actionable information accessible to physicians and patients” using its proprietary technology;
- (5) Theranos would have to dilute “micro-samples” and run them on traditional lab machines of competitors in order to create the illusion that their proprietary technology was working;
- (6) Theranos's processes were not faster, cheaper and more accurate than the conventional methods, and (7) Theranos could not “help clinicians provide a new standard of care across all specialties and areas of treatment” with its proprietary technology.

B. Defendants Court New Investors

26. Using the publicity generated from the September 8, 2013 Wall Street Journal article, and the September 9, 2013 Walgreens/Theranos press release, Defendants solicited new investors. Plaintiffs began considering an investment in Theranos through intermediaries and investment funds, or directly. Immediately after announcing plans to roll out Theranos “wellness centers,” Defendants invited “a select group of people” to invest in follow-on extensions of a 2010 Preferred financing, claiming a valuation in 2010 of \$6 billion and a current valuation of \$10 billion: For example, Lucas wrote its investors on September 9, 2013:

Through its long-standing relationship with Theranos, Inc. and its Founder, CEO and Chairman, Elizabeth Holmes, [] has been invited to invest up to \$15 million in a follow-on extension of the 2010 Preferred financing made available to a select group of people. . . . Please see the attached two articles about Theranos: . . .

[Referencing the WSJ article and Theranos Press Release above]

This transaction must close by the end of September.

27. The letter also included statements provided by Defendants which were meant to be conveyed to potential investors. These representations included that Theranos “has signed contracts and partnerships with very large retailers and drug stores as well as various pharmaceutical companies, HMO's, insurance agencies, hospitals, clinics and various government agencies” and

1 “Pharmaceutical companies use Theranos' systems to streamline and tailor the customization of drug
 2 compounds subject to patent expiration for new market applications, thus enabling the creation of
 3 more sustainable drug compounds and a drastic reduction in drug development cost and time to
 4 market.” These statements were false or misleading as (1) the contracts with companies other than
 5 Walgreens were preliminary, immaterial or non-existent, such that the other companies and or
 6 agencies had not vetted Theranos technology, and (2) Theranos was incapable of performing any
 7 contracts using its proprietary technology.

8 28. On November 13, 2013, Theranos and Walgreens issued a press release entitled,
 9 “Theranos and Walgreens Expand Diagnostic Lab Testing to the Phoenix Metropolitan Area, New
 10 Theranos™ Wellness Centers at Walgreens stores provide consumers with less invasive, fast,
 11 affordable testing on samples as small as a few drops of blood.” The press release described “blood
 12 sample[s] as small as a few drops – 1/1,000 the size of a typical blood draw” and similarly advertised
 13 that Theranos had “eliminat[ed] the need for large needles and numerous vials of blood typically
 14 required for diagnostic lab testing.” The press release stated:

15 Theranos, Inc. and Walgreens (NYSE: WAG) (NASDAQ: WAG)
 16 today celebrate the opening of new Theranos Wellness Centers located
 17 at Walgreens stores in the Phoenix metropolitan area. This marks the
 18 beginning of Theranos and Walgreens planned national rollout. . . .

19 The new Theranos Wellness Centers will provide Phoenix area
 20 consumers with access to less invasive and more affordable clinician-
 21 directed lab testing from a blood sample as small as a few drops –
 22 1/1,000 the size of a typical blood draw. The micro-samples collected
 23 by certified phlebotomists or trained Walgreens technicians are taken
 24 from either a tiny finger stick or traditional methods, eliminating the
 25 need for large needles and numerous vials of blood typically required
 26 for diagnostic lab testing. . . .

27 Theranos test results can be made available to physicians in a matter of
 28 hours, enabling fast diagnoses to help make informed treatment
 choices. . . .

“For the past 10 years, Theranos has worked relentlessly to help make
 actionable information accessible to individuals and their physicians at
 the time it matters most. . . .” said Elizabeth Holmes, Founder and
 CEO of Theranos. “By making it possible to run laboratory tests from
 a tiny sample, children, elderly, and those with chronic conditions or a
 fear of needles **will now** be able to partake in a new experience. . . .”

As the nation’s largest retail pharmacy chain with more than 8,100
 neighborhood pharmacies – including 188 in the Phoenix area –

Walgreens has the infrastructure to enable Theranos to bring its services to consumers nationwide.⁸

29. This press release was false and misleading in (1) Theranos was not “now” (or ever) capable of performing its agreement with Walgreens; (2) Theranos did not have necessary regulatory approval to use its “tests using micro-samples” on its proprietary device --- the nanotainer; (3) Theranos’ labs were not in compliance with CLIA standards; (4) Theranos proprietary technology had not “reached a point at which [it] could make actionable information accessible to physicians and patients” using its proprietary technology; (5) Theranos would have to dilute “micro-samples” and run them on traditional lab machines of competitors in order to create the illusion that their proprietary technology was working; (6) Theranos’ processes were not faster, cheaper and more accurate than the conventional methods, and (7) thus, Walgreens’ size and infrastructure could not “enable Theranos to bring its services to consumers nationwide” since the technology was not ready for commercial use.

C. Defendants Continue to Barrage the Media with Their False Narrative to Attract Investors

30. Holmes paid relentless attention to building Theranos’ “narrative.” According to *Vanity Fair*, Holmes reiterated in an interview that Theranos’ proprietary technology could take a pinprick’s worth of blood, extracted from the tip of a finger, instead of intravenously, and test for hundreds of diseases—a remarkable innovation that was going to save millions of lives and, in a phrase she often repeated, “change the world.” Defendants publicly declared through presentations and intermediaries the roll out of their proprietary technology, representing that commercially available tests were performed by finger stick, stored in nanotainers, and tested on the Company’s proprietary analyzers. Theranos and its executives also continued to represent publicly that the Company had submitted its tests to the FDA for clearance. In these and other public statements, Defendants portrayed Theranos as revolutionizing the commercial laboratory industry with the finger

⁸ Theranos press release, *Theranos and Walgreens Expand Diagnostic Lab Testing to the Phoenix Metropolitan Area; New Theranos™ Wellness Centers at Walgreens stores provide consumers with less invasive, fast, affordable testing on samples as small as a few drops of blood* (Nov. 13, 2013), available at <https://news.theranos.com/2013/11/13/theranos-and-walgreens-expand-diagnostic-lab-testing-to-the-phoenix-metropolitan-area/> (last accessed Nov. 25, 2016).

1 stick, nanotainer, and tests that were specifically designed to run, and were being run, on customers'
 2 drops of blood using Theranos' proprietary analyzers. Holmes adorned the covers of *Fortune*,
 3 *Forbes*, and *Inc.*, among other publications. She was profiled in *The New Yorker* and featured on a
 4 segment of Charlie Rose.⁹

5 31. As an essential part of this narrative to draw in investors, Defendants caused Theranos
 6 to issue well over twenty press releases repeating the "false narrative" as to the state of Theranos'
 7 technology, capabilities and roll-out, including:

8 a. *Theranos Appoints Riley P. Bechtel to its Board of Directors* ("Theranos'
 9 clinical laboratory offers comprehensive laboratory tests from samples as small as a few drops of
 10 blood at unprecedented low prices.").¹⁰

11 b. *Theranos Appoints William H. Frist, M.D., to its Board of Directors* (same).¹¹

12 c. *Theranos Appoints William H. Foege, M.D., M.P.H., to its Board of Directors*
 13 (same).¹²

14 d. *Theranos Files Comment In Support Of Food and Drug Administration*
 15 *Oversight Of Laboratory-Developed Tests*, which included the following statement:

16 [W]e provide individuals with testing that is designed to be faster,
 17 cheaper, and less painful at the highest levels of quality. Our mission
 18 depends upon meeting the highest standards of test quality – standards
 19 set by the Food and Drug Administration (FDA). . . . Theranos is
 20 submitting and will continue to submit all our tests to the FDA. We are
 21 not required to do so, but we have made this commitment because we
 22 believe that FDA oversight plays a critical role in ensuring that
 individuals and their physicians get the most accurate test results. . . .
 there are limits on the adequacy of the peer review system. . . . That is
 why we will continue to submit our work to the FDA and why we

23 ⁹ Interview, *Elizabeth Holmes, C.E.O. and founder of the blood diagnostics company, Theranos*,
 24 Charlie Rose (June 3, 2015), available at <https://charlierose.com/videos/27979#> (Charlie Rose: "You
 get the same results"; Elizabeth Holmes: "We do") (last accessed Nov. 23, 2016).

25 ¹⁰ Mar. 15, 2014, available at [https://news.theranos.com/2014/03/15/theranos-appoints-riley-p-](https://news.theranos.com/2014/03/15/theranos-appoints-riley-p-bechtel-to-its-board-of-directors)
 26 [bechtel-to-its-board-of-directors](https://news.theranos.com/2014/03/15/theranos-appoints-riley-p-bechtel-to-its-board-of-directors) (last accessed Nov. 23, 2016).

27 ¹¹ Apr. 16, 2014, available at [https://news.theranos.com/2014/04/16/theranos-appoints-william-h-](https://news.theranos.com/2014/04/16/theranos-appoints-william-h-frist-m-d-to-its-board-of-directors)
 28 [frist-m-d-to-its-board-of-directors](https://news.theranos.com/2014/04/16/theranos-appoints-william-h-frist-m-d-to-its-board-of-directors) (last accessed Nov. 23, 2016).

¹² Aug. 5, 2014, available at [https://news.theranos.com/2014/08/05/theranos-appoints-william-h-](https://news.theranos.com/2014/08/05/theranos-appoints-william-h-foege-m-d-m-p-h-to-its-board-of-directors)
[foege-m-d-m-p-h-to-its-board-of-directors](https://news.theranos.com/2014/08/05/theranos-appoints-william-h-foege-m-d-m-p-h-to-its-board-of-directors) (last accessed Nov. 23, 2016).

believe the decision to do so is essential in providing accurate results for individuals and physicians.¹³

e. *Theranos and Cleveland Clinic Announce Strategic Alliance to Improve Patient Care through Innovation in Laboratory Testing* (“Theranos offers a full spectrum of laboratory tests, from the most common panels to highly specialized tests, on blood samples as small as a few drops. This eliminates the need for larger needles and numerous vials of blood required for many diagnostic lab tests.”).¹⁴

f. *Theranos Founder and CEO Elizabeth Holmes Speaks at Arizona Bill Signing* (“Theranos’ clinical laboratory offers comprehensive laboratory tests from samples as small as a few drops of blood at unprecedented low prices.”).¹⁵

g. *Theranos Hires Heather King as General Counsel* (same).¹⁶

h. *Theranos to Begin Global Work in Mexico*, which included the following statement:

“[T]he Theranos technology will help attain faster results more easily and at a lower cost, generating changes in the way people take care of their health.’ Theranos’ platform is a global model for health care, shifting the paradigm away from diagnosis and treatment, to one focused on early detection and prevention. Theranos offers a full spectrum of laboratory tests, from the most common panels to highly specialized tests, on blood samples as small as a few drops.”¹⁷

i. *Theranos to Launch Online Resource Connecting Patients to Doctors*.¹⁸

¹³ Mar. 6, 2015, available at <https://news.theranos.com/2015/03/06/theranos-files-comment-in-support-of-food-and-drug-administration-oversight-of-laboratory-developed-tests> (last accessed Nov. 23, 2016).

¹⁴ Mar. 9, 2015, available at <https://news.theranos.com/2015/03/09/theranos-and-cleveland-clinic-announce-strategic-alliance-to-improve-patient-care-through-innovation-in-laboratory-testing> (last accessed Nov. 23, 2016).

¹⁵ Apr. 16, 2015, available at <https://news.theranos.com/2015/04/06/theranos-founder-and-ceo-elizabeth-holmes-speaks-at-arizona-bill-signing> (last accessed Nov. 23, 2016).

¹⁶ May 7, 2015, available at <https://news.theranos.com/2015/05/07/theranos-hires-heather-king-as-general-counsel> (last accessed Nov. 23, 2016).

¹⁷ June 23, 2015, available at <https://news.theranos.com/2015/06/23/theranos-to-begin-global-work-in-mexico> (last accessed Nov. 23, 2016).

¹⁸ July 1, 2015, available at <https://news.theranos.com/2015/07/01/theranos-to-launch-online-resource-connecting-patients-to-doctors> (last accessed Nov. 23, 2016).

j. *Theranos receives FDA clearance and review and validation of revolutionary finger stick technology, test, and associated test system.*¹⁹

k. *Theranos Recognizes Milestone in New Era of Preventive Health*, (“Theranos brings a much needed innovative technology to the healthcare industry. . . . Patients appreciate finger stick over venipuncture, the ease of access with locations throughout the Valley, and flexibility of available times at their Wellness Centers.”).²⁰

l. *Theranos and Capital BlueCross Team Up to Provide Innovative, Low Cost, Accessible Lab Testing Services in Central Pennsylvania*, which included the following:

“Theranos, which received clearance of its lab technology from the FDA last week, . . . will make available its full menu of tests in Central Pennsylvania. . . . Theranos has already performed millions of tests since its launch and continues to provide full service labs and testing throughout Arizona and Palo Alto, California. Capital BlueCross reviewed the accuracy and quality of Theranos’ systems, technology, science, processes and overall performance over several years.”²¹

m. *First-of-its-Kind Partnership between Theranos and AmeriHealth Caritas to Improve Health Care for the Underserved*, which contained the following statement (emphasis added):

Theranos **is leading transparency in lab testing**, including voluntarily committing to FDA review of all of its LDTs and publishing its prices, lab proficiency testing scores, customer satisfaction scores, guest visit times, and more. **Theranos offers a full spectrum of laboratory tests, from the most common panels to highly specialized tests, on smaller samples than traditional labs.**²²

n. *Theranos Receives CLIA Waiver, Paving the Way for Greater Accessibility of Health Information at the Time and Place it Matters*, which included the following statement:

¹⁹ July 2, 2015, available at <https://news.theranos.com/2015/07/02/theranos-receives-fda-clearance-and-review-and-validation-of-revolutionary-finger-stick-technology-test-and-associated-test-system> (last accessed Nov. 23, 2016).

²⁰ July 3, 2015, available at <https://news.theranos.com/2015/07/03/theranos-recognizes-milestone-in-new-era-of-preventive-health> (last accessed Nov. 23, 2016).

²¹ July 8, 2015, available at <https://news.theranos.com/2015/07/08/theranos-and-capital-bluecross-team-up-to-provide-innovative-low-cost-accessible-lab-testing-services-in-central-pennsylvania> (last accessed Nov. 23, 2016).

²² July 15, 2015, available at <https://news.theranos.com/2015/07/15/first-of-its-kind-partnership-between-theranos-and-amerihealth-caritas-to-improve-health-care-for-the-underserved> (last accessed Nov. 23, 2016).

FDA has concluded that the Theranos test and technology is eligible for waiver under CLIA. The waiver means FDA determined the Theranos test and technology is reliable and accurate and can be used in a broader set of locations outside of a traditional CLIA certified laboratory, including Theranos Wellness Centers.²³

o. *Theranos Hosts Vice President Biden for Summit on a New Era of Preventive Health Care*, which included the following:

Vice President Biden, along with industry leaders who participated in the summit, saw firsthand Theranos' laboratory as well as its proprietary systems on which it runs its groundbreaking finger stick blood tests. In addition, the group toured the manufacturing facility where its proprietary systems are manufactured. The FDA recently cleared Theranos' HSV-1 test as well as the finger stick blood test technology and underlying system on which the test is run, and approved a waiver that paves the way for putting Theranos' tests in the field at point of care, a major milestone for the company and the national preventive care landscape.

Selected Highlights from the Summit

Vice President Biden..."[T]his is the laboratory of the future""Talk about being inspired. This is inspiration. It is amazing to me, Elizabeth, what you've been able to do""I know the FDA recently completed favorable reviews of your innovative device. The fact that you're voluntarily submitting all of your tests to the FDA demonstrates your confidence in what you're doing."²⁴

p. *Theranos' Holmes Marks 50th Anniversary of Medicare and Medicaid with Vision for Next 50 Years* ("The FDA recently cleared Theranos' finger stick blood test technology and underlying system on which those tests are run,...").²⁵

32. Defendants' narrative was also conducted by an "endless infomercial" of hundreds of articles and interviews in newspapers, press, online and conferences, including:²⁶

²³ July 16, 2015, available at <https://news.theranos.com/2015/07/16/theranos-receives-clia-waiver-paving-the-way-for-greater-accessibility-of-health-information-at-the-time-and-place-it-matters/> (last accessed Nov. 23, 2016).

²⁴ July 23, 2015, available at <https://news.theranos.com/2015/07/23/theranos-hosts-vice-president-biden-for-summit-on-a-new-era-of-preventive-health-care> (last accessed Nov. 23, 2016).

²⁵ July 30, 2015, available at https://news.theranos.com/2015/07/30/theranos_holmes_marks_50th_anniversary_of_medicare_and_medicaid_with_vision_for_next_50_years (last accessed Nov. 23, 2016).

²⁶ For a fairly comprehensive list see Bruce Quinn MD, PhD, *Theranos: A Library of Articles and Links 2006-2016* (Dec. 24, 2014), Discoveries in Health Policy, available at <http://www.discoveriesinhealthpolicy.com/2014/12/theranos-some-recent-journalism.html> (last accessed Nov. 23, 2016).

1 a. *Walgreens Buys More Drugstores While Expanding Lab Services For*
 2 *Obamacare.*²⁷

3 b. *What Health Care Needs is a Real-Time Snapshot of You*, which included the
 4 following:

5 Getting your blood drawn by Theranos doesn't require needles, large
 6 vials, or tubing. . . . Theranos is already making this vision a reality.
 7 Their partnership with Walgreens will bring the new testing service to
 8 stores nationwide.²⁸

9 c. *One Tiny Drop Changes Everything, Elizabeth Holmes, Founder & CEO,*
 10 *Theranos in conversation with Caitlin Roper*, an interview which included the following:

11 Holmes: "We built the first laboratory capable of processing any of our
 12 laboratory tests from a tiny droplet of blood or what we call a
 13 microsample, so that for the first time people can get any of the
 14 laboratory tests that we do from a finger stick instead of from a
 15 phlebotomy. . . ."²⁹

16 d. *Get Your Blood Tested at the Store*, which included the following:

17 A Silicon Valley lab-testing company will open clinics inside two
 18 metro Phoenix Walgreens stores today, part of a planned nationwide
 19 expansion for the startup diagnostics company.

20 Theranos of Palo Alto, Calif., says its automated technology allows
 21 blood draws that are quicker and less expensive than labs used by
 22 hospitals or large doctors practices. The company said a typical test
 23 requires a few drops of blood compared with the vials' worth often
 24 required by a traditional lab. . . .

25 Wade Miquelon, Walgreens chief financial officer, described
 26 Theranos' Holmes as a "disruptive force" whom he believes will
 27 change the lab-testing industry.

28 "She can do it much cheaper, more accurately and in a shorter period
 of time," said Miquelon, who would not disclose the financial terms of
 the in-store testing partnership. "That's a very disruptive force to the
 space. She has made the process better."³⁰

²⁷ Sept. 13, 2016, available at <http://www.forbes.com/sites/brucejapsen/2013/09/10/walgreen-buys-more-drugstores-while-expanding-services-for-obamacare/#57d00ae32be0> (last accessed Nov. 23, 2016).

²⁸ Nov. 6, 2013, available at <https://www.wired.com/2013/11/wired-data-life-theranos> (last accessed Nov. 23, 2016).

²⁹ Nov. 6, 2013, available at http://library.fora.tv/2013/11/06/one_tiny_drop_changes_everything (last accessed Nov. 23, 2016).

³⁰ Nov. 13, 2013, available at <http://archive.azcentral.com/business/news/articles/20131113get-your-blood-tested-store.html> (last accessed Nov. 23, 2016).

e. *Creative Disruption? She's 29 and Set to Reboot Lab Medicine, Elizabeth Holmes plans to revolutionize testing by using tiny blood draws and offering near instantaneous results, which included the following:*

In an exclusive interview, Ms. Holmes talks to Medscape Editor-in-Chief Eric J. Topol, MD, about the current availability of the "finger prick, painless" test developed for "every test that is recognized by Medicare" which have been validated and verified "over the years, and will be available through "recently announced" partnership with Walgreens "across the country." Also claiming "We can, on a given sample, automatically run to other assay methodologies that traditionally would require a separate draw, which means that if something is out of range, we can, on the same sample, run tests that a physician would like to have ordered to better figure out why it's out of range."³¹

f. *This Woman Invented a Way to Run 30 Lab Tests on Only One Drop of Blood.*

In this interview. Holmes stated:

And this can be very helpful for doctors and patients, because it means that someone could, for example, go to a Walgreens in the morning to get a routine test for something their doctor is tracking, and the physician can have the results that afternoon when they see the patient. And we're able to do all the testing using just a single microsample, rather than having to draw a dedicated tube for each type of test.

So if I got a blood test and my doctor saw the results and wanted other tests done, I wouldn't have to have more blood drawn?

Exactly. And on their lab form, the physician can write, "If a given result is out of range, run this follow-up test." And it can all be done immediately, using that same sample.

Some conventional tests, like pH assays, can be done quickly. Others, like those that require culturing bacteria or viruses, can take days or even weeks. Are there some tests that take Theranos longer? **Can everything really be turned around in four hours?**

Yes, we had to develop assays or test methodologies that would make it possible to accelerate results. So we do not do things like cultures. In the case of a virus or bacteria, traditionally tested using a culture, we measure the DNA of the pathogen instead so we can report results much faster.³²

³¹ Nov. 18, 2013, available at http://www.medscape.com/viewarticle/814233_2 (last accessed Nov. 23, 2016).

³² Feb. 18, 2014, available at <https://www.wired.com/2014/02/elizabeth-holmes-theranos> (last accessed Nov. 23, 2016).

g. *Forget Vials of Blood – New Tests Require Just One Drop, How a Stanford dropout is revolutionizing the blood-testing industry* (“With just a single, tiny drop of blood in Theranos' 'nanotainer' tube, which is smaller than a dime, almost 200 conditions can be tested for, including blood typing, cholesterol, HIV, syphilis, and respiratory virus....The big draw of course, is that there is none.”):³³



h. At a presentation before the Arizona Senate Health and Human Services Committee, Balwani stated and showed on a slide presentation that Theranos was “able to provide a *majority of the testing from only two or three drops of blood*,” and although those drops of blood could be taken from a traditional venipuncture, “most likely patients will prefer a simple finger stick, and we are able to do that.” Balwani also touts the partnership with Walgreens and states “we have already launched this service in Arizona.”³⁴

i. Theranos director David Boies stated in court that Theranos could “run a full battery of blood tests . . . by just taking small drops, a few drops of blood.” He continued, “[y]ou don’t have to go to [the] doctor and have them take it out of your arm the way they do traditionally.”³⁵

³³ Feb. 28, 2014, available at <http://www.takepart.com/article/2014/02/28/meet-stanford-dropout-revolutionizing-blood-tests> (last accessed Nov. 23, 2016).

³⁴ Mar. 12, 2014, available at http://azleg.granicus.com/MediaPlayer.php?clip_id=13816 (last accessed 11/25/16).

³⁵ Oct. 16, 2016, WSJ, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology* *Silicon Valley lab, led by Elizabeth Holmes, is valued at \$9 billion but isn’t using its technology for*

j. *This CEO is out for blood*, which included the following:

Theranos runs what's called a high-complexity laboratory, certified by the federal Centers for Medicare & Medicaid Services (CMS), and it is licensed to operate in nearly every state. It 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....

"I just think this is so exciting," says Mark Laret, the CEO of UCSF Medical Center, about what he's seen so far. "I mean, here it is. This is the true transformation of health care, right here in front of us."³⁶

k. *Elizabeth Holmes, Who Wants To Shake Up The Blood Testing Industry, Is A Billionaire At 30*, which included the following (emphasis added):

Elizabeth Holmes who *developed a way to quickly diagnose a few drops of blood with minimal draw at a fraction of the price of commercial labs*, is a billionaire.... Last September, Walgreen WAG +%, the largest retail pharmacy with more than 8,100 stores, announced plans to roll out Theranos Wellness Centers inside its pharmacies. So far, there is one center at Walgreens in Palo Alto, and 20 in Arizona. In addition, *UCSF Medical Center, Dignity Health, and Intermountain Healthcare have signed on with Theranos to deploy its services at their facilities. The company has also generated revenue by working with drug companies in clinical trials by providing quick results for blood tests.*³⁷

l. *Theranos: Small Sample, Big Opportunity* ("Countless banners displaying statements such as 'welcome to a revolution in lab testing' and 'one tiny drop changes everything' were spread throughout the store making it immediately clear that I had arrived at the right place."³⁸

m. *Theranos 'Nanotainer' revolutionizes blood testing*. In this interview, Holmes states:

all the tests it offers, <http://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901> (last accessed 11/25/16).

³⁶ June 12, 2014, available at <http://www.takepart.com/article/2014/02/28/meet-stanford-dropout-revolutionizing-blood-tests>. Laret later admitted he had "no information" about Theranos's technology, but had great respect for Ms. Holmes and the company's board. Oct. 29, 2015, New York Times, *The Narrative Frays for Theranos and Elizabeth Holmes*, available at http://www.nytimes.com/2015/10/30/business/the-narrative-frays-for-theranos-and-elizabeth-holmes.html?_r=0 (last accessed Nov. 25, 2016).

³⁷ June 17, 2014, available at <http://www.forbes.com/sites/zinamoukheiber/2014/06/17/elizabeth-holmes-who-wants-to-shake-up-the-blood-testing-industry-is-a-billionaire-at-30/#590f14a15675> (last accessed Nov. 25, 2016).

³⁸ June 20, 2014, available at <http://www.decibio.com/blog/2014/06/20/theranos-small-sample-big-opportunity> (last accessed Nov. 26, 2016).

1 “Over the last 10 years Theranos has worked to redevelop all of the
2 tests run in a traditional laboratory to be able to take a tiny sample, a
3 few droplets of blood, instead of the big tubes that are traditionally
4 drawn from an arm.”³⁹

5 n. *Quinn: Meet Elizabeth Holmes, Silicon Valley’s latest phenom* (“Over the past
6 year, Holmes has embraced a more public profile, recently snagging the cover of Fortune magazine
7 in what bore all the hallmarks of a carefully orchestrated media push.”).⁴⁰

8 o. *Theranos bringing 500 new jobs to Scottsdale’s SkySong* (“The company’s
9 proprietary technology allows blood tests to use a tiny drop of blood from a finger prick, offering
10 a painless way for patients to get their blood tested, said Elizabeth Holmes blood tested, said
11 Elizabeth Holmes.”).⁴¹

12 p. *Meet Elizabeth Holmes, the Youngest Female Self-made Billionaire Changing
13 the World with Medical Technology*.⁴²

14 q. *How One Entrepreneur is Transforming Blood Testing*.⁴³

15 r. *She’s America’s youngest female billionaire – and a dropout*, (Video
16 interview of Holmes claiming they are doing all their tests on own platform and reinvented all the
17 chemicals to run tests. Also claims certified as a high complexity lab.).⁴⁴

18 s. *Walgreen: Tech-Savvy Investments Mean Major Upside for WAG Stock* (“The
19 single biggest catalyst for WAG stock in the future may be the company’s decision to partner with
20 the privately held health-tech firm Theranos.”).⁴⁵

21 ³⁹ July 8, 2014, available at <http://www.usatoday.com/videos/tech/2014/07/08/12270761> (last
22 accessed Nov. 26, 2016).

23 ⁴⁰ July 14, 2014, available at [http://www.mercurynews.com/2014/07/14/quinn-meet-elizabeth-
24 holmes-silicon-valleys-latest-phenom/](http://www.mercurynews.com/2014/07/14/quinn-meet-elizabeth-holmes-silicon-valleys-latest-phenom/) (last accessed Nov. 26, 2016).

25 ⁴¹ July 15, 2014, available at [http://www.bizjournals.com/phoenix/blog/health-care-
26 daily/2014/07/theranos-to-hire-500-expands-into-scottsdale.html?page=all](http://www.bizjournals.com/phoenix/blog/health-care-daily/2014/07/theranos-to-hire-500-expands-into-scottsdale.html?page=all) (last accessed Nov. 26,
27 2016).

28 ⁴² July 21, 2014, available at [http://womensilab.com/2014/07/21/wilab-spotlight-elizabeth-
holmes/](http://womensilab.com/2014/07/21/wilab-spotlight-elizabeth-holmes/) (last accessed Nov. 26, 2016).

⁴³ Oct. 1, 2014, available at
[http://www.slate.com/blogs/business_insider/2014/10/01/theranos_elizabeth_holmes_painless_blood_
testing_invention_makes_her_third.html](http://www.slate.com/blogs/business_insider/2014/10/01/theranos_elizabeth_holmes_painless_blood_testing_invention_makes_her_third.html) (last accessed Nov. 26, 2016).

⁴⁴ Oct. 16, 2014, available at [http://money.cnn.com/2014/10/16/technology/theranos-elizabeth-
holmes/](http://money.cnn.com/2014/10/16/technology/theranos-elizabeth-holmes/) (last accessed Nov. 26, 2016).

t. *A Conversation with Elizabeth Holmes at MPW Next Gen*, a video which included the following:

Holmes discussed the fact that Theranos uses “tiny drops of blood from the finger as opposed to vials and vials of blood coming from the arm.” Plan is to be 5 miles from everyone’s home in 5 years. Spent the last 11 years to make sure data is “actionable”, “of the highest integrity available.” Holmes stated that “[w]hereas traditional labs . . . have not ever submitted any of their laboratory-developed tests to FDA, we think it’s really important” and “so we’re doing that.”⁴⁶

u. *Blood, Simpler. One Woman’s Drive to Revolutionize Medical Testing*, which included the following:

Holmes says that Theranos has a positive cash flow; it is clearly expanding. For many years, it has earned income from large pharmaceutical companies, including Pfizer and GlaxoSmithKline, which use its tests when they are conducting clinical trials on new drugs. It also earns revenue from the “wellness centers” that it has set up in Walgreens stores, its hospital work, and the U.S. military, although Holmes would not discuss the company’s arrangements with the latter.

When I asked Holmes for evidence that her tests were independently audited, she said that there have been “tens” of audits and “external third-party comparisons” of Theranos’ tests, including those done by the hospital groups that are adopting its finger-prick tests and the pharmaceutical companies that have contracted with Theranos for testing their products. . . . Holmes also pointed me to a pilot study published by Hematology Reports, an online-only peer-reviewed journal; she is listed as a co-author. The report, released in April, concluded that Theranos tests “correlated highly with values obtained” from standard lab tests.⁴⁷

v. *Elizabeth Holmes, Theranos: Transforming Healthcare by Embracing Failure*
This interview discusses Theranos today, the qualifications of the Board, and attacks other labs.

⁴⁵ Nov. 17, 2014, available at <http://investorplace.com/2014/11/walgreen-wag-stock-healthcare-theranos/%20-%20.WDNyrLlrIkj#.WDnuBU3FCUk> (last accessed Nov. 26, 2016).

⁴⁶ Dec. 8, 2014, available at <https://www.youtube.com/watch?v=vsSt-tiFuCQ> (last accessed Nov. 26, 2016).

⁴⁷ Dec. 15, 2014, available at <http://www.newyorker.com/magazine/2014/12/15/blood-simpler> (last accessed Nov. 26, 2016). *See also Theranos didn’t work with the huge drug company it supposedly made money from, huge drug company says*, available at <http://www.theverge.com/2015/10/26/9618390/Theranos-glaxosmithkline-denies-partnership-pfizer-blood-test> (last accessed Nov. 26, 2016) (“I cannot find any evidence that we’ve done business with them in recent years,” a spokesperson for GSK told The Financial Times. Pfizer, on the other hand, told The Financial Times that the company’s dealings with Theranos were limited. “We’ve done only very limited historical exploratory work with Theranos through a few pilot projects,” the Pfizer representative said, “and we do not have any current or active projects with them”).

1 Claims have validated “every single one of “our tests” and have submitted them to the FDA. “You
2 take a bunch of finger sticks, and you take a bunch of straws and see if they’re the same.” It’s “not a
3 challenge to the company so much as a commitment.”).⁴⁸

4 w. *Breakthrough Branding: Theranos, with Walgreens, Revolutionizes*
5 *Healthcare*. This article repeats narrative from other articles and posts, along with company-created
6 videos of companies and patients touting Theranos).⁴⁹

7 x. *Disruptive Technology Main Focus at Clinton Health Matters Conference*,
8 which states: “Access to health information is a basic human right,” said Elizabeth Holmes, a young
9 Silicon Valley entrepreneur who founded Theranos, a blood analytics and diagnostics company.
10 [President] Clinton, who applauded her work to provide low-cost testing to the general public, said
11 the company is valued at \$9 billion.).⁵⁰

12 y. *New Programs and Strategic Partnerships Announced at Fourth Annual*
13 *Health Matters Activation Summit; Clinton Health Matters Initiative brings together hundreds of*
14 *leaders from across sectors to announce strategic partnerships to impact the health and wellness of*
15 *Americans* (Holmes billed as top participant after Clinton).⁵¹

16 z. *Meet the Most Impressive Woman on Forbes’ Female Billionaire List*
17 (“Holmes’ company seeks to help democratize healthcare. Her modus operandi is through
18 revolutionizing blood testing. Theranos blood tests are not only technologically superior to
19 traditional blood tests — they are painless and can detect multiple ailments using about one one-
20 hundredth to one one-thousandth the amount of blood normally required, according to Fortune — but
21 they are, most notably, far more affordable...”).⁵²

22 _____
23 ⁴⁸ Jan. 28, 2015, available at <https://www.youtube.com/watch?v=hLTAFbKbC8w> (last accessed
Nov. 26, 2016)

24 ⁴⁹ Feb. 3, 2015, available at <http://brandchannel.com/2015/02/03/breakthrough-branding-theranos-with-walgreens-revolutionizes-healthcare/> (last accessed Nov. 26, 2016).

25 ⁵⁰ Feb. 5, 2015, available at <http://californiahealthline.org/news/disruptive-technology-main-focus-at-clinton-foundations-health-matters-conference/> (last accessed Nov. 26, 2016).

26 ⁵¹ Jan. 26, 2015, available at <https://www.clintonfoundation.org/press-releases/new-programs-and-strategic-partnerships-announced-fourth-annual-health-matters> (last accessed Nov. 26, 2016).

27 ⁵² Mar. 12, 2015, available at <https://mic.com/articles/111622/meet-the-most-impressive-woman-on-forbes-female-billionaire-list#.cDBtIwKJu> (last accessed Nov. 26, 2016).

1 aa. *Comment to Docket No. FDA-2011-D-0360, Draft Guidance for Industry,*
 2 *Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory*
 3 *Oversight of Laboratory Developed Tests (LDTs)* (Boosts that Theranos is voluntarily submitting
 4 their proprietary tests to the FDA, has had positive interactions with FDA and Theranos commitment
 5 to the “ensure all of our tests meet the highest standards of quality...”).⁵³

6 bb. *Health care in America: Shock treatment, A wasteful and inefficient industry is*
 7 *in the throes of great disruption.*⁵⁴

8 cc. *Cleveland Clinic taps Theranos, bets on cheaper diagnostics* (Article as a
 9 result of joint Theranos Cleveland Clinic press release stating Cleveland Clinic “partnered with
 10 Theranos to use the startup’s diagnostic technology that can take a drop of blood from the finger and
 11 screen for a spectrum of conditions and diseases at half the price of Medicare.”).⁵⁵

12 dd. BruceDocumentBlog, *Fox Interviews Theranos and Cleveland Clinic* (Video
 13 and Transcript of FoxBusiness interview of Holmes and Cleveland Clinics Toby Cosgrove MD
 14 discussing why they are teaming up. TC: “Theranos has developed some new technology with and
 15 the opportunity to reduce the cost and trauma of lab tests. A real game changer...and people won’t be
 16 afraid of a finger prick...Think about a new born baby, if you can do a two drop heel prick, a huge
 17 advantage. Tremendous potential.” EH: “We can do combinations of tests from tiny samples. We
 18 redeveloped the whole [what hospital labs used to do] infrastructure. It’s a privilege to partner with
 19 Cleveland Clinic”).⁵⁶

20 ee. Crain’s Cleveland Business, *Cleveland Clinic enters ‘long-term strategic*
 21 *alliance’ with Theranos Inc.* (Reiterating press release and stating, “Clinic plans to use Theranos’
 22 tests on its own patient populations. Theranos — a company now valued at about \$9 billion — is

23 ⁵³ Mar. 1, 2015, available at
 24 https://www.theranos.com/content/pdf/theranos_comment_ldt_guidance.pdf (last accessed Nov. 26, 2016).

25 ⁵⁴ Mar. 7, 2015, available at <http://www.economist.com/news/business/21645741-wasteful-and-inefficient-industry-throes-great-disruption-shock-treatment> (last accessed Nov. 26, 2016).

26 ⁵⁵ Mar. 9, 2015, available at <http://www.healthcarefinancenews.com/news/cleveland-clinic-taps-theranos-bets-cheaper-diagnostics> (last accessed Nov. 26, 2016).

27 ⁵⁶ Mar. 9, 2015, available at <http://brucedocumentblog.blogspot.com/2015/03/march-9-2015-fox-interviews-theranos.html> (last accessed Nov. 26, 2016).

known for its blood tests that require only a few drops of blood, eliminating the need for larger needles and numerous vials of blood required for many diagnostic lab tests.”⁵⁷

ff. *Theranos seeks FDA approval for early-detection Ebola test—George Schultz*, which included the following:

George Shultz, a former U.S. secretary of state and current Theranos board member, let slip Friday that the company is seeking approval from the Food and Drug Administration for a test that can spot Ebola early.

Shultz revealed the information while moderating a discussion at Stanford University. Theranos founder and CEO Elizabeth Holmes then said, “We’re working with the agency. *We have a very good relationship with the agency.*”⁵⁸

gg. *Theranos: Elizabeth Holmes TEDMED 2014*, a video which included the following:

Holmes said that Theranos had “made it possible to run comprehensive laboratory tests from a tiny sample or a few drops of blood that could be taken from a finger” and had “made it possible to eliminate the tubes and tubes of blood that traditionally have to be drawn from an arm and replaced with the nanotainer.”⁵⁹

hh. *Patients can soon get lab tests without doctors’ orders.* (Holmes attending Arizona bill signings and stating, “[E]xpanded testing options puts more people in charge of their health care--- *to order tests and make health decisions* before chronic disease starts, not after.”)⁶⁰

ii. *The 100 Most Influential People*, an article written by former U.S. Secretary of State and Theranos board Member, Henry A. Kissinger stating (emphasis added):

Elizabeth Holmes’ is a story that could happen only in America... Elizabeth accepted only one option: making a difference. Striking, somewhat ethereal, iron-willed, she is on the verge of achieving her vision—through *a new method of blood testing that significantly*

⁵⁷ Mar. 9, 2015, available at <http://www.crainscleveland.com/article/20150309/FREE/150309848/cleveland-clinic-enters-long-term-strategic-alliance-with-theranos> (last accessed Nov. 26, 2016).

⁵⁸ Mar. 13, 2015, available at <http://www.bizjournals.com/sanjose/news/2015/03/13/theranos-seeks-fda-approval-for-early-detection.html?page=all> (last accessed Nov. 26, 2016).

⁵⁹ Mar. 13, 2015, available at <https://www.youtube.com/watch?v=kZTfgXYjj-A> (last accessed Nov. 26, 2016).

⁶⁰ Apr. 7, 2015, available at <http://www.azcentral.com/story/money/business/consumer/2015/04/07/patients-can-soon-get-lab-tests-without-doctors-orders/25413251/> (last accessed Nov. 26, 2016).

1 *reduces costs, tests for a whole range of infections and is mobile and*
 2 *can therefore be easily transported to underdeveloped regions... She*
 3 *manages an expanding global business by the refusal to be daunted by*
any obstacle....Elizabeth is in the process of turning an
*undergraduate's vision into a global reality.*⁶¹

4 jj. *The world's youngest self-made female billionaire*, which states:

5 Elizabeth Holmes was named to this years' TIME 100 list of the
 6 world's most influential people Thursday. She's being compared to
 7 visionaries like Bill Gates and Steve Jobs. Just as Gates wanted a
 computer on every desk, Holmes wants a blood test in every
 drugstore...

8 Her company, Theranos, has created what they call a painless, needle-
 9 free way to draw blood and test it -- for a fraction of Medicare
 costs...."We've created these little tiny tubes, which we call the
 10 'nanotainers,' which are designed to replace the big, traditional tubes
 that come from your arm, and instead allow for all the testing to be
 done from a tiny drop from a finger," Holmes

11 Some critics argue the Theranos method doesn't extract enough blood
 12 to do all the tests it claims.

13 "Every time you create something new, there should be questions, and
 14 to me that's a sign that you've actually done something that is
 transformative," Holmes said.

15 "Making it *possible to do tests on tiny samples*; any cancer patient, any
 16 child, any elderly person whose veins collapse will tell you not having
 to have their blood drawn that way *is a big deal*," Holmes said.⁶²

17 kk. *Holmes CBS Morning News Interview.*⁶³

18 ll. *Theranos sticks it to critics, plans expansion of lab services (Video)* (Theranos
 19 changes message stating, that it can now draw blood in larger quantities for "specialty" blood
 20 tests).⁶⁴

21 mm. *Theranos jump-starts consumer lab testing* ("My last routine blood tests,
 22 drawn at my physician's office . . . cost me \$433 out of pocket, even after application of my "gold"-

23 ⁶¹ Apr. 16, 2015, available at <http://time.com/3822734/elizabeth-holmes-2015-time-100/> (last
 24 accessed Nov. 26, 2016).

25 ⁶² Apr. 16, 2015, available at [http://www.cbsnews.com/news/elizabeth-holmes-youngest-self-
 26 made-female-billionaire-revolutionize-health-care/](http://www.cbsnews.com/news/elizabeth-holmes-youngest-self-made-female-billionaire-revolutionize-health-care/) (last accessed Nov. 26, 2016).

26 ⁶³ Apr. 20, 2015, available at [http://brucedocumentblog.blogspot.com/2015/04/april-17-2015-
 27 holmes-cbs-morning-news.html](http://brucedocumentblog.blogspot.com/2015/04/april-17-2015-holmes-cbs-morning-news.html) (last accessed Nov. 26, 2016).

27 ⁶⁴ May 5, 2015, available at
 28 [http://www.bizjournals.com/sanfrancisco/blog/biotech/2015/05/theranos-elizabeth-holmes-quest-
 labcorp-lh-dgx.html?page=all](http://www.bizjournals.com/sanfrancisco/blog/biotech/2015/05/theranos-elizabeth-holmes-quest-labcorp-lh-dgx.html?page=all) (last accessed Nov. 26, 2016).

1 level insurance. . . . Had I not been insured, the lab's price for those tests would have been \$2,411,
 2 according to the explanation of benefits sent me. The same tests, according to Theranos' price menu,
 3 would have cost me \$75."').⁶⁵

4 nn. *Elizabeth Holmes Interview (Video)*: Video interview of Holmes by Charlie
 5 Rose, including transcript. In the interview, Holmes sticks to her narrative of small sample from a
 6 prick, but slides in, as she did a month earlier, that they may be doing some tests traditionally:

7 Charlie Rose: The process is easier because you just prick your
 8 finger. You don't have to have the kind of blood test that scares some
 people --

9 Elizabeth Holmes: Myself included, yes.

10 Charlie Rose: -- in drawing a vial of blood.

11 Elizabeth Holmes: Yes. *And we focused on smaller samples, period.*
 12 So for urine, for other types of major -- for bloods we can do drops
 13 from a finger. *We can also take blood from the arm and just take less*
blood than would traditionally be required in a venal puncture...

14 Holmes sticks to her narrative about accuracy of the proprietary tests:

15 Charlie Rose: Part of this is about process. It is also about science, I
 16 assume. You get the same results that you get through Theranos if, in
 fact, you went to a doctor and had him take a vial of blood from your
 veins.

17 Elizabeth Holmes: We do.

18 Charlie Rose: You get the same results.

19 Elizabeth Holmes: We do.

20 Charlie Rose: Or they would give you the same results as you get
 21 from a prick of the finger.

22 Elizabeth Holmes: Yes....

23 Holmes then evades answering any question about the technology, other than the narrative than that
 24 the chemistry, hardware and processes are all "redeveloped";

25 Charlie Rose: What's the science, what is the scientific change that
 26 allows you to do this? What did you discover, find, create that enabled
 to you get the same results in an easy way?

27 ⁶⁵ May 7, 2015, available at [http://fortune.com/2015/05/07/theranos-jump-starts-consumer-lab-](http://fortune.com/2015/05/07/theranos-jump-starts-consumer-lab-testing/)
 28 testing/ (last accessed Nov. 26, 2016).

Elizabeth Holmes: There are many elements to it. One is you know, test by test, *redeveloping the chemistry that is used in the traditional laboratory framework to be able to work on smaller samples. Another is, having to redevelop the hardware that those tests are run on. The software, and for automating laboratory processes is another.* The collection technology in terms of the tiny tubes is another

oo. *With Carlos Slim, Billionaire Elizabeth Holmes Brings Innovative Blood*

Testing Method To Mexico, which included:

With [Carlos] Slim Helú at her side, Holmes, founder and CEO of Theranos, said in Mexico City that with the technology her company has developed, it is possible to carry out, with a single drop of blood drawn with a pin prick and next to no pain, a very broad number of lab tests at very low cost, making it an accessible method for the entire population.

Theranos can quickly test a drop of blood at a fraction of the price of commercial labs, and can run up to 70 different tests.

pp. *Theranos' new deal with billionaire Carlos Slim may take it to another level.*⁶⁶

qq. *Disruptive diagnostics firm Theranos gets boost from FDA.*⁶⁷

rr. *Biden visits Theranos lab as part of healthcare innovation summit*, which

states in part:

Talk about being inspired," [Vice President] Biden said, according to statements provided by Theranos. "This is inspiration. It is amazing to me, Elizabeth, what you've been able to do. What's most impressive to me is you're not only making these lab tests more accessible ... empowering people whether they live in the barrio or a mansion, putting them in a position to help take control of their own health."⁶⁸

ss. *World's Youngest Billionaire - Another Steve Jobs?*, which includes the

following:

"This is a revolutionary company that threatens to change healthcare the same way that Amazon changed retail or Intel and Microsoft

⁶⁶ June 23, 2015, available at <http://www.bizjournals.com/sanfrancisco/blog/biotech/2015/06/theranos-carlos-slim-foundation-mexico-casalud.html> (last accessed Nov. 26, 2016).

⁶⁷ July 2, 2015, available at <http://fortune.com/2015/07/02/theranos-fda-approval/> (last accessed Nov. 26, 2016).

⁶⁸ July 24, 2015, available at <http://www.usatoday.com/story/tech/2015/07/24/biden-visits-theranos-lab-part-healthcare-innovation-summit/30634739/> (last accessed Nov. 26, 2016).

changed computing, or Apple changed the cellphone," the "Mad Money" host said.⁶⁹

tt. *Elizabeth Holmes On Using Business To Change The World.*⁷⁰

uu. *Self-Made Billionaire Elizabeth Holmes on Re-Inventing Blood Tests: "It's Like Cocaine."*⁷¹

vv. *How Theranos is Disrupting the Health Care Industry* ("A cholesterol test is \$2.99, was it could cost hundreds in other locations. . . . The response from the lab industry, they have so aggressively seeded false information about us into the press, into journalists, into physicians in the market we are in.").⁷²

ww. *CME Group Announces Elizabeth Holmes as the 2015 Melamed-Arditti Innovation Award Recipient*, which states:

"It is an honor and a privilege to receive this award, and be named among the many other talented and innovative leaders who have come before me," said Elizabeth Holmes, founder and CEO of Theranos. "Innovation and technology should be used to address the world's greatest challenges. At Theranos, our mission is to make actionable health information accessible to everyone at the time it matters. *This award recognizes our success in using technological innovations in laboratory testing to make tests more accessible – both logistically and financially – and less painful*, which will help facilitate early detection and prevention of disease."⁷³

D. Promises on Theranos' Website and in Walgreens' Stores, and an Advertisement Were Also Used to Court Investors and Promote the "Narrative"

33. In addition to the above representations and promises, Theranos filled the Walgreens stores with promises, and published advertisements that promoted the "Narrative." At the Walgreens Wellness Centers, Theranos promised:

⁶⁹ Sept. 23, 2015, available at <http://www.cnbc.com/2015/09/23/worlds-youngest-female-billionaire-next-steve-jobs.html> (last accessed Nov. 26, 2016).

⁷⁰ Oct. 5, 2015, available at <http://www.forbes.com/sites/sarahhedgecock/2015/10/05/elizabeth-holmes-on-using-business-to-change-the-world/#76449a82202f> (last accessed Nov. 26, 2016).

⁷¹ Oct. 6, 2015, available at <http://www.vanityfair.com/news/2015/10/elizabeth-holmes-theranos-ceo> (last accessed Nov. 26, 2016).

⁷² Oct. 6, 2015, available at <http://www.bloomberg.com/news/videos/2015-10-06/how-theranos-is-disrupting-the-health-care-industry> (last accessed Nov. 26, 2016).

⁷³ Oct. 12, 2015, available at <http://www.marketwatch.com/story/cme-group-announces-elizabeth-holmes-as-the-2015-melamed-arditti-innovation-award-recipient-2015-10-12> (last accessed Nov. 26, 2016).

theranos

the blood tests that need just a
tiny sample.

Walgreens partners with Theranos to provide
lab services

Theranos is working to shape the future of lab
testing. Now, for the first time, their high-
complexity CLIA-certified laboratory can perform
your tests quickly and accurately using tiny
samples.¹

[Learn more at Theranos.com](#)

[Para información en español haga clic aquí](#)

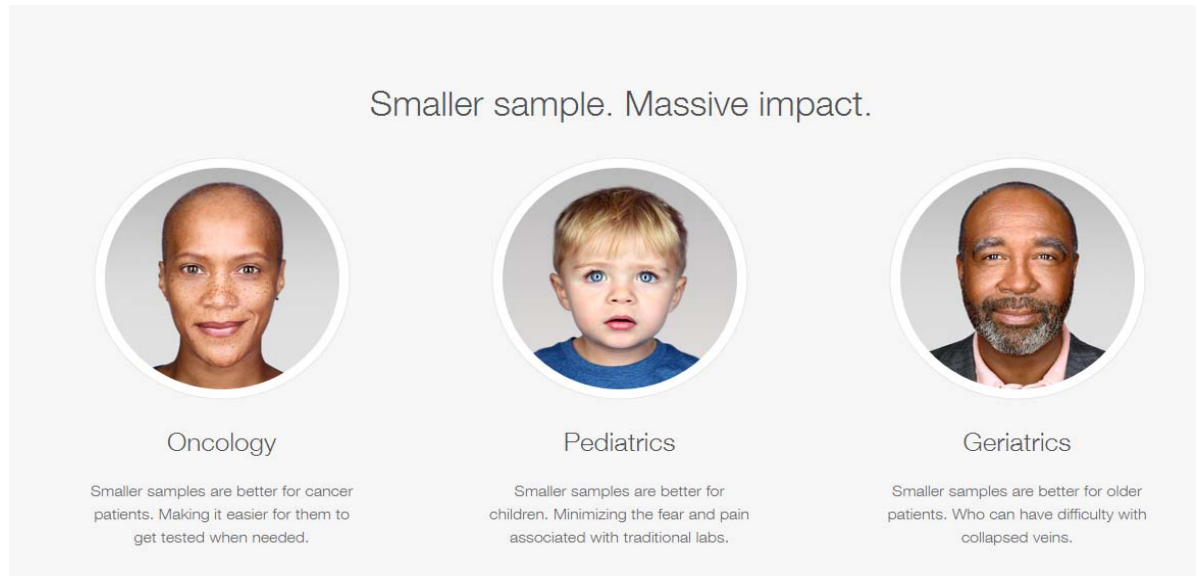


34. The key feature Theranos used to market its tests and differentiate itself was that it brought a new technology and approach to the staid, established blood test industry, with its tagline being, “one tiny drop changes everything.” This theme was prominent in its advertisements: Theranos boasted it could analyze samples as small as 1/1,000 the size of the typical blood draw and perform tests on any sample type, including blood, urine, and other samples. “It’s fast, easy, and the highest level of quality,” Theranos informed prospective customers. Theranos stressed it used smaller samples and less invasive techniques, pushing this difference in advertisements and on company web pages:

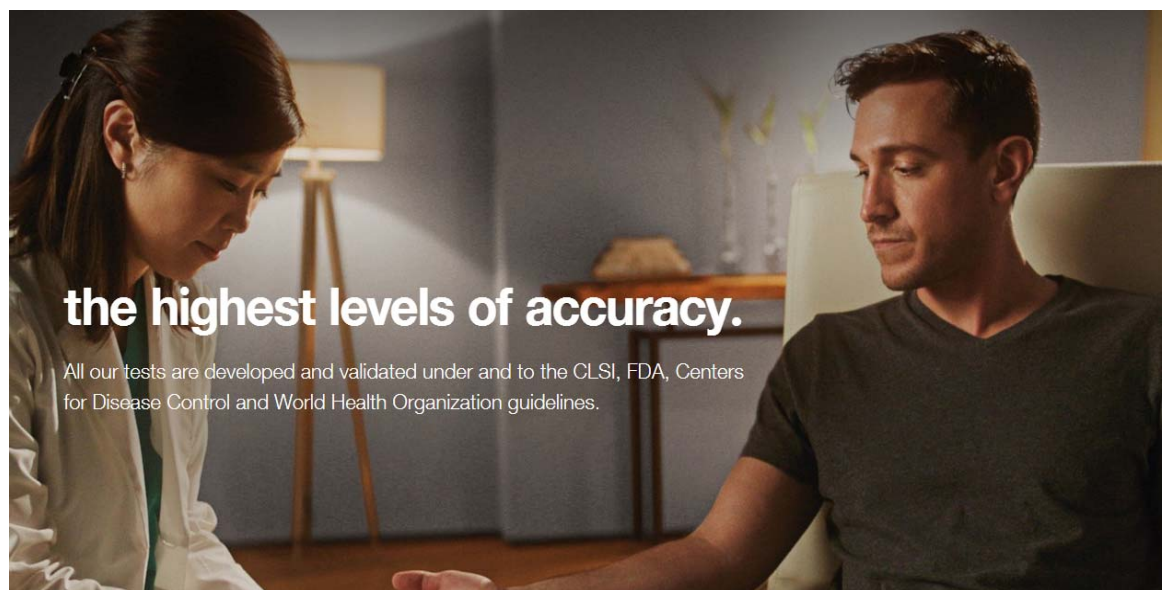
goodbye, big bad needle.

Instead of a huge needle, Theranos-trained technicians can use a tiny finger stick² or collect a micro-sample from a venous draw.² It's practically painless and a lot less scary. Now the entire lab testing process is comfortable, accommodating, and less intimidating—for people big and small.





35. Despite using tests requiring only a little blood, Theranos promised consumers it could still deliver the best in accuracy and quality.



36. It endorsed that getting accurate results in a timely manner is essential, declaring "what you decide about your health should be informed and timely enough to protect or improve it.

**fast results. fast answers.**

Theranos performs their test analyses fast, so they can return results to your clinician³ faster than ever before.³ That means a more timely diagnosis to support better, more informed treatment.

37. Theranos summed up its approach this way, “Our technology and our process are all configured to put you and your preventive outcomes first.”

38. Theranos claimed vigilance in providing the highest quality tests. “We continuously conduct proficiency testing and participate in multiple proficiency testing programs,” and all “tests are developed and validated under and to the CLSI, FDA, Centers for Disease Control and World Health Organization guidelines,” touting that it had “processed hundreds of thousands of tests in validating our work for 10 of the 15 largest pharmaceutical companies.”

39. Theranos claimed to have performed “more than six million tests in the nearly two years since we began serving individuals and physicians through our clinical labs,” and worked with over 9,000 physicians.

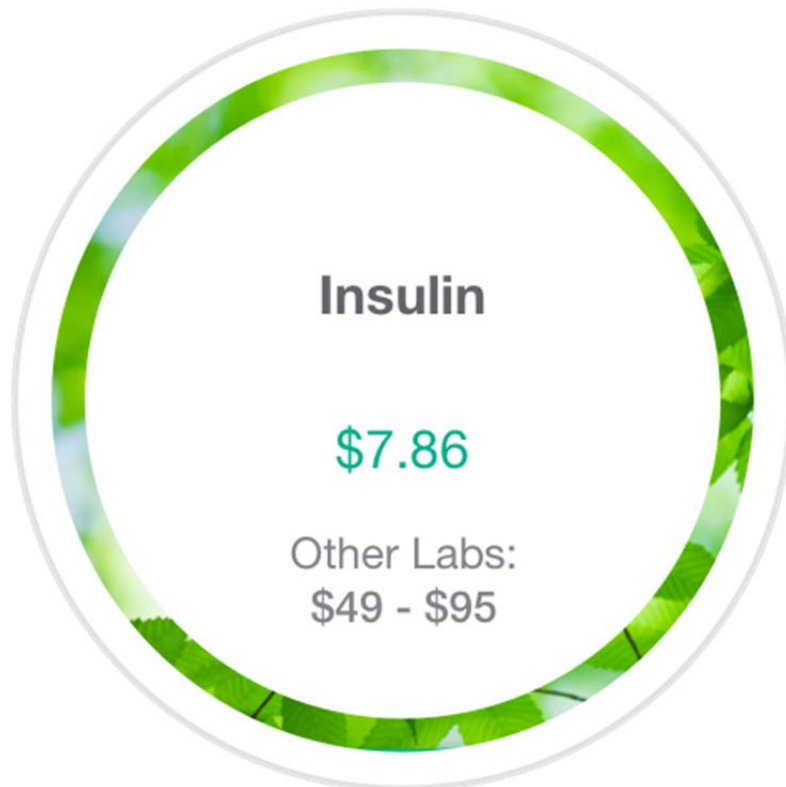
40. Theranos also advertised its tests on Walgreen’s website promising a test that would support “better, more informed treatment”:

theranos Theranos Lab Testing at Walgreens

- the lab test, reinvented.

At Theranos, we're working to bring about a day when lab testing is accessible and affordable for everyone. So people can engage with their health and their physicians like never before, and no one has to say goodbye too soon.

[Learn more at theranos.com](http://theranos.com) ›



To help evaluate
insulin production

• **Fast results. Fast answers.**

At Theranos, we've dramatically reduced the time it takes to analyze samples. So you and your physician get your results faster than ever before.¹ Which means a more timely diagnosis to support better, more informed treatment. So you can engage with your physician, and your health, like never before.¹

E. Plaintiffs and Class Invest Hundreds of Millions of Dollars in Theranos⁷⁴

41. Prior to September 2013, Defendants raised approximately \$93 million dollars from four rounds of investors, including one Series C round in 2010. These early investors reportedly include Draper Fisher Jurvetson (including Tim Draper and Jennifer Fonestad, July 2010), ATA Ventures (including T Peter Thomas July 2010), The Lawrence J. Ellison Trust, Continental Ventures or Continental Properties, Donald L. Lucas, Tako Ventures, Richard Kovacevich, former

⁷⁴ Generally, venture capital funding goes through three stages. Series A funding begins after a business has shown some track record. The investors involved in the Series A round come from more traditional venture capital firms. Series B rounds are all about taking businesses to the next level, past the development stage. In Series C rounds, investors inject capital into the meat of successful businesses. In Series C, groups such as hedge funds, investment banks, private equity firms and big secondary market groups accompany the before-mentioned investors. Shoshann Delvanthal, *Series A, B, C Funding: What It All Means and How It Works*, Investopedia (Oct. 20, 2015).

Wells Fargo CEO, Thomas C. Hawes (Sandbox Industries where he manages several BCBS venture funds) Bob Shapiro (SandBox Industries), Colton Dillion, Ryan Orr (Cofounder, CEO Chronicled), John Levinson, Al Eisaian (2012 Series B) and The Hall Financial Group (Craig Hall).

42. After September 9, 2013, Defendants offered, sold or caused to be sold Theranos securities, or interests in Theranos securities, to Plaintiffs (and the Class) and raised at least \$632.73 million for Theranos from Plaintiffs. Public information on Theranos securities sales is as follows:

Date	Amount	Investors	Type	Stage	Valuation	Est. Fully Diluted Shares	Price Per Share	Deal Terms
10/12/2015	M		Equity	Later Stage	-	-	\$20.00	Series C Participating Preferred
03/06/2015	\$432.73M	Unknown	Equity	Later Stage	\$10,451,203,979	614,776,704	\$17.00	Series C Participating Preferred
02/07/2014	\$200.00M	Unknown	Equity	Later Stage	\$9,942,098,259	584,829,309	\$17.00	Series C Participating Preferred
07/01/2010	\$45.00M	ATA Ventures	Equity	Expansion	\$932,731,288	310,910,429	\$3.00	Series C Participating Preferred
10/26/2006	\$32.36M	Draper Fisher, Juvetson, ATA Ventures, Undisclosed Firm	Equity	Expansion	\$165,400,541	293,263,370	\$0.56	Series C Participating Preferred
02/16/2006	\$9.10M	Draper Fisher, Juvetson, ATA Ventures	Equity	Early Stage	\$41,370,847	224,076,776	\$0.18	Series B Conventional Convertible
12/17/2004	\$5.82M	Draper Fisher, Juvetson, Undisclosed Firm,	Equity	Early Stage	\$23,514,579	156,763,864	\$0.15	Series A Conventional Convertible

F. Defendants' Private Solicitations are Consistently Misleading and Demonstrate Intent to Mislead

43. Defendants also met privately with intermediaries, such as investment funds, to convince them to solicit investors in Theranos. For example, on December 15, 2013, three private investment fund representatives who filed suit in *Partner Investments, LP et al. v. Theranos, Inc. et al.* (the "PIM investors") had pre- and post-investment meetings with Defendants Holmes and Balwani at Theranos where they tried to perform due diligence.⁷⁵

⁷⁵ *Partner Investments, LP et al. v. Theranos, Inc. et al.*, No. 12816-VCL in the Court Of Chancery of the State of Delaware (Oct. 10, 2016). The PIM investors claim to have invested in Series C-2 Preferred Shares at a purchase price of \$17 per share on February 4, 2014, through investment funds. PIM, HCMF and HCP claim to have purchased a total of 5,655,294 shares for a total investment of \$96,139,998. Specifically, PIM invested \$55,479,993 for 3,263,529 shares;

1 44. Holmes and Balwani touted to the PIM investors their existing contracts with the
2 Walgreens pharmacy chain and the Safeway grocery chain, both of which were claimed to be
3 contractually committed to opening a minimum number of Theranos locations. The Company also
4 touted their contracts with several of the country's largest healthcare provider systems. Allegedly,
5 Holmes and Balwani presented Theranos' business strategy and rollout schedule as concrete, in
6 process, and profitable, thus supporting selling its shares to the PIM investors at \$17 per share.

7 45. In a January 10, 2014 meeting with the PIM investors, Defendants presented a two-
8 phase rollout schedule that would ensure Theranos' national presence over the course of the
9 following two years. In phase one, Theranos would distribute its proprietary nanotainers to testing
10 locations (including retail pharmacies, hospitals, and physicians' offices) but would maintain its
11 proprietary analyzers in offsite laboratories. Once a patient gave blood via a finger stick, a nanotainer
12 containing the blood would be sent to a Theranos laboratory, the sample would be run on Theranos'
13 proprietary analyzers, and Theranos "guaranteed" results within four hours. By the end of 2014, any
14 test requested by a customer—not just the "99.9%" said by Defendants to be already available as of
15 the January 2014 meeting—would be performed using a finger stick. In phase two, beginning in
16 2015, Theranos would install its analyzers in the testing locations themselves (as opposed to testing
17 the samples at its centralized laboratories), and patients would receive their results within 30 minutes
18 (as opposed to four hours).

19 46. Also on January 10, 2014, Holmes and Balwani walked the PIM investors through a
20 PowerPoint presentation comparing test data generated on Theranos' proprietary analyzers to test
21 data generated on traditional laboratory machines. Holmes and Balwani represented that the
22 Theranos data was generated on its proprietary analyzers using small samples drawn with its
23 proprietary methods. Holmes and Balwani stated that the majority of the tests featured in the
24 presentation had correlation coefficients of 0.95 or higher—which, they represented, meant that they
25 were substantially equivalent to traditional laboratory tests. Holmes and Balwani stated that, as of
26 that January 2014 meeting, the correlation data had been submitted to the FDA for clearance and

27 _____
28 HCMF invested \$38,336,632 for 2,255,096 shares; and HCP invested \$2,323,373 for 136,669 shares
and distributed interests in those shares to the PIM investors.

Theranos was still working on the small number of tests that had correlation coefficients lower than 0.95. Balwani and Holmes also stated that Theranos had filed for FDA clearance or approval of all its tests in November 2013.

47. In fact only one test, a relatively easy one involving the herpes virus, was ever submitted to the FDA.⁷⁶

48. On January 21 and 24, 2014, Balwani stated to the PIM investors that Theranos had waited to actively publicize its launch until it could compete effectively with rival commercial laboratory testing companies and that it now performed “99%” to “99.9%” of all laboratory requests using its proprietary technologies. Balwani represented that the Company had developed around 300 blood tests, and only 1% to 2% of those tests could not be performed using Theranos’ capillary samples and had to be performed with micro-samples taken from a venous blood draw instead. Balwani further represented that the use of venous micro-samples for only 1% to 2% of its customers’ tests was a short-term solution that would be in place for only six months, at which point Theranos would be able to perform all of its tests with finger sticks and nanotainers.

49. In fact, Theranos ran only about 12 tests using its finger stick technology, and its device, the “capillary tube nanotainer”, was an unapproved medical device. Moreover, Theranos admitted, when it voided all of its test results run on its proprietary technology, that less than 1% of all the tests it had performed using its proprietary device.

G. Defendants Attack Their Critics

50. On October 16, 2015, the WSJ and other media outlets began to publish disturbing allegations about the nature of Theranos’ technology and operations, and that questions arose about the veracity of Defendants’ statements. An October 15, 2015 WSJ exposé contended that Theranos was using its technology on very few tests:

⁷⁶ Holmes had chosen to submit for FDA’s approval a single test for viral screening. A viral probe, as opposed to a more ordinary blood test for something like red blood cell counts, doesn’t need to be precise, just sensitive. It doesn’t need to quantitate a level, just detect the binary presence of a viral contaminant. Theranos surely knew the distinction. Apr. 28, 2016, *Theranos Woes Offer Lesson In How Labs Should Be Regulated*, available at <http://www.forbes.com/sites/scottgottlieb/2016/04/28/theranos-woes-offer-lesson-in-how-labs-should-be-regulated/#df9625075f53> (last accessed 11/22/16)

- a. One former senior employee says Theranos was routinely using the device, named Edison after the prolific inventor, for only 15 tests in December 2014.
- b. One Theranos employee accused the company of failing to report test results that raised questions about the precision of the Edison system.
- c. Asked about the claim on the company's website, their outside lawyer and soon to be director, David Boies replied that using the device for the "full range" of blood tests is a goal Theranos will eventually achieve.
- d. During the Journal's reporting, Theranos deleted a sentence on its website that said: "Many of our tests require only a few drops of blood." It also dropped a reference to collecting "usually only three tiny micro-vials" per sample, "instead of the usual six or more large ones." Heather King, the company's general counsel, says the changes were made for "marketing accuracy."
- e. As of the end of 2014, Theranos did less than 10% of its tests on Edison (Theranos proprietary technology) machines, including tests for prostate cancer and pregnancy, one former senior employee says.

51. Theranos immediately responded that day, taking issue with the WSJ article in a press release entitled: *Statement from Theranos*:

Today's Wall Street Journal story about Theranos is factually and **scientifically erroneous and grounded in baseless assertions by inexperienced and disgruntled former employees and industry incumbents**. Theranos presented the facts to this reporter to prove the accuracy and reliability of its tests and to directly refute these false allegations, including more than 1,000 pages of statements and documents. Disappointingly, the Journal chose to publish this article without even mentioning the facts Theranos shared **that disproved the many falsehoods in the article.**⁷⁷

52. As more media began to question the Theranos narrative, Defendants and their advisers, including outside counsel David Boies, caused Theranos to issue a barrage of retorts, denials, misinformation and misdirection in press releases, many of which were provided directly to its investors, as follows:⁷⁸

- a. On October 16, 2015, Theranos issued another press release:

⁷⁷ Oct. 15, 2015, available at <https://news.theranos.com/2015/10/15/statement-from-theranos/> (last accessed Nov. 26, 2016).

⁷⁸ Theranos claims to and in fact has altered or "updated" past posts on its website, and it appears that some claims may have been altered or removed. See, for example Oct. 22, 2015 TechCrunch, *Theranos Takes Yet Another Swipe At WSJ Allegations In A Lengthy Statement*, available at <https://techcrunch.com/2015/10/22/theranos-takes-yet-another-swipe-at-wsj-allegations-in-a-lengthy-statement/> (last accessed 11/23/16) ("we explained to the reporter that the changes to the website were simply done to emphasize that, regardless of whether Theranos takes a venous sample or a finger-stick draw, our blood draws are smaller and less painful, improving the overall patient experience. Theranos updates our website regularly.")

1 “We are disappointed to see that The Wall Street Journal still can’t get
 2 its facts straight. . . . Here are the facts: There are just 3 steps to
 3 Theranos’ groundbreaking finger-stick technology. 1. Take a few drops
 4 of blood. 2. Put the blood in the Nanotainer™ tube. 3. Analyze the
 5 blood. That’s it. 3 simple steps. 1, 2, 3. We sought out and asked FDA
 6 to review those steps for everything we do – like no lab before us.”⁷⁹

7 b. On October 22, 2015, Theranos issued another press release, *Theranos Facts*,
 8 available at <https://news.theranos.com/2015/10/22/theranos-factsstatic/> (last accessed Nov. 17,
 9 2016). Theranos also published a second response on its website, but that response has been removed
 10 and replaced by this press release. The original press release was at
 11 <https://news.theranos.com/2015/10/22/theranos-facts>. The contents are still available via a third party
 12 site <http://genius.com/Theranos-theranos-facts-oct-22-2015-press-release-annotated> (last accessed
 13 Nov. 23, 2016). In this post, Theranos launches into a lengthy attack on the WSJ report, claims at the
 14 end of 2014 some 80 tests were performed using its finger-stick technology. But Theranos also
 15 admits that only one is performed currently, and implausibly implies it was not using “Edison”
 16 because it was just an “earlier version of just one of our proprietary technologies.”

17 c. Oct. 28, 2015 Press Release, *Statement from Theranos*, available at
 18 <https://news.theranos.com/2015/10/28/statement-from-theranos-3/> (last accessed Nov. 17, 2016).

19 d. Nov. 5, 2015 Press Release, *Statement from Theranos*, available at
 20 <https://news.theranos.com/2015/11/05/statement-from-theranos-4/> (last accessed Nov. 17, 2016).

21 e. Nov. 10, 2015 Press Release, *Statement from Theranos*, available at
 22 <https://news.theranos.com/2015/11/10/statement-from-theranos-5/> (last accessed Nov. 17, 2016).

23 f. Dec. 22, 2015 Press Release, *Wall Street Journal: Letter to the Editor*,
 24 available at <https://news.theranos.com/2015/12/22/wall-street-journal-letter-to-the-editor/> (last
 25 accessed Nov. 17, 2016).

26 g. Jan. 27, 2016 Press Release, *Statement from Theranos*, available at
 27 <https://news.theranos.com/2016/01/27/statement-from-theranos-6/> (last accessed Nov. 17, 2016).

28 ⁷⁹ Oct. 16, 2015, available at <https://news.theranos.com/2015/10/15/statement-from-theranos/> (last
 accessed Nov. 26, 2016).

h. Mar. 7, 2016 Press Release, *Statement Regarding Newark, California Lab Survey*, available at <https://news.theranos.com/2016/03/07/statement-regarding-newark-california-lab-survey/> (last accessed Nov. 17, 2016).

i. Mar. 28, 2016 Press Release, *Theranos Letter to The Journal of Clinical Investigation*, available at <https://news.theranos.com/2016/03/28/theranos-letter-to-the-journal-of-clinical-investigation/> (last accessed Nov. 17, 2016).

j. Mar. 31, 2016 Press Release, *Theranos Statement on CMS 2567 Report*, available at <https://news.theranos.com/2016/03/31/theranos-statement-on-cms-2567-report/> (last accessed Nov. 17, 2016).

k. Apr. 7, 2016 Press Release, *Theranos Announces Leading Medical and Laboratory Experts Join Scientific and Medical Advisory Board*, available at <https://news.theranos.com/2016/04/07/theranos-announces-leading-medical-and-laboratory-experts-join-scientific-and-medical-advisory-board/> (last accessed Nov. 17, 2016).

l. May 11, 2016 Press Release, *Theranos Announces Expansion of Board of Directors and New Organizational Structure*, available at <https://news.theranos.com/2016/04/07/theranos-announces-leading-medical-and-laboratory-experts-join-scientific-and-medical-advisory-board/> (last accessed Nov. 17, 2016).

m. June 12, 2016 Press Release, *Statement from Theranos*, available at <https://news.theranos.com/2016/06/12/statement-from-theranos-7/> (last accessed Nov. 17, 2016).

n. July 8, 2016 Press Release, *Theranos Statement and Q&A on CMS Findings*, available at <https://news.theranos.com/2016/07/19/theranos-statement-on-cms-findings/> (last accessed Nov. 17, 2016).

o. July 21, 2016 Press Release, *Theranos Names New Executives for Regulatory and Quality, and A Chief Compliance Officer*, available at <https://news.theranos.com/2016/07/21/theranos-names-new-executives-regulatory-quality-chief-compliance-officer/> (last accessed Nov. 17, 2016).

1 p. Aug. 25, 2016 Press Release, *Theranos to Appeal CMS Sanctions*, available at
2 <https://news.theranos.com/2016/08/25/theranos-to-appeal-cms-sanctions/> (last accessed Nov. 17,
3 2016).

4 **H. Defendants' Theranos Story Unravels**

5 53. After the October 16, 2015 Wall Street Journal's exposé and attendant fallout
6 beginning in or about October 2015, nearly every month brings new information about the truth
7 regarding Theranos' technology and business model including:

8 **1. Defendants Misrepresented the Extent to Which Theranos Tested Blood Samples** 9 **Using Its Own Proprietary Analyzers**

10 54. Prior to the WSJ exposé, Theranos prominently featured in its website a nanotainer
11 balanced on the tip of a finger and the slogan: "one tiny drop changes everything." But after the
12 exposé, in a glaring reversal and whitewashing of its prior public statements, the website read:
13 "Smaller Samples. Smaller Needles. A better Experience."

14 55. As the media would later report and the Defendants later shockingly admit, Theranos
15 was relying on traditional machines made by other companies to run blood tests, rather than using its
16 own proprietary analyzers. For example, Theranos board member, David Boies, admitted to the WSJ
17 that at the time of a December 2013 audit of Theranos' laboratory in Newark, California, by CMS,
18 90% of the samples were run in the laboratory's "Jurassic Park" room, which contained only the
19 traditional laboratory machines the Company promised that it was making obsolete. On October 21,
20 2015, Holmes admitted to the PIM investors that in instances when Theranos drew a venous micro-
21 sample from customers, it performed the blood tests using traditional machines made by other
22 companies, *not Theranos' proprietary analyzers*.

23 56. Notwithstanding this admission, Holmes claimed in a March 20, 2016 letter to
24 stockholders, that "[s]amples collected via venipuncture were run using Theranos' [sic] proprietary
25 technologies for certain ordering patterns."

26 57. In a meeting with the PIM investors on April 27, 2016, Holmes admitted that, as of
27 January 2014, Theranos was still using traditional machines made by other companies to test blood
28

1 samples, but claimed that it was only so that Theranos could handle customer volume quickly while
2 “phasing in” its proprietary analyzers.

3 58. These articles and admissions took Walgreens by surprise. Walgreens promptly
4 sought answers from Theranos. Theranos explained that it had decided to transition from finger-stick
5 blood draws to the traditional venous draws while its blood-collection device was being reviewed for
6 FDA approval. This was the first time Walgreens learned of this information. Theranos did not
7 cooperate with Walgreens’s requests for information. Theranos only responded to some of
8 Walgreens’s requests, missed multiple deadlines and delayed for several weeks for others, and failed
9 to provide any information in response to others. Finally, when Theranos allowed Walgreens to
10 speak with the director of Theranos’ Newark lab, Dr. Sunil Dhawan, on November 14, 2015,
11 Walgreens learned that Dr. Dhawan was a full-time dermatologist, had no experience prior to
12 Theranos with any field outside of dermatopathology, and spent only one day a week at the Newark
13 lab.

14 59. Holmes also admitted to the PIM investors on January 26, 2016, that Theranos had
15 236 tests on its Walgreens pharmacy chain menu but performed, as of that meeting, *only 87 of these*
16 *tests—i.e., 37%— using capillary samples*. Director David Boies now described the transition to
17 performing every test with nanotainers and Theranos devices would be “a journey.” And Theranos’
18 then-General Counsel admitted to Fortune in October 2015 that *most of the tests listed on Theranos’*
19 *commercial test menu are done by venipuncture*.

20 **2. Defendants Misrepresented the Reason Theranos Stopped Using Its Finger-Stick**
21 **and Nanotainer Collection Method for All but One Test**

22 60. Unbeknownst to the public, the FDA had warned Theranos on September 16, 2015,
23 that the nanotainer was an “uncleared medical device” that Theranos was unlawfully “shipping . . . in
24 interstate commerce.” Theranos continued to mislead its partners, investors, and the public when it
25 posted on Twitter on October 22, 2015: “Finger-sticks work[.]”

26 61. After the WSJ exposé, the Company admitted in an October 28, 2015 press release
27 that, when the FDA informed Theranos of its position regarding the nanotainer, Theranos stopped
28 using nanotainers “immediately.” On October 21, 2015, Holmes disclosed to the PIM investors that

Theranos was no longer using its finger-stick and nanotainer collection method for tests that had not been cleared by the FDA (i.e., for all but the HSV-1 test). But Defendants concealed this material information from the public until the FDA posted it on its website and it was first reported by Bloomberg on October 27, 2015.⁸⁰

62. Nevertheless, in a November 2, 2015 interview at Fortune’s Global Forum, Holmes claimed she “was the person who chose, voluntarily, to stop using our nanotainer tubes” and that it was the “decision to transition our systems to the FDA framework, which led us right now, as of this moment, for the last few weeks only, to run just one test” using the finger-stick and nanotainer collection method. Thus, she said, “temporarily, as we transition, which has now been just a few weeks, we would not be using that [nanotainer] tube to collect our samples.”

63. In truth, Theranos had stopped using its finger-stick and nanotainer collection method for all but one of its tests at least as early as September 2015, in response to the communication it received from the FDA. Nor was this shift away from finger sticks and nanotainers “temporary.”

3. Theranos Labs Get Shut Down As Non-Compliant with Federal Regulations and Federal Agencies Begin to Investigate Theranos

64. After inspecting Theranos’ laboratory in Newark, California, in November 2015, CMS notified Theranos of various deficiencies in a survey report dated November 29, 2015. Based on this survey, CMS informed Theranos in a letter dated January 25, 2016, that the laboratory was “not in compliance” with five conditions necessary for CLIA certification and that “the deficient practices of the laboratory pose immediate jeopardy to patient health and safety.” CMS subsequently rejected Theranos’ attempt to remedy these deficiencies, informing it in a letter dated March 18, 2016, that its submission did “not demonstrate that the laboratory has come into Condition-level compliance and abated immediate jeopardy.”

65. On April 18, 2016 the WSJ reported, based on anonymous sources, that the U.S. DOJ has launched a criminal investigation into whether Theranos “misled investors about the state of its technology and operations[.]” Theranos and its executives also have acknowledged that there is an

⁸⁰ Available at <https://www.bloomberg.com/news/articles/2015-10-27/theranos-device-validation-is-flawed-fda-inspection-finds> (last accessed Nov. 17, 2016).

1 ongoing SEC investigation, and the April 18, 2016 WSJ article reported, based on anonymous
 2 sources, that the SEC is similarly “examining whether Theranos made deceptive statements to
 3 investors when it solicited funding[.]”

4 66. On May 2, 2016, Theranos announced the “retirement” of Defendant Balwani, a 50-
 5 year-old executive and member of the Board of Directors of Theranos who has been with the
 6 Company since its inception and has been one of its primary spokespersons and conveyors of false
 7 and misleading information about the Company.

8 67. On May 18, 2016, the WSJ revealed that Theranos threw out all Edison test results,
 9 and some from traditional tests, from 2014 and 2015, thereby voiding tens of thousands of test
 10 results it provided to patients because they were invalid.⁸¹ Theranos admitted in a May 19, 2016
 11 letter to stockholders that “[t]he basis for voiding test results in [its] Newark lab was the Newark
 12 laboratory’s failure to implement and adhere to sufficient quality assessment procedures[.]”
 13 Significantly, the vast majority of those tests were not even performed using Theranos’ proprietary
 14 technology. Amazingly, Defendants admit:

15 What the Journal refers to as ***“the Edison,” is not and has never been***
 16 ***the “linchpin” or basis for our strategy, valuation or business.*** That
 17 assertion reflects a fundamental misunderstanding and
 18 misrepresentation of our business and our proprietary technologies,
 19 and appears specifically calculated to inflate the importance of the
 20 Journal’s reporting. ***Rather, what Theranos spent over a decade***
 21 ***working on prior to becoming consumer-facing is the portfolio of***
 22 ***technologies that enable small volume diagnostic testing to be***
 23 ***performed across multiple assay methodologies, and that can be***
 24 ***operationalized onto different platforms, including the platform that***
 25 ***the Journal refers to as “an Edison machine.”***

26 68. On June 12, 2016, the Walgreens pharmacy chain ended its strained relationship with
 27 Theranos and announced it would close all Theranos wellness centers immediately.

28 69. Sounding the death knell for Theranos’ laboratory operations, CMS issued a notice on
 July 7, 2016, stating that it would impose significant sanctions against the Company, Holmes, and

⁸¹ May 18, 2016, Wall Street Journal, *Theranos Voids Two Years of Edison Blood-Test Result*,
 available at <http://www.wsj.com/articles/theranos-voids-two-years-of-edison-blood-test-results-1463616976> (last accessed Nov. 22, 2016).

Balwani.⁸² Among other penalties, CMS is revoking the CLIA certificate for Theranos' Newark laboratory and imposing the following sanctions:

- Revocation of the laboratory's CLIA certificate;
- Limitation of the laboratory's CLIA certificate for the specialty of hematology;
- A Civil Money Penalty;
- A Directed Portion of a Plan of Correction;
- Suspension of the laboratory's approval to receive Medicare and Medicaid payments for any services performed for the specialty of hematology; and
- Cancellation of the Newark laboratory's approval to receive Medicare and Medicaid payments for all laboratory services.

These sanctions ban Holmes and Balwani, and thereby Theranos itself, from owning or operating a laboratory for at least two years.

70. CMS's July 7, 2016 letter to Theranos further underscores the falsity of the representations made by the Company, Holmes, and Balwani to Plaintiffs. For example, the letter states that documentation supplied by Theranos to CMS indicated that Theranos' Proprietary System "was not used for patient testing after June 25, 2015." In other words, Defendants ceased using their proprietary analyzers for blood tests even as it issued press releases stating otherwise.

71. The CMS letter appears to indicate that only twelve blood tests were performed by Theranos at its Newark, California laboratory using the Company's proprietary technology. Testing began on November 6, 2013, and the amount of blood tests dwindled to two until June 15, 2015, when no further tests were performed:

⁸² July 27, 2016 CMS letter to Theranos, available at http://online.wsj.com/public/resources/documents/r_Theranos_Inc_CMS_07-07-2016_Letter.pdf (last accessed Nov. 17, 2016).

Test	Initial Use	End Use	QC Data Submitted
Vitamin D	11/6/2013	3/10/2015	3/10/14-3/29/15
TSH	11/7/2013	2/4/2015	3/25/14-2/4/15
FT4	11/11/2013	2/4/2015	3/21/14-2/4/15
TPSA	11/11/2013	6/25/2015	3/21/14-6/16/15
TT3	2/12/2014	2/4/2015	3/15/14-2/3/15
TT4	2/12/2014	2/4/2015	3/15/14-2/4/15
TST	3/19/2014	3/10/2015	4/2/14-3/10/15
HCG	5/9/2014	1/19/2015	5/5/14-1/15/15
SHBG	7/28/2014	6/25/2015	7/30/14-6/9/15
Vitamin B12	8/12/2014	3/6/2015	8/15/14-3/1/15
Estradiol	9/25/2014	12/18/2014	9/26/14-12/17/14
Prolactin	9/25/2014	12/18/2014	9/30/14-12/18/14

72. In a July 8, 2016 press release in response to CMS's findings, Theranos admitted that it had already effectively shut down its Newark laboratory. It stated in that press release that its "Arizona lab currently processes all the samples that Theranos tests"—though for many patients, "including for [its] California patients," it is using "a third party reference lab to process samples[.]" The Company subsequently reiterated in its August 25, 2016 press release that it "is not conducting patient testing at its Newark facility."

65. On July 26, 2016, members of the House Committee on Energy and Commerce sent letters to CMS and the FDA requesting information about Theranos and its response to the agencies' actions, noting the Company's "disregard for patient safety and its failure to immediately address concerns by federal regulators[.]"

73. On August 1, 2016, at the annual AACC meeting, Holmes presented a supposedly new version of the Theranos proprietary analyzer, called the "minilab," but in her AACC presentation, Holmes admitted that only a handful of tests could be run on a single cartridge, and that multiple nanotainers of blood may be required to fulfill certain patient requests.

74. Yet another setback came in August 2016, when the FDA issued a notice stating that Theranos had collected data supporting the accuracy of its Zika test—which Holmes had touted at the AACC presentation—without implementing a protocol approved by an institutional review board to ensure patients are treated safely and ethically during medical studies. In an August 27, 2016 letter

1 to stockholders, the Company admitted that it had withdrawn both its Zika submission and its Ebola
2 submission to the FDA.

3 75. On October 5, 2016, Theranos announced it was closing all of its clinical laboratories
4 and patient testing centers and laying off approximately 340—more than 40%— of its employees.
5 Holmes wrote that the Company would “return [its] undivided attention to [its] miniLab platform”
6 and that its “ultimate goal is to commercialize miniaturized, automated laboratories capable of small-
7 volume sample testing[.]”

8 76. On October 10, 2016, the PIM investors filed suit, claiming fraud. The next day,
9 Theranos responded in a press release entitled, *Company Statement Regarding Investor Lawsuit*,
10 available at <https://news.theranos.com/2016/10/11/company-statement-regarding-investor-lawsuit/>
11 (last accessed Nov. 17, 2016):

12 The suit is without merit, the assertions are baseless, and the plaintiff is
13 engaging in revisionist history.

14 Most of the company statements the plaintiff has cited in its suit were
15 made *after the time the plaintiff invested*, and could not possibly have
16 been the original basis for investment. This wholesale reliance on post-
investment statements, therefore, negates the claim that the plaintiff
was misled.

17 77. On November 15, 2016, Walgreens filed suit claiming breach of contract. Theranos
18 stated in a press release two days later, entitled, *Theranos Statement on Walgreens Suit*, available at
19 <https://news.theranos.com/2016/11/08/theranos-statement-walgreens-suit/> (last accessed Nov. 17,
20 2016), that:

21 Walgreens consistently failed to meet its commitments to Theranos.
22 Through its mishandling of our partnership and now this lawsuit,
23 Walgreens has caused Theranos and its investors significant harm. We
will respond vigorously to Walgreens’ unfounded allegations, and will
seek to hold Walgreens responsible for the damage it has caused to
Theranos and its investors.

24 Several years ago, Theranos adapted its business plan to become a
25 clinical lab, and gave up significant opportunities in order to formalize
26 an exclusive relationship with Walgreens. As a small company, we
relied on Walgreens’ promise to help us build a substantial commercial
27 footprint. By failing to follow through on that promise and others,
Walgreens breached our contract and inflicted damage on Theranos
28 and its investors. Theranos has been considering affirmative litigation
against Walgreens for some time. In light of today’s news, we will
proceed aggressively to recoup the damage caused by Walgreens.”

78. The next day, November 18, 2016, the WSJ reported that counsel and director, David Boies, severed his ties with Theranos over disagreements with Holmes.

I. Plaintiffs Have Been Damaged As Theranos' Value Has Plummeted by Over Ninety Percent

79. As a result of Defendants' conduct, Plaintiffs have lost millions of dollars. While Theranos shares are not traded on any stock market, private investors purchased stakes in 2014 at a price that implied a \$9 billion valuation for the company, according to Forbes. The implied value in 2015 was likely even higher, with shares trading as high as \$19.00 per share.

80. On June 21, 2016, Forbes lowered its estimated value of Theranos. With the disclosures above, including information that Theranos' annual revenues are less than \$100 million, and discussions with venture capitalists, analysts and industry experts, Forbes concluded that a more realistic current value was \$800 million, as opposed to \$9 billion—a drop of more than 90%.

81. Today, Plaintiffs do not know if even that valuation is accurate. Plaintiffs believe that much of the \$724 million raised by investors may have been used up, and Theranos has been sued by Walgreens, other investors, and consumers for damages alleged to be in the hundreds of millions of dollars.

VI. CLASS ALLEGATIONS

82. Plaintiffs bring this action as a class action pursuant to Fed. R. Civ. P. 23 and seek certification of the following class:

All persons or entities who, directly or indirectly, purchased or committed to purchase (and subsequently closed a binding commitment to purchase) an interest in Theranos securities from July 29, 2013, through October 5, 2016.

Excluded from the proposed Class are Defendants, their officers and directors, and members of their immediate families or their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

83. The members of the proposed Class are so numerous that joinder of all members is impracticable. Plaintiffs believe that there are several hundred members in the proposed Class. Members of the proposed Class may be identified from records maintained by Defendants.

1 84. Plaintiffs' claims are typical of the claims of the members of the proposed Class as all
2 members of the proposed Class are similarly affected by Defendants' wrongful conduct as alleged
3 herein.

4 85. Plaintiffs will fairly and adequately protect the interests of the members of the
5 proposed Class and have retained counsel competent and experienced in complex class litigation.

6 86. Common questions of law and fact exist as to all members of the proposed Class and
7 predominate over any questions solely affecting individual members of the proposed Class. Among
8 the questions of law and fact common to the proposed Class are:

- 9 a. Whether Defendants' public statements omitted and/or misrepresented
10 material facts;
- 11 b. Whether Defendants' statements omitted material facts necessary in order to
12 make the statements made, in light of the circumstances under which they
13 were made, not misleading;
- 14 c. Whether Defendants knew or recklessly or negligently disregarded that their
15 statements were false and misleading;
- 16 d. Whether Defendants' conduct violated the UCL;
- 17 e. Whether Defendants' conduct violated California's securities laws;
- 18 f. Whether Defendants' conduct violated California common laws;
- 19 g. Whether Defendants' conduct harmed Plaintiffs and members of the Class;
- 20 h. The extent of damage sustained by Plaintiffs and the appropriate measure of
21 damages; and
- 22 i. Whether Plaintiffs and members of the Class are entitled to damages,
23 restitution, rescission, equitable relief, and/or injunctive relief.

24 87. A class action is superior to all other available methods for the fair and efficient
25 adjudication of this controversy since joining all members is impracticable, and this action will be
26 manageable as a class action.
27
28

VII. CAUSES OF ACTION

COUNT I

**SECURITIES FRAUD IN VIOLATION OF
CAL. CORP. CODE §§ 25400(D) & 25500
(AGAINST ALL DEFENDANTS)**

88. Plaintiffs repeat and reallege the allegations contained above as if fully set forth herein.

89. Defendants, for the purpose of inducing Plaintiffs' purchase of securities, made or materially participated in the act of making false and misleading statements of material fact and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. These misrepresented and omitted material facts include but are not limited to an extensive advertising campaign that employed press releases, interviews with the media, and extensive social media, including web pages, in which they made statements that were materially false, misleading, or contained material omissions, including: (1) Theranos was not "now" (or ever) capable of performing its agreement with Walgreens; (2) Theranos did not have necessary regulatory approval to use its "tests using micro-samples" on its proprietary device --- the nanotainer; (3) Theranos' labs were not in compliance with CLIA standards; (4) Theranos proprietary technology had not "reached a point at which [it] could make actionable information accessible to physicians and patients" using its proprietary technology; (5) Theranos would have to dilute "micro-samples" and run them on traditional lab machines of competitors in order to create the illusion that their proprietary technology was working; (6) Theranos' processes were not faster, cheaper and more accurate than the conventional methods, (7) that Theranos' proprietary technology was not ready for commercial use; (8) that Theranos' interactions with the FDA, were neither good nor voluntary; (9) that Theranos' proprietary technology would not be used as the primary technology for the Walgreens partnership; (10) that Theranos lied to Walgreens in order to induce them to enter into a partnership; (11) that Theranos was lying to consumers and providing them with inaccurate blood tests; (12) that Theranos used equipment made by other manufacturers, as opposed to its proprietary analyzers, to test customers'

1 blood samples; and (13) that only twelve blood tests were ever run on Theranos' equipment and that
2 all tests had ceased at various points between December 2014 and June 2015.

3 90. Defendants knew or had reasonable grounds to believe that these statements and
4 omissions were false and misleading. Due to Theranos' extreme secrecy, additional information
5 regarding Defendants' knowledge of falsity is peculiarly within Defendants' knowledge and control.

6 91. As a direct and proximate result of the fraudulent conduct of Defendants, Plaintiffs
7 have been damaged.

8 **COUNT II**

9 **SECURITIES FRAUD IN VIOLATION OF**
10 **CAL. CORP. CODE §§ 25401, 25501 & 25504**
(AGAINST ALL DEFENDANTS)

11 92. Plaintiffs repeat and reallege the allegations contained above as if fully set forth
12 herein.

13 93. Defendants offered to sell, and did sell, securities to Plaintiffs by means of written and
14 oral communications that included untrue statements of material fact and omitted to state material
15 facts necessary to make the statements made, in light of the circumstances under which the
16 circumstances were made, not misleading. These misrepresented and omitted material facts include
17 but are not limited to those described in ¶ 89.

18 94. Defendants directly or indirectly controlled Theranos, or are principal executive
19 officers or directors of Theranos, or perform similar functions, or are Theranos employees who
20 materially aided the statements or omissions alleged above.

21 95. Defendants knew or had reasonable grounds to believe that these statements and
22 omissions were false and misleading and Plaintiffs, who exercised reasonable care, had no
23 knowledge of the falsity of Defendants' statements.

24 96. As a direct and proximate result of the fraudulent conduct of Defendants, Plaintiffs
25 have been damaged.

COUNT III

**VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW
(CAL. BUS. & PROF. CODE § 17200 ET SEQ.)
(AGAINST ALL DEFENDANTS)**

97. Plaintiffs repeat and reallege the allegations contained above as if fully set forth herein.

98. Defendants engaged in unlawful business practices in violation of the Unfair Competition Law by violating the Corporate Securities Law of 1968, Cal. Corp. Code §§ 25400(d), 25401, 25500, and 25501. Defendants also engaged in unlawful business practices in violation of the Unfair Competition Law by committing fraud and deceit, fraudulent concealment, constructive fraud, and negligent misrepresentation.

99. Defendants engaged in fraudulent business practices in violation of the Unfair Competition Law by making statements to Plaintiffs that were materially false, and by failing to disclose information that made other statements materially misleading, including with respect to the topics described in ¶ 89.

100. Defendants engaged in unfair business practices in violation of the Unfair Competition Law because their business practices were immoral, unethical, oppressive, unscrupulous, and caused injury to consumers, and the gravity of their conduct outweighs any alleged benefits attributable to such conduct. Defendants' business practices violate public policy because they directly implicate the public interest by impacting matters of great importance to the public. Blue sky laws like California's Corporate Securities Law of 1968 were enacted to protect the public from fraud and deception in transactions involving securities, like the investment at issue here. Moreover, Defendants' unfair business practices have caused harm to consumers as Theranos voided, as invalid, tens of thousands of test results it provided to patients.

101. Plaintiffs have suffered injury in fact and have lost money as a result of Defendants' unlawful, fraudulent, and unfair conduct.

102. Plaintiffs are entitled to restitution in the amount of their Theranos investment, because that investment was obtained through unlawful, fraudulent, and unfair business practices.

COUNT IV

**FRAUD AND DECEIT
(CAL. CIV. CODE §§ 1709 & 1710 AND COMMON LAW)
(AGAINST ALL DEFENDANTS)**

103. Plaintiffs repeat and reallege the allegations contained above as if fully set forth herein.

104. Defendants, for the purpose of inducing Plaintiffs' purchase of securities, made false and misleading statements of material fact and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. These material misrepresentations and omissions include the topics described in ¶ 89.

105. Defendants knew their representations were untrue or made such representations with reckless indifference to the truth or in a manner not warranted by the information known to Defendants.

106. Defendants purposefully made these misrepresentations to induce reliance by Plaintiffs in order to convince Plaintiffs to purchase Theranos securities directly or indirectly.

107. Plaintiffs were unaware of and reasonably and justifiably relied upon Defendants' material misrepresentations in purchasing and remaining invested in Theranos securities as well as foregoing other potential investment opportunities.

108. Plaintiffs' harm was a direct result of their reliance on Defendants' material misrepresentations.

COUNT V

**FRAUDULENT CONCEALMENT
(CAL. CIV. CODE § 1710 AND COMMON LAW)
(AGAINST ALL DEFENDANTS)**

109. Plaintiffs repeat and reallege the allegations contained above as if fully set forth herein.

110. Defendants deliberately concealed material information, including with respect to the topics described in ¶ 89. Defendants made partial representations and concealed material facts and thus had a duty to fully disclose facts in order to prevent the statements they actually made from being misleading. In addition, Holmes and Balwani, as directors and officers of Theranos, owed a

1 duty to Plaintiffs, as Theranos investors and stockholders, and had a duty to refrain from any act that
2 breached the trust reposed in them.

3 111. Defendants had exclusive knowledge of the concealed material facts and Plaintiffs did
4 not know and could not reasonably be expected to know of these facts.

5 112. Defendants knew or had reason to know that the information they concealed was
6 material, but they continued to purposefully and actively conceal material information to induce
7 Plaintiffs' reliance. Due to the Company's extreme secrecy, additional information regarding
8 Defendants' knowledge is peculiarly within Defendants' knowledge and control.

9 113. Plaintiffs reasonably and justifiably relied upon Defendants' material misstatements
10 and omissions and purchased and remained invested in Theranos securities and forewent other
11 potential investment opportunities due to Defendants' actions. Defendants' concealment was a
12 substantial factor in causing Plaintiffs harm.

13 **COUNT VI**

14 **CONSTRUCTIVE FRAUD**
15 **(CAL. CIV. CODE § 1573 AND COMMON LAW)**
(AGAINST ALL DEFENDANTS)

16 114. Plaintiffs repeat and reallege the allegations contained above as if fully set forth
17 herein.

18 115. Defendants made statements to Plaintiffs that were materially false, and failed to
19 disclose information that made other statements materially misleading, including with respect to the
20 topics described in ¶ 89. Defendants had a duty to disclose such information in order to prevent the
21 statements they actually made from being misleading. In addition, Holmes and Balwani, as directors
22 and officers of Theranos, owed a duty to Plaintiffs, as Theranos investors and stockholders, and had
23 a duty to refrain from any act that breached the trust reposed in them.

24 116. Defendants misled Plaintiffs to their prejudice by inducing Plaintiffs to purchase
25 Theranos securities, providing Defendants financial gain to their advantage.

26 117. Plaintiffs were reasonably and justifiably misled by relying on Defendants' material
27 misrepresentations and omissions.

1 118. As a direct and proximate result of Defendants' misleading statements, Plaintiffs were
2 damaged.

3 **COUNT VII**

4 **NEGLIGENT MISREPRESENTATION**
5 **(CAL. CIV. CODE § 1710 AND COMMON LAW)**
6 **(AGAINST ALL DEFENDANTS)**

7 119. Plaintiffs repeat and reallege the allegations contained above as if fully set forth
8 herein.

9 120. By virtue of their involvement in selling Theranos securities directly or indirectly to
10 Plaintiffs and accepting Plaintiffs' investments, Defendants had a particular duty to provide accurate
11 information about Theranos' business, based on Plaintiffs' pecuniary interest in that information.

12 121. Defendants supplied to Plaintiffs false material information and made material
13 omissions, including the information described in ¶ 89.

14 122. Defendants had no reasonable ground for believing their representations were true
15 when made yet intended that Plaintiffs rely on their representations in order to solicit funding for
16 Theranos.

17 123. Plaintiffs reasonably and justifiably relied on the false information communicated by
18 Defendants and sustained pecuniary loss as a direct and proximate result of such reliance.

19 **DEMAND FOR RELIEF**

20 WHEREFORE, Plaintiffs, individually and for members of the Class, respectfully request
21 that the Court enter judgment in their favor and against Defendants, as follows:

22 A. Certification of the proposed Class, including appointment of Plaintiffs' counsel as
23 Class Counsel and Plaintiffs as class representatives;

24 B. Cost, restitution, rescission, damages, including punitive damages, and disgorgement
25 in an amount to be determined at trial;

26 C. An order requiring Defendants to pay both pre- and post-judgment interest on any
27 amounts awarded;

28 D. An award of pre-judgment and post-judgment interest; and

E. Such other and further relief as may be proper.

JURY DEMAND

Plaintiffs demand a jury trial on all issues.

DATED: November 28, 2016

Respectfully submitted,

HAGENS BERMAN SOBOL SHAPIRO LLP

By: /s/ Reed R. Kathrein

Reed R. Kathrein (139304)

Peter E. Borkon (212596)
Nicholas S. Singer (306098)
715 Hearst Ave., Suite 202
Berkeley, CA 94710
Telephone: (510) 725-3000
Facsimile: (510) 725-3001
reed@hbsslaw.com
peterb@hbsslaw.com
nsinger@hbsslaw.com

Steve W. Berman (*pro hac vice* applied for)
HAGENS BERMAN SOBOL SHAPIRO LLP
1918 Eighth Avenue, Suite 3300
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594
steve@hbsslaw.com

*Counsel for Plaintiffs and Proposed Lead
Counsel for the Class*