UNITED STATES DISTRICT COURT WESTERN DISTRICT OF TEXAS

JOHN HARVEY SCHNEIDER, Individually and on Behalf of All Others Similarly Situated,

Case No. 1:22-cv-00398

Plaintiff,

v.

NATERA, INC., STEVE CHAPMAN, MICHAEL BROPHY, MATTHEW RABINOWITZ, and RAMESH HARIHARAN,

Defendants.

DEMAND FOR JURY TRIAL

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Plaintiff John Harvey Schneider ("Plaintiff"), by and through his counsel, alleges the following based upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters, including the investigation of Plaintiff's counsel, which included, among other things, a review of Defendants' (defined below) United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by Natera, Inc. ("Natera" or the "Company"), analyst reports and advisories about the Company, media reports concerning the Company, judicial filings and opinions, and other publicly available information. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION AND OVERVIEW

1. This is a class action lawsuit on behalf of a class of all persons and entities who purchased or otherwise acquired Natera common stock between February 26, 2020, and April 19,

2022, inclusive (the "Class Period"), seeking to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and SEC Rule 10b-5 promulgated thereunder.

- 2. Natera, a Delaware corporation with principal executive offices in Austin, Texas, offers genetic testing in the areas of women's health, oncology, and organ health. Among other things, the Company produces and markets a non-invasive prenatal test ("NIPT") called "Panorama," and a screening test for kidney transplant failure called "Prospera." Natera's common stock trades on the NASDAQ under the ticker symbol "NTRA."
- 3. Throughout the Class Period, Defendants repeatedly assured investors that Panorama was reliable, that Prospera was more accurate than competing tests, and that Natera's growth was driven by its superior technology and customer experience.
- 4. However, investors began to learn the truth on January 1, 2022, when *The New York Times* published a detailed report calling into question the accuracy of certain prenatal tests manufactured by Natera and other diagnostic testing companies. Among other things, *The New York Times* reported that Natera's positive results for several genetic disorders were incorrect more than 80 percent of the time.
- 5. On this news, the price of Natera common stock fell \$5.35 per share, or approximately 6% over two trading days, from a close of \$93.39 per share on December 31, 2021, to close at \$88.04 per share on January 4, 2022.
- 6. Less than two weeks later, on January 14, 2022, the Campaign for Accountability—a nonprofit watchdog group—filed a complaint with the SEC requesting an investigation as to whether "Natera repeatedly claimed in marketing materials and earnings calls that [its] tests are much more reliable than it appears they really are."

- 7. On this news, the price of Natera common stock fell \$6.29 per share, or more than 9%, from a close of \$67.37 per share on January 14, 2022, to close at \$61.08 per share on January 18, 2022.
- 8. Then, on March 9, 2022, Hindenburg Research ("Hindenburg") issued an investigative report (the "Hindenburg Report") alleging, among other things, that "Natera's revenue growth has been fueled by deceptive sales and billing practices aimed at doctors, insurance companies and expectant mothers."
- 9. On this news, the price of Natera common stock fell as much as \$28.65 per share, or more than 52%, from a close of \$54.75 per share on March 8, 2022, to an intra-day low of \$26.10 per share on March 9, 2022.
- 10. On March 14, 2022, a jury found that Natera had intentionally and willfully misled the public by utilizing false advertisements to market Prospera in violation of the federal Lanham Act, the Delaware Deceptive Trade Practices Act, and Delaware common law. Among other things, the jury found that Natera's marketing falsely claimed that Prospera was more accurate than the competing kidney transplant testing offered by CareDx, Inc. ("CareDx"). Ultimately, the jury awarded CareDx \$44.9 million in monetary damages.
- 11. On this news, Natera common stock fell as much as \$8.81 per share, or approximately 22.5%, from an intra-day high of \$39.13 per share on March 14, 2022, to close at \$30.32 per share on March 15, 2022.
- 12. On April 19, 2022, the United States Food and Drug Administration ("FDA") issued a safety communication "to educate patients and health care providers and to help reduce the inappropriate use of [NIPTs]." The FDA cautioned that statements about NIPTs' reliability and accuracy "may not be supported with sound scientific evidence" and revealed the existence of

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"cases where a screening test reported a genetic abnormality and a confirmatory diagnostic test later found that the fetus was healthy." The FDA suggested that patients discuss benefits and risks with a healthcare provider before deciding to undergo NIPT or making any pregnancy-related decisions on the basis of NIPT results. In addition, the FDA advised health care providers that they should not rely on NIPT results alone to diagnose chromosomal abnormalities or disorders.

- 13. On this news, the price of Natera common stock fell as much as \$1.53 per share, or approximately 3.9%, from an intra-day high of \$39.63 per share on April 19, 2022, to close at \$38.10 per share on April 20, 2022.
- 14. This Complaint alleges that, throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts, about the Company's business and operations. Specifically, Defendants misrepresented and/or failed to disclose: (1) Panorama was not reliable and resulted in high rates of false positives; (2) Prospera did not have superior precision compared to competing tests; (3) as a result of Defendants' false and misleading claims about Natera's technology, the Company was exposed to substantial legal and regulatory risks; (4) Natera relied upon deceptive sales and billing practices to drive its revenue growth; and (5) as a result of the foregoing, Defendants' statements about the Company's business, operations, and prospects lacked a reasonable basis.
- 15. As a result of Defendants' wrongful acts and omissions, and the significant decline in the market value of the Company's securities, Plaintiff and other members of the Class have suffered significant damages.

II. JURISDICTION AND VENUE

16. Plaintiff's claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and SEC Rule 10b-5, promulgated thereunder (17 C.F.R. § 240.10b-5).

- 17. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.
- 18. Venue is proper in this District under Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b), because Natera's principal executive offices are located in this District, and because many of the acts and conduct that constitute the violations of law complained of herein, including the dissemination to the public of materially false and misleading information, occurred in this District.
- 19. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the United States mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

- 20. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Natera common stock at artificially inflated prices during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.
- 21. Defendant Natera is a Delaware corporation headquartered at 13011 McCallen Pass, Building A Suite 100, Austin, Texas 78753.
- 22. Defendant Steve Chapman ("Chapman") served as the Company's Chief Executive Officer and a Company director throughout the Class Period.
- 23. Defendant Michael Brophy ("Brophy") served as the Company's Chief Financial Officer throughout the Class Period.
- 24. Defendant Matthew Rabinowitz ("Rabinowitz") served as the Company's Executive Chairman throughout the Class Period.

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- 25. Defendant Ramesh Hariharan ("Hariharan") served as the General Manager of the Company's Women's Health Division throughout the Class Period.
- 26. Defendants Chapman, Brophy, Rabinowitz, and Hariharan are collectively referred to herein as the "Individual Defendants."
- 27. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Natera's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, i.e., the market. Each Individual Defendant was provided with copies of the Company's reports alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and/or were being concealed from, the public, and that the positive representations that were being made were then materially false and/or misleading.
- 28. Natera and the Individual Defendants are collectively referred to herein as "Defendants."

IV. SUBSTANTIVE ALLEGATIONS

A. Background

29. Natera, a Delaware corporation with principal executive offices in Austin, Texas, offers genetic testing in the areas of women's health, oncology, and organ health. Among other things, the Company produces and markets Panorama (a NIPT) and Prospera (which screens for kidney transplant failure). The Company's technology evaluates single nucleotide polymorphisms ("SNPs"), the most common type of genetic variation among people.

- 30. Panorama assesses cell-free DNA ("cfDNA") from a pregnant woman's bloodstream to determine whether her baby is at heightened risk for certain genetic conditions. Specifically, Panorama screens for fetal chromosomal abnormalities—including Down syndrome, Edwards syndrome, Patau syndrome, Turner syndrome, and triploidy—that may result in intellectual disability, severe organ abnormalities, and/or miscarriage. Panorama can also be used to determine a baby's sex. Moreover, physicians may also order a microdeletions panel with Panorama that screens for several genetic diseases caused by missing sub-chromosomal pieces of DNA, including DiGeorge syndrome, Angelman syndrome, Cri-du-chat syndrome, and Prader-Willi syndrome.
- 31. Prospera assesses cfDNA from the blood of patients who have received kidney transplants to assess active rejection, which occurs when a patient's immune system attacks the transplanted kidney. Prospera is designed to help physicians "rule in or rule out active rejection when evaluating the need for diagnostic testing or the results of an invasive biopsy, and thereby potentially lowering the overall costs associated with transplant care and improving graft survival."

B. Defendants' False and Misleading Statements

32. The Class Period begins on February 26, 2020, to coincide with the Company's announcement of its financial results for the fourth quarter and full year 2019. Among other things, the Company reported revenues of \$302.3 million in 2019, a year-over-year increase of more than 17%. The reported figures exceeded consensus estimates of \$296.8 million. In the Company's press release announcing these results, Defendant Chapman emphasized that 2019 was "a transformational year for Natera" driven by "excellent data, securing coverage decisions, and signing significant commercial partnerships." Defendant Chapman further touted that Natera was "well positioned to continue [its] momentum in 2020 and beyond."

- 33. On March 2, 2020, the Company filed its annual report for the year ended December 31, 2019, with the SEC on Form 10-K (the "2019 Annual Report"). The 2019 Annual Report, which was signed by Defendant Brophy, stated that Natera's technology "has been proven clinically and commercially in the reproductive health space, in which we develop and commercialize non- or minimally- invasive tests to evaluate risk for, and thereby enable early detection of, a wide range of genetic conditions, such as Down syndrome." In fact, Defendants claimed that Panorama is "overall the most accurate NIPT commercially available in the United States."
- 34. As required by the Sarbanes-Oxley Act of 2002, Defendants Chapman and Brophy certified that they had reviewed the 2019 Annual Report and that it "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."
- 35. Defendants continued to tout Panorama's reliability throughout the Class Period. For example, during an earnings call on May 6, 2020, Defendant Chapman represented that Panorama is "a highly technically differentiated product" with "multiple unique clinical features that are unmatched by our competitors." Chapman further stated that Natera expected data from its ongoing SMART study, which evaluated the performance of Panorama in the context of routine clinical care over the course of five years, to be published later in 2020, and assured investors that the "study has a very significant opportunity to move the market[] the rest of the way forward if we're not there by then."
- 36. Similarly, during the Company's August 5, 2020 earnings call, Defendant Chapman again touted Panorama's purported accuracy and resulting success, stating that the

Company "continue[s] to push out evidence that shows [Panorama's] unique aspects" and that "physicians now recognize us as both the clinical and market leader" in NIPT.

- 37. On October 29, 2020, Natera issued a press release announcing that Humana, a major health plan, had extended coverage for NIPT to 17 million additional covered lives and estimated that, in all, NIPT was covered for 139 million commercial lives. In connection with this announcement, Defendant Hariharan represented that "[t]he average risk NIPT market still remains highly underpenetrated," and assured investors that Panorama's "unique SNP-based clinical advantages" placed the Company "in a very strong position to capitalize on the [market] opportunity."
- 38. During the Company's November 5, 2020 earnings call, Defendant Chapman claimed that Natera's SMART study is "the gold standard in NIPT and the gold standard in microdeletions," and that the results from the SMART study would be "strong enough to change society guidelines and to drive payer coverage" for Panorama. Chapman further represented that the Company's focus on "improving NIPT and . . . delivering [awesome] user experience" was successfully helping the Company to make its Women's Health business segment "the leading franchise" in the market.
- 39. Less than a month later, on December 1, 2020, Natera issued a press release announcing that "the largest health plan in the United Stated ha[d] extended coverage of NIPT to all pregnancies." In the press release, Defendant Hariharan claimed that "[a]s the market leader, Natera is in a strong position to capitalize on the significant volume growth opportunity and improved test economics resulting from these policy changes."
- 40. Just two days later, on December 3, 2020, Natera announced that the U.S.'s second-largest commercial insurer would also cover NIPT for all pregnancies. Defendants again touted

that "all 20 of the largest commercial payors now cover NIPT, independent of prior risk," and stating that, "[w]ith [Natera's] unique SNP-based NIPT, we will have an even greater opportunity to make a positive impact on prenatal care."

- 41. During an earnings call on February 25, 2021, Defendant Chapman described the Company's fourth quarter of 2020 as "the best quarter we've ever had at Natera." Chapman largely attributed the Company's strong results to Panorama, reporting that by January 2021, all major national insurance plans authorized NIPT coverage for all pregnant women, and that many Medicaid plans were also offering coverage for NIPT. He further represented that "Panorama is the market leading NIPT" that "deliver[s] best in class performance and differentiated clinical value."
- 42. During the same earnings call, Defendant Chapman also informed investors that the Company had released the results of its SMART study. Chapman touted the results as "even stronger than expected" and represented that the results placed Natera "in an excellent position to achieve reimbursement for [its] microdeletions tests and further drive market share gains within the NIPT space." To this end, Chapman claimed that microdeletion screening was "a rocket ship that's growing," and that if the Company achieved reimbursement, it would be "off to the races." Defendants further assured investors that the SMART study legitimized Panorama's performance, with Defendant Rabinowitz stating that the SMART study "confers a significant advantage and further separates [Natera] from NIPT that have limited or no peer-reviewed data."
- 43. On February 26, 2021, the Company filed its annual report for the year ended December 31, 2020 with the SEC, on Form 10-K (the "2020 Annual Report"). The 2020 Annual Report was signed by Defendant Brophy and again touted Panorama's accuracy, stating that the

test had demonstrated "greater than 99% overall sensitivity for aneuploidies" on certain chromosomes and for triploidy, as well as "specificity of greater than 99.9% (less than 0.1% false positive rate) for each disorder" screened. Defendants further claimed that Panorama "had a statistically significant lower false positive rate than other NIPT methods practiced by [its] U.S. competitors" and had "demonstrated the ability to identify fetal sex more accurately than competing NIPTs."

- 44. With respect to Prospera, the 2020 Annual Report represented that the test exhibits a "high degree of accuracy" in "challenging cases" where kidney donors are close biological relatives of the patient, and touted that Prospera has "superior precision" to competing tests.
- 45. As required by the Sarbanes-Oxley Act of 2002, Defendants Chapman and Brophy certified that they had reviewed the 2020 Annual Report and that it "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."
- 46. During the 10th Annual SVB Leerink Global Healthcare Conference on February 26, 2021, an SVB Leerink analyst asked Defendants about the Company's position in the future NIPT market. In response, Defendant Chapman boasted that, of competing NIPTs, Panorama had "the most significant body of evidence" in its support, further stating that the SMART study was "the most robust validation study that's ever been done where the performance of our test held up." Chapman specifically claimed that Panorama was "a truly unique assay that not only now is clinically and technically differentiated, but is now backed by just a wealth of peer-reviewed published data," and that "it's really night and day when you compare the technologies and you compare the amount of data that's out there." Chapman further assured

investors that "we see things really accelerating from here" and that Natera is "really well positioned right now to move and extend our market share as the NIPT market becomes further and further penetrated." Similarly, Chapman also claimed that because the Company has "great new data coming out" and "additional clinical differentiators," the "momentum is going to be accelerating in the NIPT space."

- 47. During the Company's May 6, 2021 earnings call, Defendant Chapman stated that the Company's "growth rates have still continued to accelerate." Specifically, Chapman represented that Natera's success was "being driven by continued strong growth in the Women's Health business," but further noted that "we are seeing some real benefit from oncology and organ health as well."
- 48. During the same call, Defendant Chapman also assured investors that Natera, which then held about 30% of the prenatal testing market for average risk patients, expected to capture a significant portion of the remaining 70% because Panorama has "higher sensitivity and specificity on things like [trisomy] 21 in the standard chromosomes." Chapman again represented that the "difference in the performance" between Panorama and other NIPTs is "really night and day," stating that "we're talking about sensitivity in the 90s versus others that have published performance sensitivity in the 20s." He also assured investors of the reliability of, and strong prospects for, Panorama's microdeletions panel:

[O]ur test works really, really well. So, the sensitivity was very high, and the positive predictive value is also very high. . . . [W]e think we're in a good position to, at some point in the future, get into the guidelines and then receive payer coverage. And we're doing hundreds of thousands of these tests already every year that are not reimbursed. So, as soon as reimbursement comes in, this is going to be an immediate, very significant impact to Natera's revenue and the bottom line.

- 49. During the Company's earnings call on August 5, 2021, Defendant Chapman told investors that "Q2 was the fastest year-on-year growth for both volumes and revenues we've had as a public company" and highlighted that Natura had "exceeded the top end of [its] preannouncement ranges in units process[ed], total revenue and product revenue." Specifically, Chapman explained that Natera had "processed 376,000 tests in Q2, which was approximately 61% growth over the same period last year."
- 50. Defendant Chapman also emphasized the performance of Natera's women's health products, stating that Natera had "been just crushing it." Chapman further claimed that the Company was "accelerating" at "a whole different level of growth" and that, given its "great technology," the Company was "in a fantastic position." Chapman once again touted Panorama's purportedly reliable data, stating that Natera was "benefiting from [its] SMART trial data..., which set a new bar in quality and size for NIPT validation data." Specifically, Chapman stated:

[S]ome of the big academic centers and maternal fetal medicine practices that hadn't been using [Panorama] before considering a switch are now looking at that data and they're excited about it, because this type of -- this quality of [data] hasn't been produced before. So . . . we are having competitive wins, but we're also seeing the market penetrate.

- 51. Chapman also projected significant growth for the Company, representing that Natera is "clearly in the early stages of expanding from roughly 1.5 million NIPTs [annually] in the United States to what could be more than 4 million NIPTs [annually] over time."
- 52. With respect to Prospera, Defendant Chapman boasted that Prospera was more accurate than a competing test, correctly identifying 5 out of 6 transplant rejections in a recent study while the competitor correctly identified only 4 out of 6 rejections. He also recalled "a previously reported head to head study where the Prospera test detected more cases of rejection" than a competing test.

- Defendant Brophy expressed further confidence in attaining future growth on the basis of Natera's technology. Specifically, Brophy projected a substantial increase in the number of NIPTs that would be performed in the upcoming years, explaining "we're starting to see that growth" and that "[w]e're just starting to see that market penetration." Brophy further assured investors that "[a]s a market leader we feel like we're very well position[ed] to get more than our fair share of that just natural increase in the NIPT testing market."
- 54. On September 9, 2021, Defendants issued a press release announcing the launch of Prospera Kidney with Quantification, the only commercially-available cfDNA test that provides three values (quantity of donor-derived cfDNA, fraction of dd-cfDNA, and total cfDNA). In the press release, Defendants touted that Prospera with Quantification "improve[d] sensitivity when evaluating transplant rejection, compared to using dd-cfDNA fraction alone."
- 55. During the Company's November 4, 2021 earnings call, Defendant Chapman again described Natera's NIPT as "the gold standard" and predicted that Prospera would follow a similar trajectory. Specifically, Defendant Chapman assured investors that "we now have the most significant prospective data in the space" and assured investors that "[w]ith regards to some of the challenges with the competitive landscape [for transplant rejection testing], we don't think that there's any blowback to Natera."
- 56. Defendant Chapman further represented that Natera was "in a very good position and [Natera] look[s] forward to competing hard." Ultimately, Defendant Chapman emphasized that the Company's "acceleration [was] being driven by continued strong growth in the women's health products and big contributions from oncology and transplant products" and that "[t]hose products are now large enough to shift [Natera's] growth rates upward."

57. The above statements identified in paragraphs 32-56 were materially false and misleading, and failed to disclose material adverse facts about the Company's business and operations. Specifically, Defendants misrepresented and/or failed to disclose that: (1) Panorama was not reliable and resulted in high rates of false positives; (2) Prospera did not have superior precision compared to competing tests; (3) as a result of Defendants' false and misleading claims about Natera's technology, the Company was exposed to substantial legal and regulatory risks; (4) Natera relied upon deceptive sales and billing practices to drive its revenue growth; and (5) as a result of the foregoing, Defendants' statements about the Company's business, operations, and prospects lacked a reasonable basis.

C. The Truth Emerges

- 58. Investors began to learn the truth about the Company's business on January 1, 2022, when *The New York Times* published a detailed report calling into question the accuracy of certain NIPTs manufactured by Natera and other diagnostic testing companies (the "NYT Report"). Specifically, the NYT Report concluded that "[t]he grave predictions made by those newer tests are usually wrong," and stated that for tests for microdeletion disorders such as DiGeorge and Prader-Willi syndromes, Natera's positive results are incorrect more than 80 percent of the time. For example, with respect to DiGeorge syndrome, the NYT Report explained that recent Natera data suggested that Panorama would return three times as many false positives as actual cases of the disorder.
- 59. The NYT Report also pointed to a number of negative impacts from false results, including pregnant women obtaining abortions based on unconfirmed positive results, and expectant parents incurring severe emotional anguish in the perhaps mistaken belief that their fetuses have incurable genetic disorders.

- 60. Moreover, the NYT Report included statements from industry experts, including a former U.S. Food and Drug Administration director and genetic experts, who characterized the information that Natera and other companies provided about their NIPTs as "misleading" and "purely a marketing thing."
- 61. On this news, the price of Natera common stock fell \$5.35 per share, or approximately 6% over two trading days, from a close of \$93.39 per share on December 31, 2021, to close at \$88.04 per share on January 4, 2022.
- 62. Notwithstanding the NYT Report, Defendants attempted to reassure investors of Panorama's reliability. For example, in a January 3, 2022 press release, Defendants asserted that the NYT Report's claims about the inaccuracy of Natera's testing were incorrect, and claimed that Panorama was accurate in over 99% of cases. In the press release, Defendants also claimed that the positive predictive value of Natera's microdeletion testing "compare[s] favorably to historically accepted maternal serum based prenatal screening methods" and argued that the NYT Report had ignored the "important role of screening tests" in identifying "the subset of high risk individuals."
- 63. On January 10, 2022, during J.P. Morgan's 40th Annual Healthcare Conference, Defendant Chapman continued to tout Panorama's reliability, stating that "[o]ne of the things [Natera is] really proud of . . . is that all of our products are supported and driven by real-world peer-reviewed data" including "more than 100 peer-reviewed papers supporting the performance of [Panorama] and that includes studying more than 1.3 million patients across those studies."
- 64. During the same conference, Defendant Chapman touted Natera's status as a "market leader" in NIPT, which Chapman attributed to four factors: (1) "having leading-edge technology and constant innovation"; (2) "extreme focus on customer experience and support

- services"; (3) "being the number one in clinical data and having expert clinical teams"; and (4) "having a broad and talented commercial team and a broad distribution channel."
- 65. Additionally, with respect to transplant rejection testing, Defendant Chapman stated that "we're seeing great growth off the strength of [Prospera]. We're working with about 50% of the top transplant centers, and we're very pleased with the uptick that we've seen."
- 66. Then, on January 14, 2022, the Campaign for Accountability—a non-profit watchdog group—filed a complaint requesting that the SEC investigate whether "Natera repeatedly claimed in marketing materials and earnings calls that [its] tests are much more reliable than it appears they really are."
- 67. On this news, the price of Natera common stock fell \$6.29 per share, or more than 9%, from a close of \$67.37 per share on January 14, 2022, to close at \$61.08 per share on January 18, 2022.
- 68. Despite the Campaign for Accountability's complaint, Defendants continued to tout the abilities of Natera's purported testing accuracy and positive user experiences to drive growth. During the 11th Annual SVB Leerink Global Healthcare Conference on February 16, 2022, Defendant Chapman again stated that Natera was "the market leader" for NIPT, had "the most patients studied in clinical trials," and was "in a good position to ride that wave of penetration for the next three years."
- 69. During the same conference, Defendant Chapman also noted that the Company had "done exceptionally well in kidney transplant" and was "continuing to see growth penetration deep into some of the core large institutions around the country."
- 70. The next day, on February 17, 2022, Natera issued a press release announcing the results of a study "confirming strong performance of its Prospera donor-derived cell-free DNA

(dd-cfDNA) test in assessing rejection for kidney transplant patients." Defendants claimed that in the study, "[e]ighteen of the 28 patients with biopsy-matched high-risk . . . test results were confirmed to have active rejection, demonstrating a reported 64% positive predictive value (PPV)."

71. During the Company's quarterly conference call on February 24, 2022, Defendant Chapman again touted Panorama's accuracy, stating:

Panorama test results were accurate[] greater than 99.9% of the time, meaning that 99.9% of the time the Panorama result[,] whether high risk or low risk[,] was confirmed to be correct. For high-risk results only we had a positive predictive value or PPV of 53% meaning that more than 1 in 2 pregnancies screening high risk with Panorama were confirmed to be effective, using a confirmatory diagnostic test. This is really strong, especially compared to traditional prenatal test[s] . . . offered routinely to all pregnant women in the United States for the past 40 years that have a PPV of only 3.5% or 1 in 29.

72. Then, on March 9, 2022, Hindenburg Research issued an investigative report alleging, among other things, that "Natera's revenue growth has been fueled by deceptive sales and billing practices aimed at doctors, insurance companies and expectant mothers." Specifically, the Hindenburg Report claimed:

Natera has driven its revenue through a combination of (a) improper insurance billing, (b) promising women they will never have to pay more than certain low rates, then later engaging in aggressive practices to charge more and (c) "unbundling" test screens into multiple payment codes to attempt to charge BOTH payors and patients for the same overall screen.

While Natera's technology seems to provide a modest edge (after the necessary sequencing has taken place) we think the company's ascension to its top position in the industry has been mostly fueled by its willingness to engage in deceitful sales and billing practices.

73. The Hindenburg Report further detailed Natera's reliance on aggressive sales tactics, including automatically ordering Panorama's optional microdeletion screening with every

Panorama test unless a physician specifically opts out of the additional panel. The Hindenburg Report also explained that Natera regularly refuses to provide customers with detailed invoices and promotes lower cash prices to patients to incentivize them to forego using their health plans, constituting possible acts of insurance fraud and tortious interference with contract.

- 74. The Hindenburg Report also revealed that state officials in Michigan are investigating Natera. Specifically, Michigan's Department of Attorney General had cited "an open and ongoing Department investigation" when declining to provide Hindenburg with documents about Natera under Michigan's Freedom of Information Act.
- 75. The Hindenburg Report concluded that "Natera's tests just don't add much value to the health industry ecosystem relative to competitors," given that "[i]ts NIPTs are [only] marginally better than the competition, and its microdeletion screens regularly result in more harm than good."
- 76. On this news, the price of Natera common stock fell as much as \$28.65 per share, or more than 52%, from a close of \$54.75 per share on March 8, 2022, to an intra-day low of \$26.10 per share on March 9, 2022.
- 77. On March 14, 2022, a federal jury in *CareDx, Inc. v. Natera, Inc.*, No. 19-cv-662-CFC-CJB (D. Del.), found that Natera had intentionally and willfully misled the public by utilizing false advertisements to market Prospera in violation of the federal Lanham Act, the Delaware Deceptive Trade Practices Act, and Delaware common law.
- 78. In the lawsuit, competing testing company CareDx alleged that Natera relied on results from a flawed clinical trial to make misleading statements about Prospera, including that Prospera was more effective than CareDx's competing AlloSure test. The jury found that Natera was liable for false advertising when it claimed, *inter alia*, that Prospera was "[m]ore sensitive and

specific than current assessment tools across all types of rejection," led to a "[1]ower risk of missing active rejection," had exhibited "[s]tronger test performance demonstrated with unique clinical capabilities," and demonstrated "[s]uperior [p]recision." The jury awarded CareDx \$44.9 million in monetary damages, which included \$23.7 million in punitive damages.

- 79. On this news, Natera common stock fell as much as \$8.81 per share, or approximately 22.5%, from an intra-day high of \$39.13 per share on March 14, 2022, to close at \$30.32 per share on March 15, 2022.
- 80. On April 19, 2022, the FDA issued a safety communication "to educate patients and health care providers and to help reduce the inappropriate use of [NIPT]." The FDA expressed concern that many NIPT providers represent that their tests are "reliable" and "highly accurate," noting that "these claims may not be supported with sound scientific evidence." Echoing concerns raised in the NYT Report, the FDA cautioned:

False claims may cause patients as well as health care providers to believe the test results are reliable and can be used alone to make decisions about the pregnancy. In addition, because some of the genetic abnormalities and disorders are so rare, in cases such as detection of a microdeletion, there may be a high chance that a positive result is actually from a fetus that does not have the genetic abnormality reported by the test.

81. The safety communication further noted the existence of "cases where a screening test reported a genetic abnormality and a confirmatory diagnostic test later found that the fetus was healthy" and advised patients to discuss the benefits and risks with a healthcare provider before deciding to undergo NIPT or making any pregnancy-related decisions on the basis of NIPT results. The FDA also advised health care providers that they should not rely on NIPT results alone to diagnose chromosomal abnormalities or disorders.

82. On this news, the price of Natera common stock fell as much as \$1.53 per share, or approximately 3.9%, from an intra-day high of \$39.63 per share on April 19, 2022, to close at \$38.10 per share on April 20, 2022.

V. CLASS ACTION ALLEGATIONS

- 83. Plaintiff brings this class action under Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons and entities who purchased Natera common stock during the Class Period (the "Class"). Excluded from the Class are Defendants, their agents, directors and officers of Natera, and their families and affiliates.
- 84. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court.
- 85. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:
 - a. Whether Defendants violated the Exchange Act;
 - b. Whether Defendants omitted and/or misrepresented material facts;
 - c. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
 - d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;
 - e. Whether the price of Natera common stock was artificially inflated; and

- f. The extent of damage sustained by members of the Class and the appropriate measure of damages.
- 86. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct.
- 87. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.
- 88. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

VI. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE

- 89. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:
 - Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
 - b. The omissions and misrepresentations were material;
 - c. The Company's common stock traded in an efficient market;
 - d. The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and
 - e. Plaintiff and the Class purchased Natera common stock between the time the Company and the Individual Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

90. At all relevant times, the market for the Company's common stock was efficient because: (1) as a regulated issuer, the Company filed periodic public reports with the SEC; and (2) the Company regularly communicated with public investors using established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services.

VII. NO SAFE HARBOR

- 91. Defendants' "Safe Harbor" warnings accompanying any forward-looking statements issued during the Class Period were ineffective to shield those statements from liability.
- 92. Defendants are liable for any false and/or misleading forward-looking statements pleaded because, at the time each forward-looking statement was made, the speaker knew the forward-looking statement was false or misleading and the forward-looking statement was authorized and/or approved by an executive officer of the Company who knew that the forward-looking statement was false. None of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

VIII. LOSS CAUSATION/ECONOMIC LOSS

93. Defendants' wrongful conduct directly and proximately caused the economic loss suffered by Plaintiff and the Class. The prices of the Company common stock significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing

investors' losses. As a result of their purchases of Natera common stock during the Class Period, Plaintiff and the Class suffered economic loss, i.e., damages, under the federal securities laws.

IX. ADDITIONAL SCIENTER ALLEGATIONS

94. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of Company securities during the Class Period.

X. CLAIMS AGAINST DEFENDANTS

COUNT I

Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Promulgated Thereunder Against All Defendants

- 95. Plaintiff incorporates by reference the allegations in the preceding paragraphs.
- 96. During the Class Period, Defendants carried out a plan, scheme, and course of conduct that was intended to and, throughout the Class Period, did: (1) deceive the investing public, including Plaintiff and the Class; and (2) cause Plaintiff and the Class to purchase Company common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, and each of them, took the actions set forth herein.
- 97. Defendants: (1) employed devices, schemes, and artifices to defraud; (2) made untrue statements of material fact and/or omitted material facts necessary to make the statements not misleading; and (3) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain

artificially high market prices thereof in violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5.

98. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the Class suffered damages in connection with their respective purchases of the Company's securities during the Class Period.

COUNT II

Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

- 99. Plaintiff incorporates by reference the allegations in the preceding paragraphs.
- 100. The Individual Defendants acted as controlling persons of Natera within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations, and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control—and did influence and control, directly or indirectly—the decision-making of the Company, including the content and dissemination of the various false and/or misleading statements. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.
- 101. In particular, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular accounting practices giving rise to the securities violations as alleged herein, and exercised the same.

As described above, the Company and the Individual Defendants each violated 102.

Section 10(b) of the Exchange Act and SEC Rule 10b-5 by their acts and omissions as alleged in

this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are

liable under Section 20(a) of the Exchange Act. As a direct and proximate result of this wrongful

conduct, Plaintiff and other members of the Class suffered damages in connection with their

purchases of Company securities during the Class Period.

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

Determining that this action is a proper class action under Rule 23 of the a.

Federal Rules of Civil Procedure;

Awarding compensatory damages and equitable relief in favor of Plaintiff b.

and other members of the Class against all Defendants, jointly and severally,

for all damages sustained as a result of Defendants' wrongdoing, in an

amount to be proven at trial, including interest thereon;

c. Awarding Plaintiff and the Class their reasonable costs and expenses

incurred in this action, including counsel fees and expert fees; and

d. Such other and further relief as the Court may deem just and proper.

XI. **DEMAND FOR JURY TRIAL**

Plaintiff hereby demands a trial by jury.

Dated: April 27, 2022

Respectfully submitted

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ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: Natera Facing Investor Class Action Over Genetic Test Accuracy Concerns