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CONSOLIDATED CLASS ACTION COMPLAINT CASE NO. 3:23-cv-02082-LL-MMP

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Lead Plaintiffs Universal-Investment-Gesellschaft mbH ("Universal Gesellschaft") and UI BVK Kapitalverwaltungsgesellschaft mbH ("UI BVK" and, together with Universal Gesellschaft, "Universal") and ACATIS Investment Kapitalverwaltungsgesellschaft mbH ("ACATIS," together with Universal, "Lead Plaintiffs" or "Plaintiffs") bring this securities class action against Illumina, Inc. ("Illumina" or "the Company"), GRAIL, LLC ("GRAIL"), and certain of their current and former senior executives and directors (collectively, "Defendants"). Lead Plaintiffs assert claims against Defendants under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder, on behalf of all investors who purchased or otherwise acquired Illumina common stock between September 21, 2020 and November 9, 2023, inclusive (the "Class Period").

The allegations in this Complaint are based upon Lead Plaintiffs' personal knowledge as to themselves and their own acts and upon information and belief as to all other matters. Lead Plaintiffs' information and belief are based on the independent investigation of their counsel. This investigation included, among other things, a review and analysis of: (1) Illumina's and GRAIL's public filings with the Securities and Exchange Commission (the "SEC"); (2) research reports prepared by securities and financial analysts concerning Illumina and GRAIL; (3) transcripts of Illumina's investor conference calls; (4) Illumina's and GRAIL's investor presentations; (5) press release and media reports; (6) securities pricing data; (7) interviews with former Illumina employees; (8) consultation with numerous experts; (9) pleadings, evidence, transcripts, and Lead Counsel's discussions with counsel in related litigation involving Illumina and GRAIL, including *In re Matter of Illumina*, Inc. and GRAIL, Inc., FTC Docket No. 9401, Icahn Partners LP v. deSouza, C.A. No. 2023-1045-PFA (Del. Ch.) ("Icahn"), City of Omaha Police & Firefighters Retirement System v. Francis deSouza, C.A. No. 2024-0172-PAF (Del. Ch.) ("Omaha"), City of Roseville General Employees Retirement System v. deSouza, 1 C.A. No. 2024-0398-PAF (Del. Ch.) ("Roseville"), and Pavers & Road Builders 2 3 4 5 6 7

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## Benefit Funds. v. Illumina, Inc., C.A. No. 2024-0136-PAF (Del. Ch.) ("Pavers"); (10) material obtained through Freedom of Information Act and similar public access requests, and (11) other material and data identified herein. Lead Counsel's investigation into the factual allegations is continuing, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

#### I. INTRODUCTION

- This case arises out of a series of misrepresentations concerning the most monumental transaction in Illumina's history—its acquisition of its former subsidiary, a cancer detection test company called GRAIL. Analysts have described this transaction as one of the "most disastrous attempted mergers in biotech history." On September 21, 2020, the first day of the Class Period, Defendants announced the acquisition of GRAIL for more than \$8 billion, touting the deal as a boon to Illumina shareholders. As Defendants represented, this was because GRAIL's cancer test, Galleri, was a "proven technology" nearing FDA approval and commercial adoption. By acquiring GRAIL, Illumina would "accelerate" Galleri's FDA approval and widespread adoption by 2025, and quickly generate billions in revenue. Defendants repeated these statements with increasing intensity when antitrust regulators moved to stop the deal—telling investors they had a "moral obligation" to defy regulators and close the deal because combining Illumina and GRAIL was "necessary" to "accelerate" the test's broad adoption and thus save "tens of thousands of lives."
- 2. Unfortunately for investors, these statements were false. In reality, GRAIL was worth far less than the price Defendants paid, Galleri's clinical validity was unproven and dubious, and—as the Fifth Circuit Court of Appeals later ruled— Illumina's statements that it would "accelerate" Galleri's commercial adoption were baseless. As a result of Defendants' fraud, the price of Illumina shares has collapsed,

causing billions of dollars in investor losses. Defendants' misrepresentations and the misconduct alleged herein are now the focus of an ongoing investigation by the SEC.

- 3. Defendants' misrepresentations about GRAIL were highly material, and driven by the need for Defendants to justify a questionable acquisition that was intensely scrutinized by investors from the start. Illumina, the foremost provider of next-generation genetic sequencing ("NGS") technology, had spun out its own subsidiary "GRAIL" in 2016 to develop a cancer detection test using a blood sample drawn from asymptomatic patients (the "Holy Grail" of cancer detection). Over the next three years, GRAIL raised billions of dollars in private financing rounds, bringing its rumored valuation to around \$4 billion after a final capital raise in May 2020.
- 4. On September 21, 2020, Illumina announced that it would reacquire GRAIL for over \$8 billion in cash and Illumina stock—twice its rumored valuation in May. When asked why the Company was willing to pay so much, so soon, Defendants provided investors with revenue projections assuming "broad reimbursement" and billions of dollars in revenue by 2025, as well as a "conservative" valuation for GRAIL of \$11 billion and an optimistic valuation reaching \$44 billion. In other words, Defendants conveyed that the more than \$8 billion price tag was a steal.
- 5. Soon after the acquisition was announced, regulators in the United States and Europe began reviewing the deal under antitrust laws because it threatened GRAIL's competitors who relied upon Illumina technology for their own tests. On March 30, 2021, the FTC sued to block the deal. In response, Defendants intensified their statements about Illumina's ability to accelerate Galleri's commercialization. For example, Illumina CEO Defendant Francis deSouza published an op-ed in *The Wall Street Journal* warning that the FTC was "jeopardizing our chance to save more lives from cancer" since the merger would

speed up the commercialization "by years," "accelerat[e] the test's broad adoption," and save "tens of thousands of lives."

- 6. These representations reassured investors and had their intended effect. By August 2021, Illumina's stock price had skyrocketed 90% from the time the controversial merger was announced on the first day of the Class Period.
- 7. However, by that time, the European Union's antitrust investigation had evolved into a full-blown inquiry as it considered whether to approve the deal. While the investigation was pending, Illumina was placed under a "standstill obligation" imposed by EU merger rules that prohibited Illumina from closing the deal. Illumina had also just completed discovery in the FTC's action, which was set to begin trial on August 24, 2021.
- 8. In a brazen and unprecedented move, Illumina stunned investors by announcing on August 18, 2021 that it had closed the GRAIL transaction in defiance of the EU standstill obligation. Illumina justified the action by telling investors that there was no "legal impediment" to the transaction in the United States, and that it needed to close to prevent regulatory proceedings from "killing the deal by running out the clock." In a media interview that day, deSouza claimed that Illumina had to close because the "stakes are just too high to risk" that the deal would fall through.
- 9. Illumina's regulators reacted swiftly. Within days, the European Commission issued a statement emphasizing that the standstill obligation was one of the "cornerstones of the Merger Regulation," and that it took Illumina's "possible breaches . . . very seriously."
- 10. Analysts were puzzled by Illumina's actions, and questioned why it closed the merger in the face of an explicit regulatory prohibition. For example, Citigroup noted the lack of "any precedent for an acquirer intentionally closing a deal ahead of regulatory approval"—and that doing so presented an obvious "risk that this tactic does not sit well with the regulatory bodies." In response to such

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27 28 concerns, deSouza reiterated that closing was a moral imperative because it would accelerate the adoption of the Galleri test and "save lives."

- As corroborated by a full record and trial before the FTC, Defendants' own testimony, and Lead Plaintiffs' forensic accounting analysis, these statements were misleading and omitted material facts. To start, Illumina's true internal valuation and revenue projections for GRAIL were materially below the lofty valuations and aggressive revenue projections Illumina reported to investors. In truth, the internal revenue projections prepared by Illumina's management and reviewed by its Board—but concealed from investors—were approximately onequarter to one-half those it publicly reported in SEC filings.
- 12. Consistent with these undisclosed valuations, and contrary to Defendants' repeated statements that acquiring GRAIL would "accelerate" Galleri's adoption, Defendants testified in the FTC proceeding that Illumina had no path to "accelerate" Galleri. In truth, Illumina had neither modeled any potential "acceleration" in its "deal model," nor identified any steps or actions it could take to "accelerate" Galleri, and did not actually have any infrastructure, expertise, or experience necessary to make any "acceleration" possible. Rather, as the Fifth Circuit held after the Class Period, "Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved."
- 13. In addition, in stark contrast to Defendants' representations about Galleri's "proven technology" and established "efficacy," in reality, the FDA had directly informed GRAIL prior to the beginning of the Class Period that its body of planned clinical trials was insufficient to show that the test worked. Specifically, the FDA told GRAIL that its proposed clinical strategy would not support FDA premarket approval because the studies did not "directly confirm the results of [the] test" or "assess how the test results impacted patient treatment decisions," and because they were based on clinical data gathered in the U.K., which has a vastly different standard of care for cancer than the United States.

14. Moreover, and unknown to investors, GRAIL's real-world experience had shown that Galleri caused substantial harm to patients, with no discernible clinical benefit, at an extraordinary cost. In one example, the San Francisco Firefighters Cancer Prevention Foundation funded Galleri screening for 1,786 active and retired firefighters at cost of over \$1 million—which the founder of the organization described to Lead Plaintiffs' counsel as being "sold a bill of goods." The tests missed numerous confirmed cancers, generated approximately 50% false positives, and only "detected" cancers that were too "late stage" to make any difference. Consistent with this striking example, and contrary to Defendants' positive statements about GRAIL's efficacy, clinicians have decried Galleri's results and "miss rates as high as 93%" as "scary," "problematic," and "misleading"—and warned the test's false positive rates will necessarily lead to a "large number of non-cancer patients who will undergo additional, unnecessary, and probably harmful testing."

15. The truth about Galleri's ineffectiveness and Illumina's inability to commercialize such an expensive and clinically useless product was no secret to Illumina's senior leadership. Defendant deSouza himself internally acknowledged that neither he nor Illumina had any actual evidence that Galleri could save lives. As reported by one former Illumina employee, in 2023, deSouza directed an effort to identify an independent scientist or other backer to publicly praise the GRAIL acquisition and provide legitimacy to deSouza's statements that Illumina would "accelerate" Galleri's adoption and "save lives." But despite weeks of work and outreach, Illumina was unable to identify anyone willing to publicly make that representation—enraging deSouza. Other former employees reported the same concern, and said that the commercial plan for GRAIL was "preposterous" and based on "dreams and magic" because private payors demanded evidence (such as FDA approval) that the test actually worked—which GRAIL simply did not have. As

another former employee put it, "GRAIL was not at that stage to determine if it could save lives."

- 16. While Defendants' representations about GRAIL lacked any basis in fact, Defendants were highly motivated to make them because they stood to—and did—profit enormously from closing the merger. Unbeknownst to investors, Illumina closed the GRAIL transaction because it enabled GRAIL's private investors, including members of the Illumina and GRAIL leadership, to secretly pocket hundreds of millions of dollars. Specifically, as alleged herein, Lead Plaintiffs' forensic analysis has shown that approximately 70 million shares of GRAIL stock, valued at over \$830 million at the time the acquisition was announced, were never publicly accounted for. In concealing this secret insider interest, Illumina violated Generally Accepted Accounting Principles ("GAAP") in the way it accounted for its ownership in GRAIL—violations specifically carried out to enable Defendants to avoid disclosing insiders' hidden interests.
- 17. That Defendants were personally motivated to close the GRAIL acquisition has been corroborated by allegations from a newly elected director who joined Illumina's Board in June 2023 following a proxy campaign by renowned activist investor Carl Icahn. Just weeks after Icahn's nominee was elected to Illumina's Board and gained access to internal privileged documents concerning the GRAIL transaction, Icahn concluded that Illumina's Board was hopelessly conflicted and "poisoned by their personal stake" in the deal. Armed with this knowledge, on October 20, 2023, Icahn sued the other members of Illumina's Board of Directors—alleging, based on a then-current Illumina director's internal and privileged documents in a sworn complaint, that they lied about the Company's reasons for closing the acquisition and demanding that investors be told "the truth about Defendants' misconduct."
- 18. The truth about Defendants' misconduct has continued to emerge after the Class Period, and evidence unearthed in other litigation against Illumina's senior

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leadership has confirmed that Defendants' explanations for closing the GRAIL acquisition were false. That evidence includes the fact that, just as Illumina was about to approve the acquisition in August 2021, the Illumina Board took out acquisition-related D&O insurance coverage of \$300 million—at the extraordinary cost of a \$100 million annual premium (multiples the cost of similar policies)—precisely because the Board and senior management were incurring personal liability for their misconduct. This unprecedented policy demonstrates Defendants knew that closing the deal was wrong and that their public justifications for doing so were false.

- 19. Defendants' culpability is also confirmed by their highly suspicious insider trades, which netted them millions of dollars in profits from selling Illumina shares at artificially inflated prices before investors learned the truth. Defendant Aravanis—GRAIL's former Chief Scientific Officer who became Illumina's Chief Technology Officer through the acquisition—sold every single Illumina share he received in the deal, soon after the deal closed, reaping over \$5 million in proceeds.
- 20. As insiders were secretly unloading shares, Defendants did not breathe a word of their secret financial motivations for closing the deal, despite analysts' questions probing its rationale. Beginning in April 2023, one analyst began to publicly question those motives following a deep dive into Illumina's public disclosures—asking how much "Illumina insiders (past and present) make from splitting-off and subsequently re-acquiring GRAIL?," and concluding that, based on his analysis, "Illumina shareholders need to consider the possibility the UNDISCLOSED financial windfall to insiders is well in excess of \$500 million."
- 21. Then, in May 2023, Icahn began posing these same questions directly to Illumina's senior leadership in connection with his proxy contest. In doing so, Icahn publicly questioned Illumina insiders' financial interest in the GRAIL transaction, imploring "the board to bring in an outside—and demonstrably independent—law firm and forensic accounting team to investigate and address these questions publicly."

22. Rather than admit the truth or conduct any investigation, in response to these demands, on May 18, 2023, Illumina Board chair and longtime deSouza confidant Defendant John W. Thompson issued a statement to investors flatly denying any wrongdoing or conflicts of interest whatsoever:

On conflicts of interest, there is an important question I would like to put to bed: "Did any Illumina directors have a financial interest in GRAIL at the time of the acquisition?" This question is not a matter of interpretation or explanation. The answer is simply no.

- 23. This statement was false and misleading. In reality, Illumina insiders and their affiliates had enormous self-interested financial motivations for closing the deal that were never properly disclosed to investors—and, in fact, were deliberately hidden through Illumina's fraudulent accounting of its ownership of GRAIL in the years before and throughout the Class Period.
- 24. While Illumina and GRAIL insiders pocketed hundreds of millions in illicit profits, Illumina's public investors—Lead Plaintiffs and the members of the Class—saw their investments plummet in value as a result of the misconduct alleged herein. Specifically, Illumina's stock price declined in a statistically significant manner following disclosures revealing that Illumina was pressing ahead with the GRAIL transaction despite the EU's prohibition; senior executives involved in the GRAIL transaction—including deSouza and Aravanis—had unexpectedly or forcibly "resigned"; scientists questioned Galleri's effectiveness; Illumina was slashing R&D spending and laying off R&D workers; and the SEC was investigating. In response to these disclosures, Illumina shares cratered, falling from \$523 per share on August 17, 2021, the day before Defendants closed the acquisition, to \$175 per share on August 14, 2023, when Illumina disclosed it was being investigated by the SEC.
- 25. Finally, on November 9, 2023, the last day of the Class Period, Illumina disclosed that it was being forced to take another near-\$1 billion write-down on GRAIL (after writing it down nearly \$4 billion the year before)—confirming it was

actually worth a fraction of what Illumina paid. On this news, Illumina shares fell another 13%, closing at less than \$100—their lowest trading price in a decade.

- 26. Since that time, additional facts have further corroborated Defendants' fraud. Those include Illumina's disclosure that it was unable to find any willing buyer for GRAIL, and was instead forced to divest it through a distribution of shares to Illumina shareholders. That divestiture confirmed that GRAIL was, in truth, worth around \$500 million—or just 6% of the \$8 billion that Illumina paid to acquire it. Those facts also include the FDA's announcement in April 2024 that it was imposing stricter rules on the very kind of cancer tests GRAIL sold in which the FDA specifically highlighted the dangers that Galleri poses for patients.
- 27. And while Illumina's public investors have seen their investments plummet in value due to Defendants' fraud, the primary architects of the GRAIL acquisition—including Defendants deSouza, Bishop, Klausner, and Aravanis—have since landed lucrative new roles at other start-ups funded by GRAIL's backers. Plaintiffs bring this action to hold Defendants accountable for the shareholder value they destroyed.

#### II. JURISDICTION AND VENUE

- 28. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.
- 29. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.
- 30. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b). Illumina maintains its corporate headquarters in San Diego, California, which is situated in this District, conducts substantial business in this District, and many of the acts and conduct that constitute the violations of law complained of herein, including the preparation and

dissemination to the public of materially false and misleading information, occurred in this District. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

## III. THE PARTIES

#### A. Lead Plaintiffs

- 31. Lead Plaintiff Universal-Investment-Gesellschaft mbH ("Universal Gesellschaft") and UI BVK Kapitalverwaltungsgesellschaft mbH ("UI BVK" and, together with Universal Gesellschaft, "Universal") are members of the Universal Investment Group. Universal Gesellschaft and UI BVK are investment companies based in Frankfurt am Main, Germany. They collectively administer fund assets of over €1 trillion as of March 2024. Universal Gesellschaft's funds and UI BVK's funds purchased shares of Illumina common stock at artificially inflated prices during the Class Period, and suffered damages as a result of the violations of the federal securities alleged herein.
- 32. Lead Plaintiff ACATIS Investment Kapitalverwaltungsgesellschaft mbH ("ACATIS"), headquartered in Frankfurt-am-Main, Germany, was founded in 1994, and is one of Germany's leading asset managers for retail and institutional clients with more than €11.7 billion assets under management as of March 2023. ACATIS's funds purchased shares of Illumina common stock at artificially inflated prices during the Class Period, and suffered damages as a result of the violations of the federal securities alleged herein.

#### **B.** Defendants

#### 1. Illumina

33. Defendant Illumina develops, manufactures, and markets systems for analyzing genetic variation and biological functions, including next-generation sequencing platforms that allow sequencing, genotyping, and analysis of gene

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Illumina is incorporated in Delaware and maintains its principal executive offices at 5200 Illumina Way, San Diego, California. Illumina's common stock trades on the NASDAQ, which is an efficient market, under ticker symbol "ILMN." As of November 6, 2023, Illumina had over 158 million shares of common stock outstanding, owned by hundreds of thousands of investors.

#### 2. **GRAIL**

34. Defendant GRAIL is a Delaware corporation that was initially founded as a subsidiary of Illumina called GRAIL, Inc. GRAIL was spun off from Illumina on February 28, 2017, and, after several funding rounds, reacquired by Illumina in August 2021 for more than \$8 billion. GRAIL's principal product, Galleri, is a multi-cancer early detection ("MCED") test purportedly designed to screen for up to 50 different cancers. Galleri uses Illumina's sequencing technology to identify cancer signals in a patient blood draw, or liquid biopsy. After GRAIL was reacquired in August 2021, it became an Illumina subsidiary named "GRAIL, LLC." On June 3, 2024, Illumina disclosed GRAIL would be separated from Illumina through a spin-off, and that 85.5% of GRAIL's shares would be distributed to current Illumina shareholders. That spin-off is scheduled to close on June 24, 2024, at which time GRAIL, LLC will be converted to a Delaware corporation named GRAIL, Inc. For ease of reference, and because the liabilities for the misconduct alleged herein were or will be assumed by the successor corporate entities described above, both GRAIL, Inc. and GRAIL, LLC are referred to as "GRAIL."

#### **3.** The Illumina Executive Defendants

35. Defendant Francis A. deSouza ("deSouza") was Illumina's Chief Executive Officer ("CEO") from 2016 until his resignation on June 11, 2023. Defendant deSouza was a member of Illumina's Board of Directors beginning in January 2014, having previously joined Illumina in 2013 as President. As CEO, Defendant deSouza spearheaded the GRAIL acquisition and made numerous false and misleading disclosures concerning the GRAIL acquisition in Illumina's securities filings and in other communications with investors. Defendant deSouza further served on the Board on August 17, 2021, and he participated in the Board's decision to proceed with closing the GRAIL acquisition despite a mandatory "standstill" obligation imposed by European antitrust regulations. Illumina paid Defendant deSouza approximately \$67 million for his service as CEO for fiscal years 2020-2023, a time period during which Defendant deSouza oversaw a decline in the Company's market capitalization of almost \$14 billion. In 2019, the year before the disastrous GRAIL acquisition, deSouza earned just \$1.5 million. After knowingly forcing through the inflated GRAIL acquisition and resigning from Illumina, Defendant deSouza joined Moonwalk Biosciences, Inc., which was co-founded by Defendant Alexander M. Aravanis, M.D., Ph.D., former Chief Technology Officer ("CTO") of Illumina, and funded by ARCH Ventures Partners ("ARCH Ventures"). As set forth below and in Appendix A, Illumina, GRAIL, and many of their respective officers and directors possess ties to ARCH Ventures, an early investor in both GRAIL and Illumina, and ARCH Ventures-backed companies.

36. Defendant Alexander M. Aravanis, M.D., Ph.D. ("Aravanis"), is a cofounder of GRAIL, where he served as Chief Scientific Officer, Head of R&D, and Chief Medical Officer ("CMO") since 2016 before becoming Illumina's CTO in May 2020. At GRAIL, Aravanis led the research, development, operational, and clinical teams developing its MCED test. Prior to GRAIL, Aravanis served as Senior Director of R&D for Illumina from 2013 to 2016. In May 2020, Defendant deSouza rehired Aravanis to rejoin Illumina as CTO, Head of Research and Product Development. He left this role in 2023. Aravanis is currently CEO at Moonwalk Biosciences, a company he co-founded with funding from ARCH Ventures and where deSouza is now also an advisor.

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- 37. Defendant Phillip G. Febbo, M.D. ("Febbo"), served as CMO of Illumina from 2018 to 2023. Febbo was responsible for developing and executing Illumina's medical strategy to drive genomic testing in healthcare practice.
- 38. Defendant Sam A. Samad ("Samad") was Illumina's CFO and Senior Vice President from January 2017 to July 8, 2022, who had responsibility for the Company's finance, accounting, investor relations, internal audit, and treasury functions. Illumina announced Samad's unexpected resignation on June 9, 2022, and analysts immediately tied his departure to GRAIL.
- 39. Defendant John W. Thompson ("Thompson") was a member of Illumina's Board of Directors beginning on May 3, 2017, and served as the Chairman from May 2021 to May 25, 2023, when he was voted off the Board at the 2023 annual stockholder meeting. As a longtime friend and colleague of deSouza at IBM and Symantec, deSouza recruited Thompson to serve on Illumina's Board.
- 40. Defendants deSouza, Aravanis, Febbo, Samad, and Thompson are collectively referred to herein as the "Illumina Executive Defendants." The Illumina Executive Defendants directly participated in the management of Illumina, had direct and supervisory involvement in Illumina's day-to-day operations (or in Thompson's case, Board oversight of Illumina's operations), and had the ability to control and did control Illumina's statements to investors. They were involved in drafting, reviewing, publishing, and/or making the Company's statements to investors, including the false and misleading statements and omissions alleged herein. The Illumina Executive Defendants also exerted control and influence over GRAIL, even after pledging to hold the former subsidiary separate after the reacquisition in August of 2021.

## 4. The GRAIL Executive Defendants

41. Defendant Hans Bishop ("Bishop") served as the Chief Executive Officer of GRAIL from June 2019 to October 2021, until its acquisition by Illumina. As reported by former GRAIL employees, Bishop was hired in order to help plan

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- the private equity investors' "exit" from GRAIL either through a sale or IPO. Bishop had recently and successfully performed that role at another ARCH Ventures portfolio company. Specifically, Bishop founded ARCH Ventures-backed Juno Therapeutics in 2013 and served as President and CEO until it was acquired by another pharmaceutical company, Celgene Corporation, in 2018. Bishop has also served as Chairman of ARCH Ventures-backed Sana Biotechnology since 2018, and founded ARCH Ventures-backed Altos Labs in 2021 with several other Illumina and GRAIL executives and directors, serving as its President and Board Co-Chair. Bishop also serves on the Board of Directors at ARCH Ventures-backed Lyell Immunopharma, Inc.
- 42. Defendant Joshua J. Ofman, M.D. ("Ofman") serves as President at GRAIL. He previously served as the CMO and Head of External Affairs of GRAIL from January 2020 to June 2022 and served as Chief of Corporate Strategy and Head of External Affairs from June 2019 to January 2020.
- 43. Defendant Richard D. Klausner, M.D. ("Klausner") was Senior Vice President and CMO at Illumina from 2013 to 2014 and then Chief Opportunity Officer at Illumina until February 2016. Klausner left Illumina to found GRAIL and served as a GRAIL director from 2016 through the GRAIL acquisition. Through Milky Way Investments Group ("Milky Way"), an opaque investment vehicle that Klausner founded and managed that was registered in the British Virgin Islands, Klausner held 27,753,292 shares of GRAIL worth approximately \$250 million at the time the GRAIL acquisition was announced. He later founded and serves as an executive or director at ARCH Ventures-backed Juno Therapeutics, Lyell Immunopharma, Inc., and Altos Labs. He was also the Executive Chairman at ARCH Ventures-backed Mindstrong Health.
- 44. Defendants Bishop, Ofman, and Klausner are collectively referred to herein as the "GRAIL Executive Defendants." The GRAIL Executive Defendants directly participated in the management of GRAIL, had direct and supervisory

involvement in GRAIL's day-to-day operations (or in Klausner's case, Board oversight of GRAIL's operations), and had the ability to control and did control GRAIL's statements to investors. They were involved in drafting, reviewing, publishing, and/or making GRAIL's statements to investors, including the false and misleading statements and omissions alleged herein.

### C. Relevant Non-Parties

### 1. The Illumina Board of Directors

- 45. The Illumina Board of Directors was comprised of numerous conflicted Directors who possessed ties to the Illumina Executive Defendants, GRAIL, and ARCH Ventures-backed companies. For example, Illumina Director Jay T. Flatley ("Flatley") previously served as Illumina's CEO for 17 years from 1999 through 2016, and served as Executive Chairman on the Company's Board from 2016 to 2020 and Chairman of the Company's Board from 2020-2021. During his time as Executive Chairman of Illumina's Board, Flatley also served as Chairman of GRAIL's Board of Directors from January 2016 to February 2017. After Flatley "resigned" from GRAIL's Board in February 2017, he continued to serve as a GRAIL Board observer "in his personal capacity." Flatley also has significant ties to Robert Nelsen, the Managing Director and Co-Founder of ARCH Ventures, having served as a director at Nelsen-founded companies Juno Therapeutics and Denali Therapeutics, Inc. Flatley also serves as Chairman of the Board at Cellanome, a company co-founded by GRAIL Director Mostafa Ronaghi, Ph.D.
- 46. Current Illumina Director Frances Arnold, Ph.D. ("Arnold") joined Illumina's Board in 2016 and approved the closing of the GRAIL acquisition. She joined the board of ARCH Ventures-backed Altos Labs beginning in 2021. Arnold also serves as a director at ARCH Ventures-backed National Resilience, Inc. and ARCH Ventures-backed Generate Biomedicines
- 47. Current Illumina Director Robert S. Epstein, M.D. ("Epstein") joined Illumina's Board in 2012 and served through the GRAIL acquisition. He also serves

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27 28 as a director at ARCH Ventures-backed Fate Therapeutics, Inc., and was a former director at ARCH Ventures-backed Mindstrong Health.

48. The Illumina Board of Directors' additional conflicts and ties are further set forth in Appendix A.

#### 2. The GRAIL Board of Directors

- 49. The GRAIL Board of Directors was comprised of numerous conflicted Directors who possessed ties to Illumina and ARCH Ventures-backed companies. For example, GRAIL Director Mostafa Ronaghi, Ph.D. ("Ronaghi") served as Illumina's Senior Vice President of Entrepreneurial Development from 2020 to 2021, and previously served as the Company's Senior Vice President and CTO from 2008 to 2020. Ronaghi was appointed to the GRAIL Board on May 4, 2020, just two weeks after Illumina's Board began discussions about acquiring GRAIL, and served through the GRAIL acquisition. Ronaghi is a co-founder and Executive Board Member at Cellanome.
- GRAIL Director Robert Nelsen ("Nelsen") is the co-founder and 50. Managing Director of ARCH Ventures, which has invested in numerous companies where former GRAIL directors and Illumina executives have held positions, having served as an early-stage investor in Illumina, Juno Therapeutics, Lyell Immunopharma, Sana Biotechnology, Inc., and GRAIL, among others.
- 51. GRAIL Director Hal V. Barron, M.D. ("Barron") was appointed to GRAIL's Board in August 2018 and served as a director through GRAIL's acquisition. Barron was a director at ARCH Ventures-backed Juno Therapeutics, and he co-founded ARCH Ventures-backed Altos Labs, where he now serves as the company's CEO and Co-Chair of the Board.
- GRAIL Director William H. Rastetter, Ph.D. ("Rastetter") was a founding board member of GRAIL and served as its CEO from August to December 2017 and as Chair of the Board from 2017 to 2018, having previously served as a director at Illumina from 1998 to 2016 and as Chair of Illumina from 2005 to 2016.

Rastetter also serves as Chairman of the Board of Directors for ARCH Ventures-backed Fate Therapeutics, Inc.

53. The GRAIL Board of Directors' additional conflicts and ties are further set forth in Appendix A.

### 3. ARCH Venture Partners

54. ARCH Venture Partners ("ARCH Ventures") was an early investor in both Illumina and GRAIL. ARCH Ventures participated in Illumina's seed round in 1998 and also participated in GRAIL's Series A and B rounds. Numerous GRAIL and Illumina executives and directors invested in and/or served at ARCH Ventures-backed companies, as set forth in Appendix A.

## IV. BACKGROUND AND OVERVIEW OF DEFENDANTS' FRAUD

- A. Illumina, a Dominant Provider of Next Generation Sequencing Platforms, Forms and Spins Off GRAIL
- 55. Illumina describes itself as "a global leader in sequencing- and array-based solutions for genetic and genomic analysis." It specializes in the manufacture and sale of next-generation sequencing ("NGS") platforms. NGS is a method of DNA sequencing that is used in a variety of medical applications. Illumina currently dominates gene sequencing, controlling over 80% of the global market. In each of 2023, 2022, and 2021, total sequencing revenue comprised 91% of Illumina's total revenue for each period.
- 56. Starting in 2012, Illumina began exploring the potential for detecting cancer in a blood sample using genetic sequencing—an approach sometimes called a "liquid biopsy." Illumina researchers soon discovered that the Company's sequencers were able to detect trace amounts of DNA in blood samples. As Klausner said at the Forbes Healthcare Summit in December 2014: "we now know that tumors put out, at very early stages, their DNA into the circulation. . . . We can now measure that with incredible precision. . . . I think one of the biggest breakthroughs we can

see in cancer in the next few years is this possibility that there could be a blood test or a urine test that detects early-stage cancer."

- 57. In mid-2015, Illumina began to consider how to develop a cancer detection test based on these signals. Illumina executives identified several reasons why it would be best to create a separate company to develop the cancer-detection test, rather than perform the work internally, including:
  - A new company could be "more nimble," "make decisions more quickly [and] change directions more quickly";
  - A new company could "retain[] and attract[] best-in-class people through equity, culture, and quality of the science";
  - A new company could "create a novel clinical and consumer brand"; and
  - Forming a new company would allow Illumina to attract outside investment.
- 58. Soon after, in September 2015, Illumina formed a wholly-owned subsidiary, GRAIL—so-named because its goal was to reach the "holy GRAIL" of cancer research, the creation of a multi-cancer early detection ("MCED") test that could identify the presence of multiple types of cancer from a single blood sample in asymptomatic individuals.
- 59. The possibility of a safe and effective MCED test has profound appeal. Cancer is the leading cause of death worldwide and is second only to heart disease in the United States. Despite being one of the leading causes of death, only five cancer types have recommended screenings—breast, cervical, colorectal, lung (smokers considered at risk), and prostate cancers. Cancers that lack population screening methods are expected to account for about half of new cancer diagnoses each year, according to the American Cancer Society. MCED tests could potentially meet this unmet need, fueling the hope that earlier and more accurate detection of cancer would reduce mortality, improve patients' lives, and reduce healthcare costs.

- 60. GRAIL's MCED test, which GRAIL would later call "Galleri," works by identifying patterns in cell-free DNA, or "cfDNA." All cells—cancer and healthy ones—shed cfDNA into the bloodstream. One of the "hallmarks of cancer" is abnormal methylation of DNA, or the chemical process at the DNA level that plays a role in gene expression. GRAIL's MCED test was developed to use Illumina's NGS and machine-learning algorithms to analyze cfDNA methylation patterns to determine if a cancer signal was present and, if so, to predict the tissue type or organ where the cancer signal originated.
- 61. On January 10, 2016, Illumina issued a press release publicly announcing the formation of GRAIL, which was funded by outside backers and 52%-owned by Illumina. In the press release, Illumina touted GRAIL's "unique structure" and highlighted how GRAIL was formed as a separate company.
- 62. At the time of GRAIL's formation, an MCED test did not exist, but then-Illumina CEO Jay Flatley stated he was "confident it [would] within a year." To accomplish that, Illumina and GRAIL's senior executives told investors that this endeavor would be costly, and that significant investment would be required. That investment included an initial capital raise of \$120 million in 2016 from Illumina and ARCH Ventures, with Illumina contributing \$40 million.
- 63. On January 5, 2017, GRAIL announced its plans to raise approximately \$1 billion more in another round of financing. GRAIL said the fundraising proceeds would be used for "continued development and validation of their blood-based test for cancer screening," which would "require large-scale clinical trials" including the "Circulating Cell-free Genome Atlas" study, or "CCGA."
- 64. By the end of the first quarter of 2017, GRAIL had raised \$900 million from investors including ARCH Ventures. As Illumina disclosed in a March 1, 2017 SEC filing, a portion of those proceeds were used to repurchase some of Illumina's stake in GRAIL, with the result that Illumina subsequently owned "slightly less than 20 percent" of GRAIL by that date.

- 65. In May 2018, GRAIL raised a further \$300 million, bringing its total equity raised to more than \$1.5 billion. And in May 2020, GRAIL raised another \$390 million, bringing the total equity raised to more than \$1.9 billion. After the final May 2020 capital raise, GRAIL was valued at approximately \$4 billion.
- 66. Following these successive fundraising rounds, GRAIL began pursuing an initial public offering ("IPO") purportedly to raise additional money to fund the launch and commercialization of its MCED test, Galleri.
- 67. The market reacted with excitement to the announcement of GRAIL's IPO. For example, on September 10, 2020, *Bloomberg* published an article noting that GRAIL was "finally taking advantage of the blistering hot market for offerings, ending a wait of over two years for the cancer test startup to reach public markets."

# B. Illumina Announces Shocking Plans to Acquire GRAIL for More Than \$8 Billion

- 68. GRAIL never went public. On September 21, 2020, the first day of the Class Period, Illumina announced its intention to acquire GRAIL for \$8 billion, comprised of \$3.5 billion in cash and \$4.5 billion in shares of Illumina common stock. The consideration for GRAIL shareholders also included contingent value rights, or CVRs, entitling investors to receive future payments representing a pro rata portion of certain GRAIL-related revenues each year for a 12-year period—payment streams that were at one point valued by analysts to represent an additional \$500 to \$1 billion in value. The over \$8 billion price tag was huge—more than 4.5 times greater than Illumina's cash and cash equivalents of \$1.76 billion and almost double its then-current assets of \$4.33 billion as of September 27, 2020.
- 69. Beginning on this day and continuing throughout the Class Period, Defendants made a series of false and misleading statements designed to convince investors that the GRAIL acquisition was a value-enhancing proposition that would deliver billions of dollars in returns for Illumina shareholders. Specifically, Defendants made a series of misrepresentations concerning: (1) the financial

projections for GRAIL; (2) Illumina's ability to "accelerate" Galleri's commercialization, regulatory approval, and payor reimbursement by acquiring GRAIL; and (3) the clinical evidence purportedly supporting Galleri's "proven technology" and ability to "save lives."

70. For example, in announcing the deal, Illumina stated that it would use its "global scale, manufacturing and clinical capabilities" to support and accelerate GRAIL's commercialization efforts. In discussing the acquisition, deSouza boasted that "[b]road adoption of Galleri could avert nearly 40% of the 5-year cancer mortality or around 100,000 deaths annually in the U.S." deSouza further stated:

The terrific progress [GRAIL] made has derisked the mission over time. Now as they stand poised to bring products to market in 2021, we believe this is the right time to bring the GRAIL team into Illumina so that we can help to commercialize and accelerate adoption. . . . The reason for why now is, frankly, the terrific progress that the GRAIL team has made over the last few years and where they stand right now. . . . And the reason to acquire them is because we have very clear line of sight into how we can accelerate the plan that they are on today. And we can only do that when they're part of Illumina.

- 71. Illumina's acquisition announcement quickly became the subject of intense investor focus and scrutiny. Analysts questioned several aspects of the deal, including the acquisition's hefty \$8 billion price tag in comparison to its reported value just months early. Analysts from UBS, for example, wanted to know, "Why buy GRAIL now, after starting GRAIL in 2016, spinning in 2017, and after the recent financings plus filing for the IPO?" The analysts pointed to questions about the "financial and profitability outlook for GRAIL," Illumina's "confidence in GRAIL's clinical performance/utility," and the "Risks/opportunity with GRAIL's regulatory and commercial strategy."
- 72. Similarly, analysts from Canaccord had a "hard time justifying the \$8B acquisition price" particularly "given the fact that several other precision oncology companies appear further along (in terms of annual revenues and clinical evidence generation)," while Wells Fargo analysts noted the "company will be challenged to convince investors of its merits at the proposed price tag." Guggenheim analysts

noted that, when GRAIL was spun off from Illumina several years before, "the implied valuation was meaningfully below the predicted \$8B valuation today" and that it "seems odd to us that the company's strategic rationale would change so quickly and at a much higher valuation."

- 73. In the months that followed the announcement, Defendants responded to these concerns by continuing to talk up the effectiveness of GRAIL's Galleri test and the "tens of thousands of lives" that would supposedly be saved by the acquisition. They told investors that GRAIL had "cracked the code" when it came to the Galleri test, repeatedly highlighting how Illumina's purchase of GRAIL would "accelerate" approval and commercial adoption, and that their statements about GRAIL's revenue potential were, if anything, "conservative."
- 74. For example, in responding to these very questions three days after disclosing the acquisition at a September 24, 2020 Cowen investor conference, Defendant deSouza pointed to the clinical data supporting Galleri's effectiveness, answering the "binary" question about whether the product would "work or not" in the affirmative. He stated that during the "last year, through the data that GRAIL started to publish from its large-scale clinical studies at ASCO, at ESMO, the peer-reviewed journal that they published earlier this year that gave us comfort to realize, well, I think they've cracked the code. Their technology works, it's been tested in very large numbers, and the data has been peer-reviewed." According to deSouza, the research on Galleri demonstrated that the "binary risk is largely retired, and that if we get involved now, we can accelerate the development of what's going to be the largest genomic application we've ever seen."
- 75. Throughout the Class Period, Defendants continued to reassure investors concerning Galleri's effectiveness by repeatedly returning to their refrain that Illumina had the ability to accelerate GRAIL's adoption and that the test's effectiveness had been proven. For example, on March 2, 2021, deSouza stated that "we don't believe additional studies are necessary for Galleri to be successful."

- 76. Similarly, deSouza explained during an August 5, 2021 call that the acquisition would "result in the savings of tens of thousands of lives that would not be saved if we didn't buy GRAIL, simply because we can accelerate the business."
- 77. In the months after announcing the acquisition, Defendants also emphasized GRAIL's economic value to justify the price. In November 2020, Illumina filed a Form S-4 with the SEC in which it discussed the GRAIL acquisition. In that Form S-4, Illumina reported on a fairness opinion offered by Morgan Stanley on behalf of GRAIL based on two forecasts "prepared by GRAIL management." Morgan Stanley "assumed" that the forecasts "had been reasonably prepared and on bases reflecting the best then-currently available estimates and judgments of GRAIL's management of GRAIL's future financial performance" but "relied upon[] without independent verification." Among other things, even the more conservative forecast assumed "that broad reimbursement would be achieved in calendar 2025, which management forecasted would significantly increase the acceptance of GRAIL's products."
- 78. As set forth in Illumina's Form S-4, using these forecasts, Morgan Stanley valued GRAIL at \$11.15 billion to \$43.95 billion using a discounted cash flow analysis and at up to \$19.80 billion using a discounted equity value analysis—figures that made the over \$8 billion acquisition look like a steal.
- 79. Defendants' representations had their desired effect, with analysts gaining comfort with Illumina's explanations of the deal rationale and price. For example, SVB analysts credited Defendants' representations that Illumina would accelerate GRAIL's adoption, giving Illumina an "Outperform," SVB's highest rating. In doing so, the SVB analysts noted the acquisition "lets ILMN leverage their scale to accelerate GRAIL's commercialization," and concluded Illumina would "significantly improve GRAIL's speed to market and eventual clinician adoption upon launch." And following deSouza's remarks at the September 24 Cowen conference, analysts from Cowen remarked that deSouza "did a

commendable job directly addressing many of the key lingering questions/concerns from earlier this week [and] directionally, we feel a bit better now than we did earlier today," with the analysts assigning Illumina an "Outperform," their highest rating.

# C. Antitrust Authorities Intervene, Questioning the GRAIL Acquisition's Impact on Competition and Ordering a "Standstill"

- 80. The GRAIL acquisition raised significant concerns in the eyes of American and European competition authorities. On March 30, 2021 and April 1, 2021, respectively, the U.S. Federal Trade Commission filed an administrative complaint and sued in U.S. federal court to block Illumina's acquisition of GRAIL. In response, Illumina published a press release stating it "disagrees with, and will oppose, the [FTC]'s challenge to its previously announced acquisition of GRAIL."
- 81. Then, on April 19, 2021, in response to a referral request from six of its member states, the European Commission agreed to review the GRAIL acquisition under Article 22 of the EU Merger Regulation. Following a preliminary investigation, the Commission announced on July 22, 2021 that it would "carry out an in-depth investigation into the effects of the transaction to determine whether its initial competition concerns are confirmed." In that announcement, the Commission explained that it had "90 working days, until 29 November 2021, to take a decision."
- 82. The gravamen of the antitrust concerns was simple. Illumina provided critical NGS products that were necessary for the work performed by GRAIL and its competitors in the MCED space, and regulators worried that, through the GRAIL acquisition, GRAIL would obtain an advantage over its competitors that would ultimately harm competition in the industry. Specifically, regulators were concerned that, in acquiring GRAIL, Illumina would favor GRAIL over its competitors and that the acquisition could: (1) increase the price for MCED tests; (2) deter others from improving MCED tests through research and development; (3) limit the supply of MCED tests; (4) limit the overall quality and availability of MCED tests; and/or

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- (5) bind MCED test developers to Illumina's products. Thus, they were concerned that the GRAIL acquisition would ultimately cause harm to the public.
- Under the EU Merger Regulation, transactions like the GRAIL acquisition are subject to a "standstill obligation" pursuant to which they are not permitted to close prior to European Commission notification or clearance. As explained by the European Commission, the standstill obligation "prevents the potentially irreparable negative impact of transactions on the competitive structure of the market, pending the outcome of the Commission's investigation."
- The European Commission has stated that it "considers any breach of 84. the standstill obligation be a very serious infringement, as it undermines the effective functioning of the EU merger control system." Under the EU Merger Regulation, Article 22(1) of Council Regulation (EC) No. 139/2004, "the Commission can impose fines of up to 10% of the aggregated turnover of companies, which intentionally or negligently breach the standstill obligation," and, "[i]n setting the amount of the fines, the Commission considers the gravity of the infringement," "the existence of mitigating or aggravating circumstances," and that the fine "ensure a sufficiently dissuasive and deterrent effect."
- Given the importance of preserving market conditions and conducting 85. its investigation, the European Commission notified Illumina that it was "prohibited" from implementing the GRAIL acquisition (i) until the European Commission cleared the acquisition or (ii) until the European Commission refused the referral of the acquisition for merger review.
- Due to the European Commission's investigation, on May 21, 2021, the 86. FTC filed an application withdrawing its request for a preliminary injunction to enjoin the transaction. The FTC explained that because the European Commission was conducting an investigation into the acquisition already, the FTC understood that Illumina and GRAIL required clearance from the European Commission before closing, and thus a preliminary injunction was no longer "necessary to preserve the

status quo." While the FTC's request was granted on June 1, 2021, the FTC administrative proceeding continued to move forward, with trial scheduled to begin on August 24, 2021. The FTC never gave Defendants the go-ahead to proceed with the closing of the acquisition.

- 87. Shortly after the European Commission's announcement that it was conducting an "in-depth investigation" into the GRAIL acquisition, Defendants assured the market that there remained ample time to close the deal after E.U. review. During Illumina's August 5, 2021 earnings call, Defendant deSouza stated that "the way the timing is going to work is the deal contract last[s] till December 20... we are not yet at the stage where the clock has run out." He further explained that Illumina remained "committed to working through this period to get this to a conclusion." At the time, analysts credited these assurances, with J.P. Morgan analysts reporting that "management expects to provide a go/no-go update in late November/early December."
- 88. As antitrust regulators continued to probe the deal, Defendants continued to vocally defend the acquisition by pointing to GRAIL's effectiveness and commercial prospects, the depth and sufficiency of the Galleri test, the value of the acquisition to Illumina shareholders, and the moral imperative of the combination's ability to help "save lives." Defendants' representations had their intended effect, with Illumina's share price nearly doubling since the deal was announced at the beginning of the Class Period and increasing 42% since the FTC announced its challenge on March 30, 2021—sending the shares up to over \$500 per share by August 2021. As Canaccord analysts noted in an August 6, 2021 report, we "view GRAIL as an excellent addition to Illumina that could significantly accelerate the company's growth, enabling direct participation in the lucrative liquid biopsy market."

# D. Illumina Defies Regulators and Closes the Acquisition, Claiming It Was Necessary to "Save Lives"

- 89. Just weeks later, on August 18, 2021, after market close, Illumina shocked investors by announcing that it had closed its acquisition of GRAIL in violation of the European Commission's automatic standstill obligation. In its press release, Illumina tacitly acknowledged that it had flouted the standstill order and the open investigations by the FTC and European Commission, stating that Illumina was keeping GRAIL as a "separate and independent unit[] pending ongoing regulatory and legal review."
- 90. Numerous reporters and analysts expressed confusion at Illumina's closing of the acquisition despite not having regulatory approval—a fact that many remarked was unprecedented. As one reporter summed up, "Illumina completes GRAIL acquisition, regulators be damned." Analysts from Cowen noted that the closing was "a surprising and seemingly aggressive tactical move," while analysts from Bank of America likewise found the move "surprising and aggressive." Citi analysts remarked that the closing of the acquisition was "confusing" and that they "could not find any precedent for an acquirer intentionally closing a deal ahead of regulatory approval particularly in a case where the approval process has been somewhat contentious with the outcome uncertain." Analysts from SVB noted "rising uncertainty with [Illumina's] action yesterday to close the GRAIL acquisition. . . . This somewhat 'rushed' closing without clearing all the regulatory hurdles raises more questions than it answers for investors."
- 91. In sharp contrast to Defendant deSouza's statements less than two weeks prior, Illumina stated that the European Commission's decision on the acquisition was "projected after the deal expires" and that Illumina was "locked into a situation where the deal terms will expire before there is a chance for full review; the clock will just run out"—and therefore the deal could only receive "a thoughtful and full review by the EU regulators and the US courts . . . if Illumina acquires

GRAIL now." Illumina further assured investors that "the company believes that the European Commission does not have jurisdiction to review the merger," and that there was no "legal impediment to acquiring GRAIL in the US."

- 92. On the same day Illumina closed the acquisition, the Company held a conference call with Defendants deSouza, Samad, Bishop, and Charles Dadswell, Illumina's General Counsel. During the call, Defendant deSouza emphasized the "high stakes" involved, underscoring that there was "a moral obligation" to close the deal because "[w]ith Illumina's acceleration, the Galleri test can conservatively save 10,000 additional lives in the U.S., and additional lives in the EU over the next nine years," and that acquiring GRAIL was "the fastest way to make this test available to everyone, everywhere."
- 93. Illumina's executives also brushed aside concerns of regulatory risk associated with the transaction. During the call, a Cowen analyst remarked that the acquisition "seems like a pretty aggressive approach," and that he had not "hear[d] anything that suggests that you've heard that the FTC will not ultimately attempt to block this transaction. So to be to the point as much as possible, has the FTC agreed to stand down?" In response, Defendant deSouza again stated that "there is no impediment for us to closing the deal here in the U.S. right now. . . . there is no hurdle for us crossing right now." Unsatisfied with deSouza's answer, the analyst again asked, "has the FTC said that you can move forward and you're in the clear?" In response, Defendant deSouza again reiterated his assertion that "the FTC has said, there is no hurdle to closing in the U.S. right now."
- 94. Analysts credited Defendants' assurances. J.P. Morgan analysts noted that "no FTC hurdles remain on the acquisition" and that "[m]anagement also dismissed the possibility of the FTC coming back to challenge the deal." Similarly, though an analyst from Canaccord "did not expect" the closing of the GRAIL acquisition, the analyst credited Defendants' assurances concerning the FTC and European Commission proceedings, as well as Defendants' justifications for the

acquisition: "[W]e reiterate our view that regulatory opposition surrounding the merger is unfounded," and that Illumina "believes it can help accelerate the commercialization and reimbursement efforts for Galleri."

95. The European Commission did not take Illumina's defiance lying down. On August 20, 2021—just two days after the acquisition closed and Defendants made numerous assurances to investors about the transaction and the regulatory proceedings—the European Commission announced that it had opened an investigation into whether Illumina had breached the standstill obligation. Executive Vice-President Margrethe Vestager of the European Commission remarked:

We deeply regret Illumina's decision to complete its acquisition of GRAIL, while our investigation into the transaction is still ongoing. Companies have to respect our competition rules and procedures. Under our ex-ante merger control regime companies must wait for our approval before a transaction can go ahead. This obligation, that we call standstill obligation, is at the heart of our merger control system and we take its possible breaches very seriously. This is why we have decided to immediately start an investigation to assess whether Illumina's decision constitutes a breach of this important obligation.

- 96. On the same day, Defendant deSouza gave an interview in which he reiterated that closing the acquisition was a moral imperative because it would accelerate the adoption of the Galleri test and "save lives," stating: "If we accelerated reimbursement in the U.S. by just one year over 10,000 American lives could be saved . . . and so given the stakes here we felt a moral obligation to do what we could to make sure this deal got heard."
- 97. As Defendant deSouza continued to tout Galleri's life-saving capabilities, the European Commission began taking steps in September and October 2021 to stop the GRAIL acquisition. On September 20, 2021, the European Commission notified Illumina of the "interim measures" that would require GRAIL be kept "separate" from Illumina and impose upon Illumina an obligation to finance additional funds necessary for the operation and development of GRAIL. Speaking on the interim measures imposed upon Illumina and GRAIL, Commission Executive

Vice-President Vestager remarked that the measures were to be taken "to prevent the potentially detrimental impact of the transaction on the competitive structure of the market" and underscored the unprecedented nature of Illumina's conduct: "This is the first time companies openly implement[ed] their deal while we are carrying out an in-depth investigation." On October 29, 2021, the European Commission formally adopted the interim measures "to restore and maintain the conditions of effective competition following Illumina's early acquisition of GRAIL."

98. Despite the regulators' efforts, Defendants continued to falsely assure investors about the GRAIL acquisition. For example, on September 13, 2021, at the Morgan Stanley Global Healthcare Conference, in response to questions about the acquisition, Defendant deSouza again repeated his assurances that the acquisition was closed because Illumina "felt a moral obligation to close the deal," and that "we will save many thousands of lives by getting this test into the hands of more people and making it more affordable than GRAIL would do on their own."

## V. UNBEKNOWNST TO INVESTORS, DEFENDANTS' STATEMENTS ABOUT GRAIL WERE FALSE AND MISLEADING

99. Unfortunately for investors, the statements made by Defendants to justify the GRAIL acquisition were untrue. Specifically: (1) Defendants' publicly reported financial projections were multiples greater than the actual, internal projections Illumina developed for GRAIL and its Board reviewed; (2) Illumina's acquisition could not and was never even designed to "accelerate" the commercialization of Galleri, FDA approval, or payor reimbursement; and (3) contrary to Defendants' statements about Galleri's "proven technology" and "efficacy," the FDA had informed Defendants prior to the Class Period that the existing clinical evidence and proposed clinical trials for Galleri were insufficient to be considered for FDA approval, let alone sufficient to support the baseless statement that acquiring GRAIL would help "save lives."

#### A. The Actual Financial Projections Reviewed by Illumina's Senior Leadership Were Far Lower than the Figures Defendants Publicly Reported to Justify GRAIL's Inflated Valuation

100. In announcing the GRAIL acquisition, Illumina publicly reported projections for GRAIL's financial performance that were prepared by GRAIL management and relied upon by Morgan Stanley in connection with a fairness opinion purportedly supporting GRAIL's over \$8 billion valuation. These projections were critical to investors, as they were the only projections provided to assess whether GRAIL's valuation was reasonable. But the publicly reported projections—which were accompanied by Defendants' false and misleading statements asserting that Illumina could accelerate Galleri's adoption, quickly commercialize the product, and obtain "broad reimbursement" by 2025—were contradicted by Illumina's own internal projections and valuations.

101. Specifically, in a Form S-4 filed with the SEC on November 24, 2020, Illumina and GRAIL publicly presented two sets of financial forecasts for GRAIL for fiscal years 2021 through 2030—one that was based on more conservative assumptions ("Case A") and one whose assumptions were more aggressive ("Case B"). As Illumina stated in the filing, under the "Case A" assumptions, GRAIL was expected to generate \$14.4 billion in annual revenues by 2030, while under the "Case B" assumptions, GRAIL's revenues would approach \$24 billion by that time:

	Fiscal year ended December 31,									
(In millions) GRAIL Forecasts:	2021E	<u>2022E</u>	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
GRAIL Total Revenue –  Management Case A  Estimate	\$ 19	\$ 119	\$ 462	\$ 892.	\$1,704	\$3.916	\$ 6.625	\$ 9.884	\$12,129 \$	14,387
GRAIL Total Revenue –  Management Case B  Estimate	56	327	1,042	2,142		9,570		17,747		23,980
GRAIL Operating Profit (Loss) – Management Case A Estimate	(427)	(586	(576)	(454)	(110)	876	1,943	3,339	4,015	4,460
GRAIL Operating Profit (Loss) – Management Case B Estimate	(436)	(589)	(427)	(37)	920	3,683	5,630	7,493	8,846	9,305
Unlevered Free Cash Flow: GRAIL Unlevered Free										
Cash Flow – Case A Estimate	(424)	(541)	(566)	(453)	(156)	714	1,650	2,464	3,048	3,440
GRAIL Unlevered Free Cash Flow – Case B Estimate	(433)	(541)	(431)	(87)	719	2,713	4,137	5,634	6,776	7,268

- 102. Even the purportedly conservative Case A forecast assumed growth in the number of health systems and employers purchasing GRAIL's products and that "broad reimbursement would be achieved in calendar 2025," which management forecasted would significantly increase the acceptance of GRAIL's products. The Case B forecast assumed an even broader acceptance of GRAIL's products across health systems and employers and more significant growth in coverage after broad reimbursement was achieved.
- 103. Analysts relied on the financial projections provided by Illumina and GRAIL when valuing GRAIL, projecting massive sales and long-term revenues for the Galleri test, and they became increasingly comfortable with the projections following Defendants' reassuring statements. For example, in a December 2020 report, Wolfe Research analysts valued "GRAIL's Enterprise Value" at \$7 billion, while Cowen analysts similarly stated in January 2021 that "GRAIL could grow to account for over one-third of total ILMN sales and for 40-50% of annual revenue growth." By March 2, 2021, Wolfe Research analysts had concluded that "GRAIL

accretion remains a key valuation driver with our forecasts reaching \$1.1bn in Galleri revenues by '25E."

104. Unknown to investors, the actual projections considered by Illumina's Board were far more pessimistic than even the supposedly conservative "Case A" scenario Defendants shared with the public. Documents produced in pending "Section 220" books and records and other shareholder derivative litigation in Delaware Chancery Court revealed that Illumina's Board reviewed management-prepared slide decks in April 2020 which showed that "[a]n acquisition of GRAIL could generate revenues of >\$8B by 2030"—approximately *half* the revenues projected in the conservative Case A and *one-third to one-fourth* of the revenues projected in the more optimistic Case B.1

105. Testimony and documents produced in the FTC proceeding, much of which still remains redacted or under seal, likewise confirm that the actual numbers secretly presented to Illumina's Board were far lower than those disclosed to Illumina's public investors. Specifically, documents produced in the FTC proceeding show that the actual "Deal Model"—the model that Illumina used to value GRAIL—projected test sales of 1.5 million from 2022 to 2024, and 50.5 million from 2025 to 2030, sales numbers that similarly translate into revenues that are *roughly half* those reported in the S-4's purportedly "conservative" Case A.

<sup>&</sup>lt;sup>1</sup> Section 220 of the Delaware General Corporation Law vests stockholders of a company with the right to examine the company's books and records, provided that (1) their demand conforms with certain requirements regarding form and manner, and (2) they express an appropriate "purpose" for the inspection. Documents produced in response to Section 220 requests have been cited in the *Omaha*, *Roseville*, and *Pavers* actions, and internal and privileged documents obtained by Illumina Board member Andrew Teno were cited in the *Icahn* action. The complaints in each of these actions were verified and sworn to be true and accurate under oath by the plaintiff representatives, Lead Counsel independently discussed the investigation and pleadings in these actions with counsel in *Omaha*, *Roseville*, *Pavers*, and *Icahn*, and Lead Counsel attended the Section 220 trial in *Pavers*, among other things and as further set forth herein.

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actually considered in April 2020 also placed GRAIL's true valuation at levels drastically lower than what Defendants publicly disclosed. Specifically, those materials showed valuations for GRAIL as low as \$3.3 billion to \$11.9 billion—figures far below the valuations Illumina broadcast to investors in the S-4 (or GRAIL's actual purchase price). The most aggressive and optimistic internal valuation in April 2020 *barely approached* the low end of the range reported in the S-4 under the purportedly "conservative" Case A scenario, and was a small *fraction* of the more optimistic \$28.2 billion to \$43.95 billion Case B:

Forecast Scenario	Equity Value Range			
	(\$ in millions)			
Case A	\$11,150-			
	\$17,450			
Case B	\$28,200-			
	\$43,950			

107. GRAIL's true value was also internally documented by outside auditors, who likewise concluded that Illumina's over \$8 billion valuation had no basis in reality. As was revealed in documents that were produced in another related Delaware litigation and made public after the end of the Class Period, in May 2023, Illumina management commissioned KPMG to conduct a third-party valuation of GRAIL. KPMG concluded that its "[c]urrent valuation aligned with prior analysis and supports \$4.7B independent valuation"—or just over half the \$8 billion Illumina paid to buy it only two years before.

108. It was highly misleading for Defendants to present these financial projections to investors to justify the more than \$8 billion deal, while holding back the actual financial projections considered by Illumina's Board in April 2020, which were roughly one-quarter to one-half of those presented to investors.

# B. Defendants Misrepresented Illumina's Ability to "Accelerate" Galleri's Commercialization, FDA Approval, and Payor Reimbursement by Acquiring GRAIL

109. Throughout the Class Period, Defendants also falsely represented that by acquiring GRAIL, Illumina would "accelerate" commercialization and reimbursement of the Galleri test and save tens of thousands of lives. For example, on the first day of the Class Period when Illumina announced the acquisition, Defendant deSouza told investors that Illumina's "reason to acquire [GRAIL] is because *we have very clear line of sight into how we can accelerate the plan* that they are on today. And we can only do that when they're part of Illumina." deSouza further elaborated that Illumina acquired GRAIL in defiance of the EU's standstill obligation because of the "lives that are at stake," explaining that Defendants felt "a moral obligation" to close so the deal. For his part, Defendant Bishop told investors that day that Illumina closed the deal because the "merger with Illumina will get the Galleri test to people far faster."

110. Defendants expanded on these representations during the rest of the Class Period. For example, in May and August 2021, deSouza stated that the merger would save "tens of thousands of lives that would not be saved if we didn't buy GRAIL," the FTC was "jeopardizing our chance to save more lives from cancer," and "with Illumina acceleration, the Galleri test can conservatively save 10,000 additional lives in the U.S. and additional lives in the E.U. over the next nine years." He also explained on August 19, 2021 that Illumina would accelerate Galleri's commercialization "by many years" because Illumina had "the teams that can work on reimbursement and regulatory approval, and so we can dramatically accelerate getting this test into the hands of people whose lives it could save." Defendant Febbo similarly stated in a February 2022 interview that the acquisition would "speed the test to market and make it more accessible more broadly, more quickly and save lives" because Illumina had "incredible...commercial capability, support capability, regulatory capability and reimbursement experience to help bring this test globally."

- 111. Analysts credited these representations. For example, SVB analysts concluded in a September 22, 2020 report that, given Illumina's clinical labs, "robust regulatory team," and prior success in clinical markets, "[f]ull ownership lets ILMN leverage their scale to accelerate GRAIL's commercialization," and that "[w]e expect ILMN to significantly improve GRAIL's speed to market and eventual clinician adoption upon launch." Similarly, after Illumina announced the closing of the acquisition in August 2021, Canaccord credited Defendants' representations that the acquisition would "accelerate the commercialization and reimbursement efforts for Galleri," while Evercore ISI concluded that Illumina "can now accelerate Grail development timelines." And in January 2022, Piper Sandler concluded that "Illumina can accelerate growth of this market, beyond what an independent Grail would have done otherwise," Morgan Stanley highlighted Illumina's "substantial experience in driving market access," "deep regulatory experience," and "operational synergies in scaling up capacity and lab infrastructure."
- 112. In truth, Defendants had no actual ability to accelerate Galleri's commercialization and never planned or modeled any "acceleration"—rendering that statement and Defendants' representation that the acquisition would "save lives" materially false and misleading when made.
- 113. As confirmed by documents and testimony in the FTC proceeding, neither Illumina nor GRAIL conducted any analysis to determine whether Illumina could in fact "accelerate" Galleri's adoption and neither planned for that possibility. For example, neither GRAIL's Financial Planning & Analysis team, which was led by then-GRAIL CFO Aaron Freidin and was responsible for assessing the combination, nor GRAIL's Medical Affairs and Regulatory teams, conducted any analysis of the extent of any acceleration to FDA approval that might occur if GRAIL were acquired by Illumina. Not surprisingly, in the FTC action, GRAIL's then-CEO, Defendant Bishop, testified that he could not quantify how much sooner

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he expected GRAIL to receive FDA approval with Illumina's assistance versus without.

114. Illumina's senior management also failed to conduct any analysis to support Defendants' "acceleration" statements and, in reality, assumed no such acceleration would occur at all. For example, during the FTC action, Illumina's then-CMO Defendant Febbo testified that Illumina did not include any acceleration efficiency in its financial model for the acquisition—a fact confirmed by Illumina's own expert. Similarly, GRAIL's then-CFO Freiden testified that Illumina had not provided GRAIL with an estimate of how much acceleration Illumina expected for Galleri as a result of the transaction—because that estimate did not exist.

115. The FTC action also confirmed that Illumina lacked any relevant experience or expertise in FDA approval or reimbursement that would support its ability to accelerate Galleri's adoption. For example, contrary to Defendants' public statements touting Illumina's supposedly "incredible" and "experienced" regulatory and reimbursement team as a key advantage in "accelerating" Galleri's FDA approval, Illumina's Global Market Access head Ammar Qadan, the individual at Illumina who would have been responsible for Galleri's regulatory and reimbursement strategy, testified that Illumina did not have that expertise. Specifically, Qadan testified that GRAIL would need half a billion dollars to achieve the clinical data needed for FDA approval and market access, and that Illumina's Market Access group (which consisted of 13 members) did not have the budget needed for Galleri's clinical tests. Moreover, Illumina admitted during the FTC proceeding that its sales team does not even sell Illumina products to physicians the target customer for Galleri—and would need to develop that sales force from scratch.

116. After voluminous discovery and trial, on March 31, 2023, the full Commission issued a 98-page opinion barring Illumina's acquisition of GRAIL, finding in relevant part that Illumina and GRAIL had failed to substantiate at all

their "claim that the Acquisition will accelerate Galleri's widespread 1 2 commercialization through faster regulatory approval and payer acceptance." Specifically, the FTC held that while Illumina and GRAIL bore the burden to 4 establish that the acquisition would accelerate the availability and adoption of the 5 Galleri test by one year, the only competent evidence they proffered was "the 6 unsupported and vague assertions of management personnel"—namely, Defendant 7 Febbo's testimony that he and others in management "feel that [the acquisition] will 8 improve our regulatory path, it will improve the payers' speed at which they provide 9 reimbursement, it will improve the efficiencies in performing the test, and those will 10 shift the availability of Galleri meaningfully forward by a year." Illumina and 11 GRAIL admitted that they were "unable to substantiate" their acceleration and efficiency claims, blaming their inability to do so based on "limitations on [post-12 13 hoc] integration planning imposed by the hold-separate" order from the EU.

- 117. Further, the FTC proceeding confirmed that Illumina did not perform any contemporaneous analysis to determine whether its laboratory operations or supply chain capabilities would lead to any efficiencies. During the FTC proceeding, Defendant Aravanis admitted that any "supply chain and laboratory operation efficiencies" arising from the merger were first identified by the Company's litigation experts the week prior to his March 30, 2021 testimony—i.e., six months *after* deSouza told investors that Illumina had a "very clear line of sight into how we can accelerate" Galleri's adoption.
- 118. In reviewing the FTC record after the Class Period, the Fifth Circuit Court of Appeals also made numerous findings that directly contradicted Defendants' statements. It found that the claimed "operational efficiencies" Defendants touted were wholly unsubstantiated, as Illumina "presented no model" or even any "underlying . . . assumptions" to support them.
- 119. The Fifth Circuit also recognized that Illumina and GRAIL's "acceleration" claims were baseless and that Illumina had no evidence that its

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supposed "clinical and regulatory infrastructure" and "robust regulatory team for market access" could accelerate Galleri's adoption:

[T]he Commission, again supported by substantial evidence, found that Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved. For instance, Illumina's own financial modeling of the merger did not assume that Galleri's widespread commercialization would be accelerated. Nor did it account for the costs that would be associated with achieving any such acceleration, such as diverting Illumina personnel to work on GRAIL projects. And, in any event, Illumina had failed to demonstrate that its claimed "regulatory expertise" was superior to that which GRAIL already possessed. Indeed, GRAIL had already obtained breakthrough device designation for Galleri on its own. Illumina, on the other hand, had only ever obtained pre-market approval for one Class III NGS-based diagnostic test, and in that instance, a third party sponsored the clinical study upon which approval was granted.

120. The findings of the FTC and the Fifth Circuit Court of Appeals were consistent with the accounts from former Illumina employees, who reported that Defendant deSouza internally admitted his statements that the acquisition would "save lives" were not supported by any actual facts. In 2023, deSouza himself directed an effort to identify an independent scientist or other backer to publicly praise the GRAIL acquisition and provide legitimacy to deSouza's statements that Illumina would "accelerate" Galleri's adoption and "save lives." According to FE1, who was directly involved in deSouza's efforts, despite weeks of work and outreach, Illumina was not able to identify a single credible source willing to publicly make that unqualified representation. This enraged deSouza, who became increasingly frustrated.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> As used herein, the term "FE" refers to Illumina and GRAIL "former employees" whose reports are discussed in this Complaint. In order to preserve the former employees' anonymity while maintaining readability, the Complaint uses the pronouns "he" and "his" in connection with all the former employees, regardless of actual gender.

#### C. Defendants Misrepresented the State of the Clinical Evidence Supporting Galleri's Ability to "Save Lives" and Obtain Approval

121. Throughout the Class Period, Defendants also made a series of misleading statements about the clinical data purportedly supporting Galleri. These statements concerned: (1) the clinical evidence obtained to date concerning Galleri's purported "efficacy" and impact on patient outcomes to "save lives"; (2) the data necessary to support FDA approval; and (3) the timeline for FDA approval of Galleri. These statements were false.

#### 1. Galleri's Purported "Efficacy" and "Proven Technology"

122. Defendants made numerous misrepresentations during the Class Period concerning the clinical evidence underlying Galleri's "proven technology" and ability to "save lives." Defendants leveraged these statements to justify GRAIL's inflated valuation. For example, on September 21, 2020, in connection with the announcement of the acquisition, Defendant deSouza represented that, over the last four years, GRAIL's team "has made exceptional progress in developing the technology and clinical data required to launch" Galleri and that GRAIL's "value has been demonstrated." Similarly, in an appearance on Bloomberg TV on April 26, 2023, deSouza described GRAIL as a "proven technology" supported by "large studies that show the efficacy of GRAIL as well as the performance metrics around GRAIL." In sum, Defendants presented GRAIL's test as a "proven technology" that "really work[ed]" and whose "efficacy" was proven by large clinical studies.

123. In truth, Defendants had not even attempted to obtain the clinical data to back this representation, as none of the studies of Galleri—completed, inprogress, or contemplated—actually assessed whether Galleri "saved lives." Rather, and unknown to investors, Defendants had been directly informed by the FDA in meetings in 2019 and in formal written feedback in February 2020 that the Galleri studies that GRAIL had proposed were wholly insufficient to support FDA approval. Specifically, the FDA privately informed GRAIL that FDA approval required clinical evidence to demonstrate that Galleri actually was effective in

improving patient outcomes and treatment decisions for the intended test population—i.e., asymptomatic patients over the age of 50 in the United States. Despite this unambiguous communication from the FDA before the Class Period, *none* of the Galleri studies actually measured the test's effectiveness in the relevant patient outcomes, including mortality. They were thus wholly inadequate to support the statement that Galleri "saves lives."

- 124. Galleri's actual real-world performance provides damning evidence that Defendants' Class Period statements about Galleri's "proven technology" were false when made, and underscores the need for the kind of rigorous clinical evaluation required by the FDA that GRAIL did not have. In one such "real-world" experiment involving the San Francisco firefighters mentioned above, the test did not identify the statistically expected number of cancers, provided false positives for half the cancers it did identify, and missed at least three cases of confirmed cancer. In other words, the exercise showed Galleri to be a disaster.
- 125. In that example—which was prominently featured on GRAIL's website and in marketing materials as an example of how "[m]ulti-cancer early detection screening can be critical for those at elevated cancer risk"—GRAIL provided 1,786 Galleri screenings to a group of San Francisco firefighters and their family members, a "high risk" group for certain kinds of cancer. During that testing round, which was conducted on December 6, 2022—i.e., in the middle of the Class Period—Galleri generated six false positives and identified only five instances of cancer.
- 126. As the clinicians Lead Counsel consulted noted, such a result is alarming in light of the fact that, based on statistical experience, cancer should have been detected in about 29 (not five) of the 1,786 tests. Moreover, of the five instances of where cancer signals were identified, two individuals already knew they had cancer to begin with. Further, all of the instances of detected cancer were at a "late stage," and where the cancer was too advanced to make a difference for the patients. One firefighter was diagnosed with stage 3 pancreatic cancer and is now

in hospice, while another firefighter was diagnosed with lung cancer, which has now metastasized to the brain.

- 127. Galleri also missed at least six instances in which the San Francisco firefighters actually had cancer—failing to identify instances of melanoma, prostate cancer, and lymphoma that were identified by private doctors just months after the Galleri test indicated "no cancer signal." About six months after the screenings, additional firefighters reported that they had been diagnosed with cancer, even though the Galleri test had shown "no cancer signal."
- 128. Further, in one instance in the San Francisco firefighters screening where Galleri generated a false positive, the patient underwent a painful bone marrow biopsy procedure to determine whether the patient did have cancer. In that case, the patient's bone marrow biopsy procedure, clinically shown to involve "bearable pain" to the "worst possible pain" a patient can experience, revealed that there was, in fact, no cancer.
- 129. The screenings provided to the San Francisco firefighters were an expensive "disappointment." According to Tony Stefani, the organization's founder, the screenings demonstrated that the probability of catching an early-stage cancer through the Galleri test was "negligible," and the screenings only caught "some serious cancers at a later stage," which likely would have been detected within one or two months without the test. In addition, as Stefani noted, the price of the tests—over \$1.1 million, more than 10 times the amount the organization had spent on other cancer prevention studies or tests—was "ridiculous." Given the test's high costs and useless real-world performance, Stefani stated that Galleri was a total "disappointment" and that the foundation had been sold a "bill of goods."
- 130. Another Galleri testing round funded by the City of Mesa, Arizona at the Vincere Cancer Center in Scottsdale beginning in October 2021 produced similarly abysmal results. In that instance, 2,000 first responders were screened—but the test missed at least 28 cancers, leading the program's director to conclude

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that Galleri "gives a false perception that you have cancer or you don't." The test's sensitivity in the Mesa program (6.7%) was *much* lower than that publicly reported by GRAIL (29%), and the test missed a staggering 93 of every 100 cancers in the screened population (93%).

- 131. Based on these and similar examples, during the Class Period, well-respected clinicians began sounding alarm bells that GRAIL's reported performance metrics are "always over-estimated," exaggerated, and misleading due to the fact that, to date, those figures have only been supported by "case-control studies" with already symptomatic (and many late stage) patients. As these clinicians began to warn in a November 23, 2021 *Diagnostics* article, Galleri's ability to detect early-stage cancers—where catching cancer "early" can actually make a difference—is "poor" and, in any event, "about 9 out of 10 small, asymptomatic tumors, which are amenable to curative therapies, will likely be missed." After GRAIL's scientists objected to these concerns, these same clinicians forcefully responded to GRAIL's arguments, stating that Galleri's results were in fact "dismal" and that the numbers of cancers GRAIL claims Galleri has identified were "likely over-estimations, since these data were derived from case-control studies."
- 132. Rather, as the FDA privately told GRAIL, the kind of clinical evidence needed to show a cancer test's "effectiveness"—i.e., that it "really works"—required GRAIL to show the test actually resulted in a clinically validated "benefit." Of course, the most obvious way to show such a benefit is through a reduction in mortality. But historically, such cancer screening trials entail very large sample sizes (hundreds of thousands of patients) and extended follow-up periods of between a decade and up to 26 years in order to be sufficiently powered to measure statistically significant reduction in mortality.<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> See, e.g., "All cause mortality versus cancer-specific mortality as never outcome in cancer screening trials: A review and modeling study," Cancer Med. 2019 Oct; 8(13): 6127-6138 (Aug. 18, 2019).

133. Thus, as investors and patients would only belatedly learn, rather than represent a "proven technology" that "really work[ed]" and whose "efficacy" was backed by large clinical studies, Galleri's performance had not been clinically validated, and there was no basis to claim it had any clinical effectiveness or efficacy. For example, as Paul Pharoah, a professor of cancer epidemiology at Cedars-Sinai in Los Angeles, explained in a May 17, 2023 Financial Times report investigating Galleri, "It is a disgrace that companies are selling these tests without knowing what the benefits and the harms are . . . False positives are a problem. False negatives are a problem. We don't know how big those problems are, and we don't know whether these tests make a meaningful difference to cancer mortality." In the same article, Susan Bewley, a consultant obstetrician and emeritus professor of obstetrics and women's health at King's College London, was even more blunt, describing Galleri as an "ethically dubious" "modern form of bloodletting with leeches: if you died it's because we didn't leech you early enough and if you didn't die then the leeches saved you." The article specifically pointed to Galleri's experience with the Arizona first responders as raising alarms about the test's accuracy, and the concern that GRAIL was "putting profits above patient welfare by selling the tests before they complete the randomised trials required to prove they work and can save lives."

134. Former employees at GRAIL reported the same thing. As GRAIL's Director of Key Accounts FE2 noted, during the Class Period, "GRAIL was not at that stage to determine if it could save lives."<sup>4</sup>

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<sup>4</sup> FE2 worked as a Director of Key Accounts at GRAIL from April 2020 through January 2022. FE2's team was charged with implementing a commercial effort to have health systems and hospitals pay for the Galleri test. He participated in meetings with the Senior Vice President to discuss the company's commercial strategy.

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135. Testimony from the FTC proceeding also confirms that it was against FDA regulations and flatly inappropriate for Defendants to suggest otherwise when they lacked any evidence to support that claim. As Kevin Conroy, Chairman and CEO of Exact Sciences—which acquired GRAIL competitor Thrive Earlier Detection Corp. ("Thrive")—explained during his testimony there: "As a CEO of a company that is regulated by the FDA, one thing we don't do is talk about saving lives as it relates to a specific test . . . as a company offering screening tests, we don't make claims that we save lives."

#### The Quality of the Data Provided by Galleri Studies Did Not 2. **Support FDA Approval**

136. Throughout the Class Period, Defendants also made numerous misrepresentations about the quality of GRAIL's Galleri clinical data as a basis for crediting Defendants' statements that FDA approval and "broad reimbursement" would be obtained by 2025. Defendants directly tied the supposedly advanced state of the clinical evidence supporting Galleri and GRAIL's "robust clinical development program" to Galleri's payor reimbursement and commercial strategy timeline. Among other things, Defendants pointed to Galleri's CCGA and PATHFINDER studies, as well as its STRIVE, SUMMIT and United Kingdom National Health Service (or "NHS") studies as supporting Defendants' publicly represented FDA approval timeline of "mid-2024" with "broad-based" reimbursement and extraordinary revenues achieved shortly thereafter.

137. Defendants repeatedly highlighted these studies and their ability to influence the FDA approval timeline in glowing terms. For example, deSouza stated on February 7, 2023, in direct response to an analyst question about FDA approval, that GRAIL had "been working . . . with the FDA for a number of years on designing the studies that will be part of the ultimate submission," was "making good progress," and that GRAIL had "been talking to the FDA about submitting data from the NHS trial as part of the FDA submission."

138. Analysts credited Defendants' representations, and cited GRAIL's assurances that the PATHFINDER, STRIVE, SUMMIT and NHS studies as supporting near-term FDA approval and broad-based reimbursement. For example, Piper Sandler noted in a December 21, 2020 report that GRAIL represented an "underappreciated" opportunity given the expected FDA submission in 2023 "supported by STRIVE (~100k women) and SUMMIT (~25k heavy smokers that will also have low-dose CT scans) data." Similarly, SVB noted in an April 7, 2021 report that "Both CTO Aravanis and CMO Febbo emphasized the importance of bringing early cancer detection technology to the market as soon as possible to save lives," that launching Galleri as an LDT would generate "robust 'real world' clinical data which can be used in future FDA submissions," and that the "current plan is for GRAIL to submit a single-site PMA for approval in 2023 with a dossier of clinical evidence including STRIVE, PATHFINDER, CCGA, SUMMIT, and real-world data from early commercialization efforts."

139. Contrary to these representations, and unknown to investors, Defendants had been directly informed by the FDA prior to the beginning of the Class Period that GRAIL's set of proposed studies would not be sufficient to obtain FDA approval for Galleri. Rather, the FDA privately informed GRAIL that FDA approval required clinical evidence to demonstrate that Galleri actually measured the test's actual benefits—i.e., an ability to improve patient treatment decisions—for the intended test population.

140. As reflected in private communications with the agency referenced in the record in the FTC proceedings, the FDA informed GRAIL senior management in May 2019 that its prospective, observational STRIVE study was "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test." Among other things, the FDA informed GRAIL that, because the Galleri test results were not returned to patients under the study design, GRAIL could not "directly confirm the results of [its] test nor will [GRAIL] assess how the

test results impacted patient treatment decisions." The FDA further told GRAIL that the STRIVE study would not support approval because it was not sufficiently representative of Galleri's intended patient population, as it enrolled women only and Galleri's "intended use population is not restricted to females." In short, as the FDA made clear to GRAIL's senior management, "the STRIVE study is not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test."

141. The CCGA, SUMMIT and PATHFINDER studies suffered from these same flaws, as none was designed to assess the right outcomes in the right patient population. In fact, Defendant Ofman conceded at trial in the FTC proceeding that the CCGA study did not involve the intended use population for Galleri—asymptomatic patients. Similarly, the PATHFINDER study could not support any effectiveness claim because it involved far too small a population and did not remotely support the claim that Galleri could identify 50 cancers. In truth, Ofman testified that "to find all 50 cancers . . . in a real-world population is going to require hundreds of thousands of people, so PATHFINDER was not designed to do that." Similarly, Defendant Bishop conceded at trial that the clinical trials that GRAIL had completed were not "sufficient" for Galleri to obtain premarket approval, which would instead require "data from some additional, very large clinical trials."

142. Along similar lines, GRAIL senior management knew and had been informed that Galleri was not going to receive FDA approval based on its NHS or SUMMIT studies, which were to be conducted in the U.K. FDA regulations are clear that foreign data will support FDA approval only when they are "applicable to the U.S. population and U.S. medical practice," 21 C.F.R. § 814.15, a fact that GRAIL would be required to support with convincing evidence. But according to a former industry consultant who was working to develop a cancer detection test for one of GRAIL's competitors and who had spoken to GRAIL senior management about GRAIL's interactions with the FDA, in or around early 2019, when GRAIL

<sup>5</sup> See, e.g., Henry Scowcroft, "We Need to Be Careful When Comparing US and UK Cancer Care," Cancer Research UK (August 17, 2009).

was in conversations with the FDA concerning how they could get FDA approval for the Galleri test, the FDA responded that there was "no way" that GRAIL could get approval for such a test through the clinical pathway GRAIL proposed.

143. Specifically, the FDA pointed to the fact that the NHS and SUMMIT trial data would not support FDA approval because of the significant difference in the standard of care and practice of medicine for cancer diagnosis in the United States and the U.K. For example, practitioners in the United States use the prostate-specific antigen, or "PSA," blood test for detection of prostate cancer far more widely than those in the U.K., with the result that the United States has one of the highest recorded rates of prostate cancer in the world—and so data on the effectiveness of Galleri in the U.K., where PSA screening is rarer, would say little about whether Galleri could improve outcomes in the United States, where PSA screening is relatively more common. More generally, significant differences in population characteristics and screening and treatment practices between the U.K. and the United States render U.K. cancer diagnostic study outcomes inapplicable in the United States.<sup>5</sup>

144. The former consultant reported to Lead Counsel that he and his team had all the information about the implementation of GRAIL's trial with the NHS, and his own discussions with the FDA made clear that there would be no way the NHS data would support FDA approval for Galleri—a fact that was conveyed to GRAIL by the FDA.

145. Rather, as the FTC concluded, Defendants' statement that Galleri "has demonstrated it can simultaneously screen for more than 50 types of cancer in asymptomatic patients and accurately localize the cancer in positive cases (i.e., detect cancer signal of origin)" was "simply false," as the clinical evidence showed

it could only screen for seven cancers out of the advertised 50. Galleri could not detect "more than 50 types of cancer" because, in truth, as corroborated by testimony by Defendant Ofman and Illumina's own experts, there was "simply no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population." In fact, as the former consultant reported, even today, GRAIL does not have an agreement with the FDA on a study design that would support FDA approval—let alone the kind of clinical study results required for approval.

#### 3. Defendants Misrepresent GRAIL's Commercial Prospects and Timeline for FDA Approval

146. Defendants' false statements about the quality of the clinical data backing Galleri gave credence to their false statements about the timeline for Galleri's FDA approval—a necessary precursor to broad-based payor reimbursement. For example, at the time the acquisition was announced, Defendants represented that GRAIL and Illumina management anticipated submitting Galleri for FDA approval in 2023, obtaining approval in 2024, and achieving broad reimbursement in 2025. And while Defendants' public timelines were pushed out slightly during the Class Period, Defendants reassured investors they remained just around the corner.

147. Defendants substantiated these timelines by referencing their purportedly "productive" discussions with the FDA about Galleri. For example, on March 2, 2021, in direct response to an analyst question about the timeline for completing the "sizeable" studies required to support approval and broader reimbursement, deSouza represented that GRAIL intended "to do an FDA submission in 2023." Similarly, during the annual JPMorgan Healthcare Conference on January 10, 2023, deSouza told investors that "GRAIL is making progress towards reimbursement, with 300,000 participants across multiple studies and a final FDA submission expected in 2024/2025" and asserted that the "exciting momentum" from these studies had "translated into an expected GRAIL revenue CAGR of 60% to 90% over the next five years." And on February 7, 2023, deSouza

explained to investors that GRAIL had been discussing using the results from the NHS-Galleri trial as part of its FDA application, calling it a "powerful" and "very large trial" that would "add to the bolus of evidence" supporting GRAIL's FDA submission. As a result, Illumina was "starting to see the benefits of that good working relationship between GRAIL and the FDA."

148. Further, Defendants reassured investors that Galleri would be a commercial success even before approval—as private payors would agree to cover the test based on Galleri's "efficacy" as established through the studies conducted to date. For example, during a March 2021 investor call, in response to an analyst asking whether Defendants' FDA approval timelines were too optimistic, deSouza explained that Galleri's already-obtained clinical results were sufficient to convince private payors to purchase the test, explaining "And so, we don't think that any studies are essential from a performance perspective but also from a launch perspective."

149. These statements had no basis in reality. In truth, Defendants knew their public timelines for FDA approval were false because they had been told by the FDA, prior to the beginning of the Class Period, that their clinical program would not be considered by the FDA as appropriate for approval. This is because that clinical program did not appropriately and sufficiently measure the right outcomes in an appropriate patient population—i.e., asymptomatic patients over the age of 50 in the United States.

150. Defendants confirmed these facts in their testimony during the FTC proceeding. For example, Defendant Bishop admitted in May 2021 testimony that GRAIL was "still years away from seeking FDA approval for its multi-cancer screening test," while Defendants' own experts concluded that it would take "seven to ten years at minimum" to conduct the prospective, interventional clinical study needed to demonstrate the effectiveness of the cancer screening test in an

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asymptomatic population—at least five years longer than Defendants reported in their public approval timeline.

151. Further, as Defendants uniformly admitted in the FTC proceedings, Illumina would never be able to successfully commercialize Galleri without FDA approval because large private payors demanded it. Defendant Bishop testified that FDA approval would likely be a requirement for a cancer detection test like Galleri to receive broad-based reimbursement, and was "very necessary for getting American citizens access to our test." Defendant Ofman similarly testified that developers of MCED tests need FDA approval for their tests to gain widespread commercialization and reimbursement, and Defendant deSouza conceded that Illumina's plans for Galleri turned on FDA approval, which was a prerequisite to private payor reimbursement.

152. Consistent with this testimony, former GRAIL employees have confirmed that private payors were never going to purchase Galleri in meaningful amounts without FDA approval and that this fact was repeatedly discussed with GRAIL's senior managers. For example, FE2, GRAIL's Director of Key Accounts, described how GRAIL's commercial plan—which involved seeking reimbursement from hospital systems and other healthcare networks—was "preposterous," based on "dreams and magic," and an obvious impossibility because such providers required detailed clinical data based on patient outcomes, and FDA approval, before they would consider paying for a test like Galleri.

153. Similarly, FE3, a former Galleri Sales Consultant from July 2022 through July 2023, reported that Defendants were "overstating what [Galleri] can do when they didn't have the data," that "everything" concerning GRAIL's prospects was based on "a hypothetical," and there were no "real-world studies completed" that were necessary in order for Galleri to be successfully commercialized.<sup>6</sup>

<sup>&</sup>lt;sup>6</sup> FE3 worked as a Galleri Sales Consultant at GRAIL from July 2022 through July

#### VI. ILLUMINA VIOLATED ACCOUNTING RULES TO CONCEAL INSIDERS' SECRET FINANCIAL INTEREST IN GRAIL

154. Defendants' decision to overpay billions of dollars to reacquire an unproven asset was not made blindly or by mistake. The decision was driven by the personal financial motivations of Illumina insiders who secretly benefited from the deal through their hidden ownership interest in GRAIL.

155. Lead Plaintiffs' investigation and forensic analysis has demonstrated that Defendants obtained a secret financial benefit from GRAIL, and concealed this fact, through several significant accounting violations. First, Illumina failed to properly disclose the existence of approximately 70 million shares of equity in GRAIL worth approximately \$830 million at the time of the acquisition. Second, Illumina improperly accounted for its ownership of GRAIL as a "fair value" investment instead of as an "equity" or "cost" investment, an accounting violation that enabled Illumina to avoid disclosure of related party transactions that would have exposed Illumina insiders' secret interests. Third, Illumina senior leadership permitted GRAIL founder and Board member, Defendant Klausner, to invest in GRAIL when Illumina's acquisition was imminent (but not public), resulting in a substantial windfall when the acquisition closed.

## A. Illumina Failed to Properly Disclose GRAIL Equity Amounting to \$830 Million at the Time the Acquisition Was Announced

156. Lead Plaintiffs' forensic analysis shows that equity representing at least 70 million worth of GRAIL shares—a stake worth at least \$830 million at the time the acquisition was announced—was not disclosed by Defendants and instead concealed from investors.

157. Specifically, as set forth in Appendix B, Lead Plaintiffs conducted a forensic accounting analysis of GRAIL and Illumina public disclosures across

<sup>2023</sup> and had years of sales experience in the oncology space. His assigned "territory" for sales covered the Bay area. As part of his work, FE3 interfaced with doctors, including internal medicine doctors, oncologists, and concierge practices.

several years, compared share counts and share ownership percentages set forth in Grail and Illumina's public disclosures and corporate filings, and calculated the actual equity (common shares, preferred equity, and other) based on those disclosures. Lead Plaintiffs' forensic accounting analysis relied upon hundreds of pages of documents that were obtained through corporate records requests, were not publicly filed by Illumina or GRAIL with the SEC, and therefore were not easily accessible to investors. These documents included a stock exchange agreement and plan of reorganization entered into by Illumina and GRAIL in June 2016, which was never filed publicly with the SEC, and the existence of which was not disclosed until GRAIL filed its Form S-1 in 2020. Through this forensic accounting analysis, Lead Plaintiffs have identified that undisclosed investors received approximately 70 million shares in GRAIL through the initial round of "Series A" funding.

158. Specifically, in connection with GRAIL's initial round of Series A funding, Illumina owned 122,500,000 shares of GRAIL common stock, which Illumina disclosed comprised 52% of GRAIL's fully diluted common stock at the time. This, in turn, establishes that GRAIL had 312,500,000 shares of common stock on a fully diluted basis. Of those, Illumina owned 162,500,000 shares. A further 80,000,000 shares were sold to outside investors—leaving 70,000,000 shares of unknown GRAIL equity owned by undisclosed shareholders, or approximately 22.4% of GRAIL's common shares on a fully diluted basis. These equity interests were not accounted for in Illumina or GRAIL's public disclosures, as reflected in the chart below.

1 '	Disclosed Shareholders	Common Stock	Series A	Unknown GRAIL Equity (in shares)	Total	Fully Diluted
	Illumina	122,500,000	40,000,000	-	162,500,000	52%
	Series A Investors	-	80,000,000	-	80,000,000	25.60%
	Undisclosed Shareholder(s)	13,611,111	-	56,388,889	70,000,000	22.40%
	Total	136,111,111	120,000,000	56,388,889	312,500,000	100%

In other words, forensic analysis of Illumina's and GRAIL's ownership establishes the existence of at least 70,000,000 "missing" GRAIL shares that were never accounted for in Illumina's public disclosures. Moreover, as explained below, the existence and ownership of these missing shares would have been revealed had Illumina not taken steps to sell some of its equity in GRAIL (just a few years before deciding to buy GRAIL back again), thereby allowing Illumina to "deconsolidate" GRAIL from Illumina's financial reporting. Because this deconsolidation was intentionally designed to conceal the true facts about these undisclosed GRAIL shares—and because Illumina in fact retained "significant influence" over GRAIL throughout this time—the financial engineering Illumina engaged in to deconsolidate GRAIL was improper and violated GAAP.

#### B. Illumina Violated Accounting Rules In Order to Disguise Insiders' Interests in GRAIL

159. Shortly after Illumina spun out GRAIL as an independent entity in 2016, and after secretly issuing GRAIL equity interests to undisclosed shareholders around the time of the Series A funding round, Illumina quickly determined to lower its stake to below a 20% ownership interest. In announcing this move, Illumina stated that reducing its ownership to below 20% ostensibly provided it with the ability to report its GRAIL investment under the "cost" or "fair value" accounting method, instead of as an "equity" investment. Reporting GRAIL as an "equity" investment would have entailed far great public disclosure to Illumina's investors

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about GRAIL's finances and any related party transactions involving GRAIL. Switching to the cost method allowed Illumina to avoid these disclosures.

- 160. In January 2016, the same month Illumina and unrelated third-party investors founded GRAIL, GRAIL raised \$120 million from a Series A convertible preferred share offering, which included \$40 million from Illumina. GRAIL also entered into a long-term supply agreement with Illumina that encompassed perpetual licenses, employees, and discounted supply terms in exchange for 112.5 million shares of GRAIL's Class B common stock. For the three months ended April 3, 2016, Illumina disclosed it owned 90% of GRAIL's common stock and 52% of GRAIL's equity. And, consistent with its common stock ownership, Illumina absorbed 90% of GRAIL's losses.
- 161. At this time, Illumina accounted for its investment in GRAIL as a consolidated variable interest entity ("VIE"), a business structure which first gained notoriety in the early 2000s due to its role in the Enron scandal. Under a VIE structure, an investor (here, Illumina) has a controlling interest in the entity but does not have a majority of the voting rights. Illumina accounted for its ownership in GRAIL as a consolidated VIE following the Series A funding round in April 2016 until February 2017, when it completed another funding round.
- 162. Specifically, on June 23, 2016, just several weeks after the 112.5 million Class B common stock capital raise in April, GRAIL issued a new class of preferred shares—97.5 million shares of Series A-1 convertible preferred stock—to Illumina in exchange for 97.5 million shares of GRAIL's Class B common stock. This transaction effectively reclassified the vast majority (86.7%) of the GRAIL Class B common stock Illumina received for the long-term supply agreement as convertible preferred stock. As a result of this transaction, as of the end of the second quarter, July 3, 2016, Illumina disclosed that it owned approximately 50% of GRAIL's common stock and continued to own 52% of GRAIL's equity. Consistent with its common stock holdings, Illumina would now absorb 50% of GRAIL's losses

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going forward, and continued to account for its investment in GRAIL as a consolidated VIE.

- 163. The next year, however, immediately following Defendant Samad's hiring as Illumina's CFO in December 2016, on February 28, 2017, GRAIL completed the initial close of its Series B fundraising round, which raised over \$900 million. Concurrent with the financing, GRAIL repurchased 35 million shares of Series A preferred stock and 34 million of Series A-1 preferred stock from Illumina for an aggregate purchase price of \$278 million. As a result of this transaction, Illumina then owned 5 million shares of Series A preferred stock and approximately 78 million Class A common shares.
- 164. Significantly, these transactions meant that Illumina's ownership in GRAIL had been reduced from approximately 52% to approximately 19%, or just under 20%—a significant threshold under the accounting rules. The accounting standards state that an investor (Illumina) should account for its investment in an investee (GRAIL) using the equity method if the investor's ownership of the investee is between 50% and 20%; and, there is a presumption that an investor should use the fair (cost) value method to account for investments where its ownership of the investee is below 20%. Again, the change from "equity method" to "cost method" accounting treatment is significant because, under the "cost method" accounting treatment, Illumina would have to provide far less public disclosure of GRAIL's financial condition, executive compensation, and related party transactions, than it would if Illumina was reporting its ownership under the "equity method."
- 165. However, even when the investor's ownership falls below 20%, the accounting standards (ASC 323-10-15-6) require the investor to continue reporting its ownership under the equity method if it exercises "significant influence" over the Specifically, the accounting standards under ASC 323-10-15-6 provide entity. several factors an investor must consider when determining whether it exerts "significant influence," including whether it has representation on the board of

directors or participates in policy-making decisions, as well as whether there exists material intra-entity transactions, interchange of managerial personnel, or technological dependency.

166. In February 2017, when Illumina took advantage of these accounting rules by reducing its ownership interest to just below 20%, it also ostensibly took measures facially designed to enable Illumina to state it no longer had "significant influence" over GRAIL, and could publicly report its ownership interest in GRAIL on an "cost method" basis instead of under the "equity method."

167. In particular, Illumina reported that it would no longer have representation on GRAIL's Board, had amended its long-term supply agreement (with certain perpetual licenses) with GRAIL, and had therefore begun to account for its investment in GRAIL using the fair value accounting method for investments. Illumina's 2017 Form 10-K filed on February 13, 2018 and signed by Defendant Samad, deconsolidated GRAIL's financial statements and reported Illumina's investment in GRAIL based upon its cost of \$159 million.

168. As a result of deconsolidating GRAIL and determining that it could report its ownership in GRAIL on a cost-method accounting basis, Illumina's required reporting and disclosures of its investment in GRAIL were substantially reduced. Illumina's 10-Q and 10-K filings for 2017, 2018, and 2019 make no meaningful disclosures about Illumina's investment in GRAIL whatsoever.

169. However, as Lead Plaintiffs' forensic analysis shows, based on numerous Illumina and GRAIL former employee accounts and other non-public information, Illumina in fact exerted "significant influence" over GRAIL during this time and was, under the relevant accounting rules, required to publicly report its ownership interest on an equity-method basis (and *not* under the "cost method"). Specifically, Illumina's accounting treatment for GRAIL from 2017 through 2021 as a fair value investment violated ASC 323-10-15-6 and, in reality, Illumina should have reported GRAIL as an equity method investment.

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170. That is because, during this time, Illumina asserted "significant influence" over GRAIL, as GRAIL was almost entirely dependent upon Illumina for critical aspects of its operations and financing—which was the reality at GRAIL since inception. Since its founding, GRAIL relied almost entirely upon Illumina's intellectual property, Illumina employees with specialized technical knowledge, access to Illumina's research and development resources, access to Illumina's proprietary products and supplies, assignment of key joint development agreements with third parties (including assays and data), and access to confidential information. These factors demonstrate that Illumina exerted "significant influence" over GRAIL throughout GRAIL's history, and required Illumina to report its interests in GRAIL under the equity method.

171. The accounting literature and ASC 323-10-15-6 provide a list of indictors of "significant influence" that show that Illumina exercised such an influence over GRAIL—including because of GRAIL's "technological dependence" on Illumina; the extent of "material intra-entity transactions" between Illumina and GRAIL; Illumina's "participation in policy-making decisions" at GRAIL; Illumina's undisclosed "representation on the board of directors"; and the extensive "interchange of managerial personnel" between Illumina and GRAIL. All of these factors demonstrate Illumina's "significant influence":

dependent on Illumina. As GRAIL's former CEO Defendant Bishop testified in the FTC proceeding, Illumina was GRAIL's "only" supplier of NGS instruments and reagents that could be used with Galleri and the only supplier GRAIL even attempted to "validate[] with our technology, so if they're not available to us, we don't have a validated alternative." Similarly, FE4, a GRAIL Data Scientist from September 2019 to October 2021, explained that Galleri was entirely dependent upon Illumina's NGS sequencers and that to replace Illumina's NGS sequencers with a different supplier would require re-validation of an enormous amount of data and a complicated process that would take

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- Material Intra-Entity Transactions: Illumina entered into material intra-entity transactions with GRAIL through which GRAIL purchased highly specialized NGS sequencers and reagents from Illumina, which was GRAIL's only supplier. For example, the February 2017 supply commercialization agreement supplied GRAIL with products and certain rights GRAIL required to run the Galleri tests, including, for example, products needed to conduct genomic sequencing and service contracts for Illumina's NGS sequencers.
- **Interchange of Managerial Personnel:** Former and current members of Illumina's senior leadership served in significant management roles at GRAIL. As set forth in Appendix A, these included: Defendant Aravanis, who served as Illumina's CTO, was GRAIL's co-founder and previously served as GRAIL's Chief Scientific Officer and Head of R&D from 2016 to 2020; Mostafa Ronaghi, who served at Illumina from 2008 to 2021 in various roles, including most recently as Senior Vice President of Entrepreneurial Development, was GRAIL's cofounder, and served as a GRAIL director from 2020 through the acquisition; Defendant Klausner, who served as Illumina's CMO from 2013 to 2014 and Illumina Chief Opportunity Officer from 2014 to 2016, was GRAIL's co-founder, and served as a GRAIL director from 2016 through the acquisition; William H. Rastetter, who served as a director at Illumina from 1998 to 2016 and Illumina Chair from 2005 to 2016, and then served as GRAIL CEO from August to December 2017 and Chair from 2017 to 2018; Gautam Kollu, who previously served at Illumina from 2013 to 2019 in various roles, including most recently as Global Head of Market Development, and GRAIL's Chief Commercial Officer from 2019 to 2022; and Satnam Alag, who served as Illumina's Vice President of Software Engineering, Enterprise Informatics from 2013 to 2020 and previously served as GRAIL's Senior Vice President of Software Engineering and Chief Security Officer from 2020 to the present.
- Representation on the Board of Directors: Illumina had representation on GRAIL's Board of Directors. Specifically, although

<sup>&</sup>lt;sup>7</sup> FE4 served as a Data Scientist at GRAIL from September 2019 through October 2021. In his role, FE4 conducted process monitoring and handled the data quality process for operational, business, and research systems and presented this information to the CMO, the head of clinical, and members of operations.

it was not disclosed to investors at the time, Jay Flatley, Illumina's then-Executive Chairman and former long-time CEO, served as an "observer" of GRAIL's Board of Directors in 2017 and participated in GRAIL Board decisions. Similarly, Ronaghi, an Illumina employee, was appointed to GRAIL's Board by Illumina in May of 2020, in connection with an additional investment in GRAIL by Illumina at that time.

- 172. Illumina's representation on GRAIL's Board through Flatley's undisclosed role as an "observer" is highly suspicious and indicative of its "significant influence" over GRAIL. In February 2017, at the time Illumina reduced its equity stake to just under 20% and sought to treat its investment in GRAIL under the "cost-method" basis, the Company told investors that it "no longer had representation on GRAIL's board of directors."
- 173. But this was false or at least misleading. As subsequently disclosed in Illumina's 2018 proxy filed on April 6, 2018, Illumina's then-executive Chairman, Jay Flatley—the most-senior decisionmaker at Illumina—actually continued to serve on the GRAIL Board as an "observer in his personal capacity." This significant fact was not disclosed in Illumina's 2017 Annual Report filed on Form 10-K with the SEC on February 13, 2018, which stated that Illumina had relinquished its GRAIL Board seat and made no mention of the fact that the Company was given board observer rights, or the fact that it filled the board "observer" position with its Executive Chairman.<sup>8</sup>
- 174. Illumina also violated GAAP by continuing to treat GRAIL as a deconsolidated VIE after it appointed one of its current employees, Mostafa Ronaghi, to GRAIL's board in May of 2020. Guidance provided by

<sup>&</sup>lt;sup>8</sup> The failure to disclose Flatley's role on the GRAIL Board contrasts with Illumina's disclosures concerning the Board observer and advisor it had in place before the 2017 deconsolidation. Specifically, according to Illumina's SEC filings, Illumina Board member Robert Epstein served as Illumina's Board's observer and advisor to the GRAIL Board up until March 1, 2017, when Illumina began reporting its GRAIL ownership under the cost method.

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PricewaterhouseCoopers ("PwC"), GRAIL's auditor, on this point notes that "[a]n investor that has representation on the board of directors can influence the operating and financial policies of an investee through its presence and participation at the board of directors meetings" even when owning less than 20% of the company. Likewise, Ernst & Young ("EY"), Illumina's auditor, notes that "representation on the board of directors may indicate that an investor has the ability to exercise significant influence over an investee's operating and financial policies."

175. Each factor listed by PwC as relevant to whether a board seat constitutes significant influence unambiguously militates in favor of such a finding, including (i) board representation relative to an investor's ownership interest, (ii) the number of board seats relative to the size of the board, and (iii) the manner of Ronaghi's appointment. Three out of 11 GRAIL directors at the time of Ronaghi's appointment (Ronaghi, Defendant Klausner, and Rastetter) possessed ties to Illumina—significant representation on a small board, and proportionally greater than the 14.5% minority stake Illumina retained in GRAIL. Moreover, Ronaghi was appointed to the Board by Illumina.

176. Perhaps most striking, in February 2017, GRAIL used \$278 million of the \$900 million of the capital it raised to purchase shares *from Illumina* specifically in order to bring Illumina's ownership down to exactly 19%, which is just below the 20% threshold for equity method accounting.<sup>9</sup> This is significant because Lead Plaintiffs have not been able to identify any other examples of a strategic investor (like Illumina) in a high-profile biotech start-up (like GRAIL) diverting hundreds of millions of dollars of capital from technology development to repurchase shares

<sup>&</sup>lt;sup>9</sup> The SEC staff has indicated publicly that, while the starting point in any evaluation of significant influence is the investor's common stock ownership in the investee, the staff does not apply a bright line test in the application of ASC 323. Nor does the SEC consider the difference between a 20% common stock investment and a 19.9% investment to be substantive. *See* Paul R. Kepple, Remarks made at Annual National AICPA Conference on Current SEC Developments (Dec. 7, 1999).

from the strategic investor. And here, the share repurchase occurred just one year after GRAIL's founding, when GRAIL was rapidly ramping up its research and development efforts. There is nothing to suggest Illumina had any funding need at that time, having generated \$875 million in operating cash flow from the \$2.75 billion in revenue it earned that year—suggesting that the repurchase was solely intended to influence the accounting treatment for GRAIL. Further, within a year, GRAIL would go out to raise another \$300 million in outside funding, or just over the amount it spent to repurchase its shares from Illumina the year before, demonstrating its need for capital.

177. To put this in context, through the share repurchase that brought Illumina's equity stake down to 19%, Illumina gave up 14% of its equity ownership in GRAIL—a heralded start-up—in exchange for cash it did not need. That equity stake that would have been worth approximately \$1.1 billion when Illumina acquired GRAIL in 2022.

### C. Defendants Secretly Invested in GRAIL While Knowing About the Acquisition, Reaping Tens of Million Dollars in Illicit Profits

178. While the GRAIL acquisition has been a disaster for Illumina's public shareholders, certain Illumina and GRAIL insiders profited enormously by "investing" in GRAIL knowing that Illumina was poised to reacquire it an extraordinary premium before that information became public. Preparations for these insiders to "exit" and reap millions of dollars in profits from GRAIL had already begun when Defendant Bishop joined GRAIL as CEO in June 2019. As FE5 and FE4 both reported, Defendant Bishop had been hired to achieve a "fast" exit for GRAIL due to his past experience with company exits. <sup>10</sup> For example, prior to his

<sup>&</sup>lt;sup>10</sup> FE5 worked at GRAIL as a Staff Bioinformatics Scientist from July 2017 through December 2022. In his role as a bioinformatics scientist, FE5 was responsible for computational research, which involves the use of algorithms, statistics, and mathematical models. When he joined his team, FE5 built programs for the Galleri

tenure at GRAIL, Defendant Bishop had been President and CEO at Juno Therapeutics until it was acquired by another pharmaceutical company in 2018.

179. Illumina's plan to reacquire GRAIL was hatched prior to GRAIL closing its final fundraising round—the Series D round—which was the last private capital raise before the acquisition.

180. As explained by Defendant deSouza in an August 2021 interview, Illumina "initiated the process to acquire GRAIL" after GRAIL published the results from the CCGA Galleri study at the end of 2019. Over the next several months, deSouza continued exploring the possibility of reacquiring GRAIL. And Illumina Board materials that were disclosed after the Class Period in other proceedings reveal that, by April 2020, Defendant deSouza had begun discussing reacquiring GRAIL with Illumina's Board. Specifically, as reflected in those Board documents, deSouza recommended to Illumina's Board on April 28, 2020 that Illumina conduct "further due diligence into GRAIL as a potential acquisition target."

181. But deSouza had already been conducting that "diligence" in the weeks leading up to the April 28 Board recommendation. By that time, deSouza had already discussed a leadership transition with GRAIL's Chief Scientific Officer, Defendant Aravanis, whom deSouza sought to elevate to serve as Illumina's CTO. At the same time, deSouza was discussing with Illumina's then-CTO, GRAIL cofounder Mostafa Ronaghi, the plan for Ronaghi to relinquish that position, take on a new non-executive role of Senior Vice President of Entrepreneurial Development at Illumina, and to serve as a new, additional director on the GRAIL Board.

182. Illumina disclosed these two extraordinary personnel changes on May 4, 2020. The transfer of senior personnel between GRAIL and Illumina and the

test. At GRAIL, FE5 worked under the Senior Vice President of Data Sciences, as well as Defendant Aravanis, who was then-Chief Scientific Officer, Head of R&D at GRAIL.

creation of a board seat for Illumina's Ronaghi necessarily required approval of GRAIL's board—which included Defendant Richard Klausner.

183. These significant personnel changes were happening at the same time that GRAIL was conducting another private fundraising round. On May 6, 2020, just two days after announcing that Aravanis would be Illumina's CTO and Ronaghi joined GRAIL's Board, GRAIL disclosed that it had raised \$390 million in Series D financing from "[n]ew investors including Public Sector Pension Investment Board (PSP Investments) and Canada Pension Plan Investment Board (CPP Investments), as well as two undisclosed investors." GRAIL's amended Form S-1 filed on September 17, 2020 subsequently disclosed that one of those "undisclosed investors" was, in fact, the British Virgin Islands-registered investment vehicle Milky Way, which owned 24,471,417 shares of Illumina's Series D preferred stock, and that Klausner was the "founding partner" of Milky Way. Milky Way's other investors, if any, have never been disclosed.

184. In other words, Defendant Klausner, a former Illumina executive and then-current GRAIL Board member, purchased approximately 25 million shares of GRAIL common stock for \$5.1080 per share—or an approximately \$125 million investment—in the Series D round announced on May 6, 2020, at the exact same time Illumina was making plans to reacquire GRAIL and while GRAIL's Board was expanding its membership and approving substantial personnel changes in anticipation of that acquisition in April and May 2020. Just four months later, in September 2020, the shares Klausner purchased through Milky Way while he was overseeing and approving these extraordinary measures as a member of GRAIL's Board would more than double in value when Illumina publicly announced the GRAIL acquisition, delivering Klausner and Milky Way over \$100 million in risk-free profits. Tellingly, Milky Way was dissolved on July 4, 2023, just weeks after deSouza's resignation from Illumina, allowing Defendants to continue concealing what became of Defendant Klausner and Milky Way's massive stake in GRAIL.

## VII. DEFENDANTS CONTINUE TO CONCEAL THE TRUE FACTS ABOUT GRAIL AND GALLERI WHILE DEFYING REGULATORS AND SELLING THEIR PERSONALLY HELD ILLUMINA SHARES

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# A. Defendants Secretly Obtain an Extraordinary Insurance Policy and Insiders Sell Stock While Defendants Continue Misleading in the Face of Regulator Pushback

185. In order to monetize Defendants' GRAIL shareholdings, Illumina had to actually close the transaction—which was the moment that GRAIL shares were converted into Illumina stock and cash under the merger agreement. As described above, Illumina and GRAIL did so on August 18, 2021 despite the fact that Illumina was then under a mandated standstill obligation imposed by its EU regulators.

186. Unknown to investors at the time, and in a powerful sign that Defendants' Class Period representations about the GRAIL transaction were knowingly or recklessly false at the time they were made, Illumina's Board of Directors sought out and secured an extraordinary insurance policy to cover their own and Illumina senior management's personal liability for pursuing the transaction. Just two weeks before closing on the transaction, on August 4, 2021 Illumina's Board doubled its D&O insurance coverage to \$300 million—at the unprecedented cost of a \$100 million annual premium—specifically to insure the Board's and senior management's acquisition-related conduct. Notably, the D&O insurance agreement does not cover any fines or sanctions that may be imposed on the Company, such as the European Commission's €432 million fine for violating the EU standstill obligation; it only covers the acquisition-related conduct of Illumina's executives and directors. On August 18, the Board approved the additional coverage. This extraordinary policy with an unprecedented premium demonstrates that Defendants knew proceeding with the transaction was wrong, gave rise to liability, and that Defendants' positive statements and the reasons Illumina was closing the transaction were not true.

187. Moreover, after securing this policy and closing the deal in the face of a mandatory standstill obligation, Illumina and GRAIL insiders began dumping their

Illumina shares, reaping tens of millions of dollars in profit. They did so at the same time Defendants continued to make additional false statements to justify their closing of the GRAIL acquisition in defiance of Illumina's regulators.

after spending his career as co-founder and Chief Scientific Officer at GRAIL, offloaded his personally-held Illumina shares within months after the GRAIL acquisition closed. Specifically, on August 18, 2021, the day the GRAIL acquisition closed, Defendant Aravanis was awarded 11,704 shares of Illumina stock in total, having previously been awarded 5,503 shares total in July 2020 and February 2021. Then, in a highly suspicious series of transactions in October and November, Defendant Aravanis sold 12,065 shares of stock, totaling approximately \$5 million in value—disposing of all of the equity he received in connection with the GRAIL acquisition as soon as he possibly could.

189. Aravanis had unique insider insight into the true facts about GRAIL—the supposedly "transformative," "life-saving" product that Illumina said would generate tens of billions of dollars in revenue over the next several years. And he liquidated all of the stock he received through the GRAIL acquisition as quickly as possible, reaping \$5 million in profit and avoiding the dramatic decline in Illumina's share price that followed shortly thereafter. Defendant Aravanis's massive offloading of Illumina shares shortly after the GRAIL acquisition is highly unusual and particularly suspicious in light of Defendants' repeated touting of the GRAIL transaction and their representations that the acquisition would create value for shareholders.

## B. Antitrust Authorities Continue to Push Back on the GRAIL Acquisition

190. After the GRAIL acquisition closed, the FTC and European Commission's antitrust proceedings continued to move forward. On September 6, 2022, the European Commission announced that it had "prohibited . . . the

implemented acquisition of GRAIL by Illumina." The Commission explained that the "merger would have stifled innovation, and reduced choice in the emerging market for blood-based early cancer detection tests," and that Illumina failed to "offer remedies sufficient to address these concerns." In the release, the Commission noted that Illumina's were the only NGS sequencers that met the requirements for MCED test developers, and further that "there [were] no credible alternatives to Illumina in the short to medium term."

191. Illumina announced that it intended to appeal the European Commission's decision. It also announced that, in order to prepare for the anticipated divestment order from the European Commission "in the coming months," it would "begin reviewing strategic alternatives for GRAIL in the event the divestiture is not stayed pending Illumina's appeal." Cowen analysts estimated that GRAIL would have a "\$2.8B price tag today," a fraction of the over \$8 billion deal value at the close of the acquisition approximately one year prior. SVB analysts further estimated that the divestment would be "a drawn-out process during which [Illumina] will continue to recognize dilution while the \$50B+ MCED opportunity (SVB's estimate) remains years ahead."

192. On April 3, 2023, the full Commission of the FTC issued an order requiring Illumina to divest GRAIL, finding that the deal would stifle competition and innovation in the U.S. market for MCED tests while increasing prices and decreasing choice and quality of tests. The FTC's opinion explained that "Illumina has an enormous financial incentive to place a thumb on the scale in GRAIL's favor" and that the "integrated Illumina will have every reason to keep rival test developers from the competitive race or to slow their progress so that they do not take sales from GRAIL."

# C. Following Increasing Scrutiny by Analysts, Illumina Lied about Its Accounting and Insiders' Secret Financial Interest

- 193. After Illumina announced its decision to appeal the FTC's order to divest from GRAIL on April 3, 2023, *Bloomberg* published an article explaining how Defendant deSouza "has been on a three-year obsessive quest to complete the \$7 billion acquisition" of GRAIL, "describing it frequently as a matter not of corporate expansion but life and death."
- 194. In response to the increasing questions of analysts and investors, billionaire activist Carl Icahn launched a proxy battle, criticizing the GRAIL deal, and ultimately winning a seat on Illumina's Board.
- 195. In an open letter to shareholders published on March 13, 2023, Icahn echoed growing skepticism by analysts and investors about the judgment in, and reasons for, closing the GRAIL acquisition in defiance of regulators. As Icahn wrote, "Perhaps overpaying for the venture business can be forgiven, but it is inexplicable and unforgiveable that under these circumstances the management team and board of directors went ahead with the deal anyway without first ascertaining whether they would get clearance from the European regulators."
- 196. Alongside Icahn's proxy battle, analysts began to more closely examine the GRAIL acquisition and Defendants' purported justifications for it. On April 24, 2023, a financial journalist, former activist investor and author of a newsletter called Nongaap Investing published an article titled "Illumina: Malignant Governance." The article asserted that Illumina insiders reaped a financial windfall "in excess of \$500 million" from the GRAIL acquisition. Tracing the changes in Illumina's equity stake of GRAIL, the author alleged that "up to 70 million GRAIL shares went to insiders, right out-of-the-gate."
- 197. Icahn issued a letter to shareholders on April 28, 2023, and called for Illumina to conduct an unbiased investigation into the "murky issues" concerning the possibility that Illumina insiders had pocketed significant financial benefits as a

result of the GRAIL acquisition. He further stated that he "would not be surprised at all if some or all of the assertions turned out to be accurate."

Additionally, we read an interesting piece recently on Illumina, entitled "Malignant Governance," which asks the question that has been on the mind of virtually every long term shareholder with whom we have spoken: "How much money did Illumina insiders (past and present) make from splitting-off and subsequently re-acquiring GRAIL?" We have no idea if the allegations are true. However, based on what we do know of the past actions and lack of transparency exhibited by Illumina CEO Francis deSouza and the incumbent directors, we would not be surprised at all if some or all of the assertions turned out to be accurate. We therefore implore the board to bring in an outside – and demonstrably independent – law firm and forensic accounting team to investigate and address these questions publicly, with enough time prior to the upcoming annual meeting to allow shareholders to take the results into account when casting their votes for directors. We believe that an unbiased investigation into these murky issues is necessary and appropriate.

198. To date, Illumina has not conducted an independent forensic investigation into these allegations. Instead, on May 1, 2023, Illumina responded to the questions raised by Icahn, the journalist, and other investors in a proxy statement, stating:

None of Illumina's directors involved in either the decision to sign or the decision to close the GRAIL acquisition – including our former CEO and Executive Chairman Jay Flatley, our current CEO Francis deSouza and each of Illumina's current directors – has ever held any equity interest in GRAIL. At the time of Illumina's various investment rounds in GRAIL, no individuals at Illumina were investors in GRAIL. Illumina's employees, executive officers and Board members were not permitted to participate in GRAIL investment rounds and did not otherwise receive any GRAIL equity. Illumina, Inc. was the founder of GRAIL and individuals employed by Illumina moved to GRAIL as part of the spin-out in 2016. Those who moved to GRAIL terminated their relationship with Illumina at the time of transition and directors and employees who remained at Illumina could not receive any GRAIL equity.

199. Defendants' carefully worded response did not provide any disclosure or explanation of the over \$830 million worth of shares at the close of the GRAIL transaction held by Illumina management and directors, the existence of which was not publicly disclosed by Defendants, and which Defendants concealed through fraudulent accounting mechanisms in violation of GAAP. The response further omitted mention of Defendant Klausner's massive stake in GRAIL.

200. On May 8, 2023, Icahn issued another letter to shareholders, questioning why Goldman Sachs had been chosen to serve as Illumina's financial advisor in connection with the GRAIL acquisition when the bank had just served as one of the lead underwriters for GRAIL's aborted IPO. As Icahn wrote, Goldman Sachs was "embarrassingly conflicted" and could not be "trusted to provide unconflicted advice"; he further wrote that Illumina had offered "an insanely high amount to acquire GRAIL, which we understand dwarfed the valuation at which GRAIL was preparing to offer shares to the public."

201. On May 18, 2023, in a letter to Illumina shareholders, Illumina Board director Defendant Thompson gave another carefully worded response to questions about Illumina insiders' conflicts of interests:

On conflicts of interest, there is an important question I would like to put to bed: "Did any Illumina directors have a financial interest in GRAIL at the time of the acquisition?" This question is not a matter of interpretation or explanation. The answer is simply no. As we have said before, no director who oversaw any part of the GRAIL transaction has ever owned any equity interest in GRAIL – that includes Jay Flatley, Francis deSouza, myself, and any member of the Board now or at the time of acquisition. In addition, no executive officers of Illumina held GRAIL shares at the signing or closing of the GRAIL acquisition (including indirect ownership interests such as through trusts, LP or GP stakes in investment vehicles, or through derivative securities), other than Alex Aravanis, who Illumina had hired from GRAIL, and Mostafa Ronaghi, Illumina's former CTO, who received GRAIL shares upon joining GRAIL's Board in May 2020.

202. Again, Defendant Thompson's statement failed to provide any disclosure or explanation for the massive missing equity stake in GRAIL that Illumina had concealed through its fraudulent accounting. And tellingly, Thompson made a clear representation that "no *executive officers* of Illumina held . . . indirect ownership interests" in GRAIL at the time of the signing or closing "such as through trusts, LP or GP stakes in investment vehicles, or through derivative securities," but made no such representation about Illumina's *directors*—suggesting that the same was not true for them. Moreover, significantly, Thompson's statement implicitly concedes that fact by stating only that directors "who oversaw" the GRAIL

transaction did not own an equity interest—leaving equity ownership on the table for all directors who did not fall within his definition of "oversaw."

- 203. Defendant Thompson confirmed that Goldman Sachs had served as Illumina's advisor in connection with the GRAIL acquisition and disclosed that it had "delivered a customary fairness opinion to Illumina's Board immediately prior to Illumina entering into the GRAIL acquisition agreement." That Illumina sought a fairness opinion—which had never been disclosed previously—from Goldman Sachs is remarkable given that the bank had been advising GRAIL in connection with its proposed IPO in August and September 2020, just before the merger closed. The fact that Goldman Sachs performed these two roles, at effectively the same time on effectively "opposite" sides of the most consequential transaction in GRAIL's corporate history, raises serious questions as to how the conflicted banker could have faithfully delivered that fairness opinion or how Illumina's Board could possibly have relied upon it. Moreover, Defendant Thompson did not respond to Icahn's and investors' concerns about Illumina's inability to acquire a fairness opinion from an independent financial advisor without prior ties to GRAIL.
- 204. Not a single other Illumina or GRAIL director or executive signed onto Defendant Thompson's statement.
- 205. As a result, on May 25, 2023, Illumina held its shareholder vote, culminating with Carl Icahn winning one seat on the Company's Board.
- 206. Icahn's proxy battle—including his bringing to light of the possibility of insider benefits from the GRAIL acquisition—resulted in substantial changes to Illumina's management and Board. On June 2, 2023, Illumina announced a series of Board changes, including by installing independent board member Stephen P. MacMillan as Chairman, and added one additional independent Board member, Scott B. Ullem. Just over a week later, on June 11, 2023, Illumina announced that deSouza had resigned, and that Charles Dadswell, Illumina's General Counsel, was named interim CEO.

### D. The European Commission Imposes A €432 Million Fine on Illumina and Orders Illumina to Divest GRAIL

207. Soon after the proxy battle's conclusion and Defendant deSouza's resignation, on July 12, 2023, the European Commission imposed a €432 million "gun-jumping" fine on Illumina for completing the GRAIL acquisition despite the standstill obligation. The €432 million fine (approximately \$478 million) was the maximum fine that the European Commission could impose, as well as the largest gun-jumping fine ever imposed by the European Commission. In connection with the fine, the European Commission noted that "Illumina and GRAIL *knowingly and intentionally breached the standstill obligation* during the Commission's in-depth investigation" and remarked that this was "*an unprecedented and very serious infringement* undermining the effective functioning of the EU merger control system."

208. On October 12, 2023, the European Commission ordered Illumina to unwind its already completed acquisition of GRAIL and adopted measures requiring Illumina to "restore the situation prevailing before the completion of the acquisition." The Commission required Illumina and GRAIL to remain separate, and for Illumina to "maintain GRAIL's viability by continuing to fund GRAIL's cash needs on an ongoing basis to allow it to further develop and launch its early cancer detection test Galleri."

209. While analysts were not surprised by the European Commission's divestment order, many expressed concern about Illumina's obligation to continue capitalizing GRAIL. For example, analysts at Canaccord remarked that the capitalization requirement "could prove to be problematic, as GRAIL may require nearly \$1 billion in capital, which would be complicated for [Illumina] to fund independently." Likewise, Evercore ISI analysts reported that "[i]nvestors were nervous about the amount of cash that [Illumina] had to fund Grail to ensure its

viability," with an estimated potential cash outlay of \$1.5 billion assuming Illumina had to fund two-years' worth of cash.

### VIII. INVESTORS ARE HARMED AS DEFENDANTS' FRAUD TRIGGERS MASSIVE DECLINES IN PRICE OF ILLUMINA SHARES

210. As one journalist summed up, Defendants' acquisition of GRAIL and pursuit of the transaction has left a trail of "carnage" of value destruction in its wake:

Having agreed to the transaction, deSouza then set his company on a collision course with regulators, announcing in August 2021 that Illumina would close the deal despite a review by European antitrust authorities. (The company last year set aside \$453 million for a potential EU fine for completing the merger without approval.) Shareholders haven't enjoyed the ride. Illumina's shares, which traded at \$525 that month, have lost more than half of their value, wiping about \$40 billion from the company's market capitalization.

211. As set forth below, Defendants' fraud triggered massive, statistically significant declines in the price of Illumina's common stock that were causally connected to the facts that Defendants misrepresented and concealed. These declines caused billions in investor damages.

## A. Defendants Close the GRAIL Acquisition in Violation of the Automatic Standstill Obligation

- 212. On August 18, 2021, after market close, Illumina shocked investors by announcing that it had closed its acquisition of GRAIL in violation of the European Commission's automatic standstill obligation, which requires that merging companies hold off from implementing a merger until it is approved by the Commission.
- 213. Numerous reporters and analysts expressed confusion at Illumina's closing of the acquisition despite not having regulatory approval—a fact that many remarked was unprecedented. Analysts from Cowen noted that the closing was "a surprising and seemingly aggressive tactical move," while analysts from Bank of America similarly found the move "surprising and aggressive." Citi analysts remarked that they "could not find any precedent for an acquirer intentionally closing a deal ahead of regulatory approval particularly in a case where the

approval process has been somewhat contentious with the outcome uncertain." In response to Illumina's announcement, analysts from SVB downgraded Illumina stock, in part due to the "rising uncertainty with [Illumina's] action yesterday to close the GRAIL acquisition. . . . This somewhat 'rushed' closing without clearing all the regulatory hurdles raises more questions than it answers for investors."

214. Following these disclosures, the price of Illumina common stock tumbled nearly 7.9%, from a closing price of \$510.61 on August 18, 2021, to a closing price of \$470.36 on August 19, 2021 on extraordinarily high trading volume.

#### B. Clinicians Raise Serious Doubts About Galleri's Clinical Validity

- 215. On November 23, 2021, three physicians with expertise in pathology, pathobiology, and biochemistry published an article in the journal *Diagnostics* titled "Can Circulating Tumor DNA Support a Successful Screening Test for Early Cancer Detection? The Grail Paradigm." As set forth in the article's abstract, the physicians' independent analysis of Galleri's results "cast[] doubt" on whether Galleri "could become a viable pan-cancer clinical screening tool."
- 216. These disclosures began to call into question Defendants' repeated, confident assertions about Galleri's "proven" validity, and the market reacted with concern. The day the article was published, Illumina's stock price declined by more than 3%, from a closing price of \$377.15 per share on November 22, 2021 to close at \$365.74 per share on November 23, 2021.

# C. Illumina Acknowledges That Galleri Still Did Not Possess Clinical Study Outcomes Necessary for Regulatory Approval

- 217. On Thursday, May 5, 2022, Illumina held an investor conference call, during which Defendant deSouza's answers to analyst questions raised further concern about whether Galleri had or could obtain the clinical study data necessary for regulatory approval and reimbursement.
- 218. After the November 2021 *Diagnostics* article was published, in the months leading up to the May 5 investor call, prominent oncologists and other cancer

specialists had continued to raise significant questions about the clinical validity of Galleri. For example, on April 21, 2022, the Director of the Division of Cancer Prevention at the National Cancer Institute, Dr. Philip E. Castle, published an article titled "Screening for Many Cancers with One Test: Uncertainty Abounds." In the article, Dr. Castle underscored the unanswered questions that remain about MCED tests and their clinical validity, including: "Do these tests actually reduce deaths from cancer?" Dr. Castle further explained that, to achieve the aim of reducing deaths from cancer, "the screening test itself is just the beginning" and "[m]any steps must then occur to confirm that result and, if necessary, treat the cancer." Dr. Castle also explained that "more studies on the underlying basic and clinical science of MCED tests" were needed, including studies to "validate the performance of the MCED tests under development" like Galleri through "large clinical trials."

219. In the wake of such critiques, investors and analysts became increasingly skeptical of Defendants' statements about Galleri's "efficacy." During the May 5, 2022 investor call, analyst Jack Meehan from Nephron Research asked Defendant deSouza to respond to Dr. Castle's criticisms that it was not enough for MCED tests like Galleri to "detect[] cancer," but that they also needed to "improve survival." Meehan further asked for the "timeline for FDA approval of Galleri," and Defendant deSouza's "level of confidence that the study is underway" and that "the enrollment [was] large enough to get FDA approved." In response, Defendant deSouza conceded that "it will take a long time to get . . . data" concerning Galleri's impact on cancer survival rates and that there were "no new timelines to be announced" with respect to FDA approval:

Meehan: I had three questions on GRAIL. First, NCI recently had a blog post on multi-cancer testing. In that, they talked about detecting cancer itself not being enough, the [MCED] test need to improve survival. To Francis, was curious to get what your response is to that. Second, just latest thoughts on timeline for FDA approval of Galleri. And then finally, just your level of confidence that the study is underway, the enrollment is large enough to get FDA approved? Thank you.

deSouza: I'll start by talking about the ND – NCI commentary and then frankly, just the idea that look, ultimately, you do want to see the impact on survival rates. And so, that's going to be important and that's something we're going to be tracking over the next years. *Obviously, it will take a long time to get that kind of data.* 

The team has continued to make progress in terms of engaging with the FDA, *There is no new timelines to be announced*. I don't think the size of the study is going to be the problem. I think it will just take time. I think they've powered the studies they need sufficiently and the dialogues have been constructive with the FDA.

- 220. That same day, Illumina also announced that GRAIL had obtained only \$10 million in revenue during the first quarter of 2022—significantly underperforming estimates of \$70 to \$90 million for 2022.
- 221. As a result of these disclosures, analysts expressed concern about Galleri's pathway to regulatory approval and GRAIL's "long-term potential." For example, Evercore ISI highlighted GRAIL's lengthy clinical pathway and related spending, stating, "we don't think the GRAIL related spending is likely to step down any time soon . . . getting a product FDA approved is the first step potential commercial and marketing spend could total to Bns over the next 5 to 7 years." Barclays similarly expressed skepticism towards Illumina "due to uncertainty around GRAIL's long-term potential" and stated: "Our checks remain mixed on the pan-cancer test adding cost to the healthcare system, reimbursement, and inclusion in guidelines." Analysts from Evercore ISI and UBS further noted that GRAIL's revenues from the first quarter of 2022 had missed consensus.
- 222. Following these disclosures, the price of Illumina common stock tumbled nearly 14.63%, from a closing price of \$291.72 on May 5, 2022, to a closing price of \$249.05 on May 6, 2022.
  - D. Illumina Suddenly Announces the CFO's Departure as *The New York Times* Raises Further Questions About Galleri's Validity
- 223. On June 9 and 10, 2022, Illumina investors were provided with two distressing pieces of news. First, on June 9, 2022, after market close, investors learned that Defendant Samad would be departing Illumina on July 8, 2022 for Quest

Diagnostics, and that Joydeep Goswami, then-Chief Strategy and Corporate Development Officer, would serve as interim CFO.

224. Then, on June 10, 2022, before market open, *The New York Times* published an article titled "Blood Tests That Detect Cancers Create Risks for Those Who Use Them" that cast further doubt on the clinical validity of Galleri. The article specifically highlighted how a cancer statistician who was asked to join GRAIL's scientific advisor board at GRAIL's founding was mysteriously asked to leave just prior to Galleri's launch. As the article reported:

Testing Into Overtreatment?

When GRAIL was first formed, its leaders invited Donald Berry, a statistician at MD Anderson Cancer Center in Houston, to be on its scientific advisory board.

"They said they needed a skeptic," Dr. Berry said. "I told them I was a skeptic and I was quite negative. I told them there was this real hurdle—they will have to run very large clinical trials and the endpoint must be survival. They have to show that detecting cancer early is more than just detecting cancer early. It has to mean something."

A few years later, the company restructured its scientific advisory board to include many new experts, and Dr. Berry is no longer a member. He is not sure why.

"Being generous, I'd say they no longer needed my expertise," Dr. Berry said. "Being realistic, they got tired of hearing my complaints that finding cancer early was not enough."

Yet difficult questions from him and other critics remain.

225. The article went on to cite other leading cancer experts who questioned GRAIL's approach, highlighted the dangers and patient harm involved in failing to conduct clinical trials that showed cancer screening tests actually improved patient outcomes, and warned that GRAIL's approach with Galleri could "bankrupt Medicare." For example, the article quoted Dr. H. Gilbert Welch, a senior investigator at the Center for Surgery and Public Health at Brigham and Women's Hospital, as stating that "GRAIL proposes to test every Medicare beneficiary every year, making it the screening test that could bankrupt Medicare," and "finding cancers earlier could mean just as many deaths, with the same timing as without

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early diagnosis," since certain cancers may not be able to be cured even if found early. The article also quoted Dr. Barnett Kramer, a member of the Lisa Schwartz Foundation for Truth in Medicine and former director of the Division of Cancer Prevention at the National Cancer Institute, as stating that he feared that tests like Galleri would come into widespread use without ever showing they are beneficial and "I hope we are not halfway through a nightmare."

226. Illumina provided a purported justification for Defendant Samad's departure—that he was leaving for "personal reasons" to be "near family"—and GRAIL published a formal response to The New York Times article on its website that day. But analysts remained skeptical. For example, SVB remarked that Samad's "sudden departure" was "bound to come as a surprise to investors at a time when the company is facing rising competitive noise [and] uncertainty about GRAIL," while Bank of America noted that Samad's departure was troubling in light of the fact that "Grail's Galleri test is in early stages of commercialization" and "remains highly controversial in the investment community." Analysts also immediately connected Samad's departure to GRAIL, with Canaccord observing that Samad's move was "not too surprising, upon review" because his new role "may be relatively less 'noisy' (i.e., 'safer') than Illumina given the impact of GRAIL" and Evercore ISI remarking that "ILMN has had a challenging time navigating the regulatory landscape (opposition by FTC & EU Regulators over the Grail acquisition), and it has not been easy from a CFO's perspective."

- 227. Despite Illumina's efforts to blunt the impact of these two significant developments, Illumina stock reacted harshly, declining 9% on June 10, 2022, from a closing price of \$224.47 on June 9, 2022 to a closing price of \$204.19 on June 10, 2022.
- 228. Analysts and journalists tied the drop to these events. For example, in an article published the following Monday, "Illumina Will Be Fine Despite Recent Concerns, Says CEO," Barron's reported that Illumina's stock had declined in

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response to the CFO's departure and *The New York Times* article, pointing out that investors "were discomfited by news that Illumina's chief financial officer will move to another firm" and by the article, which "raised questions about the cancer blood tests that are one of Illumina's big bets." The article also quoted Defendant deSouza, who told *Barron*'s that none of the news should concern investors and touted Galleri's "unusually low rate of false positive readings."

- E. Illumina Announces Disappointing Results and Guidance for GRAIL, and Recognizes a Massive Legal Contingency Related to the EU's Investigation
- 229. On August 11, 2022, after market hours, Illumina issued second-quarter 2022 financial results that included several discouraging results for GRAIL. Among other things, GRAIL revenues came in 25% below consensus estimates and Illumina reduced fiscal-year 2022 guidance for GRAIL by approximately 25%, from a range of \$70-90 million to a range of \$50-70 million. In addition, Illumina announced that it had recognized \$609 million in legal contingencies, including an accrual of \$453 million "for the potential fine that the European Commission may impose" related to the decision to close the GRAIL acquisition in violation of the standstill obligation, which was a significant driver of Illumina's \$535 million loss for the quarter.
- 230. Analysts reacted negatively to these disclosures. Evercore ISI, UBS, and J.P. Morgan discussed the GRAIL revenue miss and guidance reduction, and J.P. Morgan also noted that Illumina's "cash position" was "pressured" by the potential European Commission fine.
- 231. In response to these disclosures, Illumina's stock price declined significantly, falling 8.4%, from a close of \$227.44 per share on August 11, 2022 to close at \$208.33 per share on August 12, 2022, on elevated volume.

### F. Illumina Lays Off 10% of Its R&D Team

232. The disastrous consequences of the GRAIL transaction continued when, in June 2023, Illumina disclosed massive cost-cutting measures needed to

offset extraordinary operating losses GRAIL was imposing and independent news sources revealed that the Company was laying off 10% of its R&D team. Specifically, on June 26, 2023, after market close, Illumina filed a Form 8-K with the SEC announcing that it had commenced layoffs in connection with a previously-disclosed plan to reduce annualized run rate expenses by \$100 million.

- 233. That plan had been announced at the end of March 2023, just weeks after Icahn published a letter to Illumina shareholders excoriating management for taking out supplemental D&O insurance in anticipation of the closing of the GRAIL transaction. It would not be disclosed until after the Class Period that the insurance was obtained at a whopping \$100 million annual premium—exactly the amount of the annual expense reduction Illumina undertook.
- 234. Later on June 26, 2023, within hours of the Company's layoff announcement, health and medicine publication *STAT* provided additional concerning details that Illumina had failed to divulge. Specifically, *STAT* reported—based on internal emails it obtained and reviewed, including emails from Defendant Aravanis and then-interim CEO Charles Dadswell—that the headcount reduction would consist of 10% of Illumina's R&D workforce, the driving engine for the Company's growth.
- 235. The newly announced layoffs in Illumina's R&D workforce had not been disclosed in Illumina's prior announcements concerning its plan to reduce annualized run rate expenses by \$100 million. In the initial announcement that took place at the end of March 2023, Illumina announced that it would "achieve these savings" by "leverag[ing] the recent modularization of R&D innovation created" as part of one of its NGS sequencing platforms, "leveraging [Illumina's] global footprint enabling activities at more cost-effective hubs," and "streamlining our organization and processes, including rationalizing the Company's global real estate portfolio and third-party vendor spend, as well as accelerating IT optimization

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efforts." These representations were repeated by Defendants on the April 25, 2023 earnings call with investors.

- 236. The R&D layoffs further directly contradicted Defendants' prior statements concerning Illumina's focus on R&D and the R&D headcount. For example, on November 3, 2022, during the earnings call with investors, deSouza explained that non-GAAP operating expenses "were up \$36 million year-over-year due primarily to headcount growth in investments we are making in R&D to support the continued advancements of our innovation road map."
- 237. On November 28, 2022, at the Evercore ISI HealthConx Conference, Sallilyn Schwartz, Illumina's Vice President of Investor Relations, stated, "you should continue to see us over time continue to put money into both our R&D expense budget to fuel the future innovations and continue to drive this forward." And two days later, on November 30, 2022, at the Piper Sandler Annual Healthcare Conference, deSouza stated that Illumina was "focused on making sure that we retain and sustain our ability to continue to innovate and provide high-quality service to our customers at the end of the day, both research and clinical."
- 238. The news of the layoffs took investors by surprise. Numerous news outlets—including *Reuters*, *Dow Jones*, and *MarketWatch* reported on the initiation of Illumina's layoffs. SVB also issued an analyst report commenting on the news.
- 239. Following these revelations, Illumina's stock price declined more than 4.40%, from a closing price of \$191.88 on June 26, 2023 to close at \$184.43 on June 27, 2023.
  - Key Senior Executives Responsible for GRAIL "Resign," and G. **Illumina Discloses an SEC Investigation**
- The fallout from the GRAIL acquisition continued when, in August 2023, Illumina suddenly disclosed the departures of two of the key executives responsible for the GRAIL debacle and that the SEC had been investigating the GRAIL acquisition. On August 9, 2023, Illumina filed a Form 8-K reporting that

Defendant Febbo had departed on August 7, 2023 after over five years with the Company. In addition, Illumina announced that Defendant Aravanis would also depart the Company. The press release explained that Defendant Aravanis was leaving Illumina "to pursue another opportunity outside of the company."

241. The next day, August 10, 2023, after market close, Illumina revealed that the SEC was investigating the Company's statements regarding GRAIL. Specifically, in its Form 10-Q for the period ended July 2, 2023, Illumina stated:

In July 2023, we were informed that the staff of the SEC was conducting an investigation relating to Illumina and was requesting documents and communications primarily related to Illumina's acquisition of GRAIL and certain statements and disclosures concerning GRAIL, its products and its acquisition, and related to the conduct and compensation of certain members of Illumina and GRAIL management, among other things. Illumina is cooperating with the SEC in this investigation.

- 242. Analysts expressed concern about these sudden departures and the disclosure of the SEC investigation. For example, UBS noted that Illumina had disclosed "that it is cooperating with SEC on the investigation regarding GRAIL acquisition." On Friday, August 11, 2023, *Bloomberg* reported that Illumina's stock was down 3.7% as a result of the investigation, putting it "among the biggest decliners in the S&P 500 Friday," while *BioSpace* reported on the SEC investigation alongside the departures of Defendants Aravanis and Febbo.
- 243. News outlets continued reporting on the SEC investigation over the next several days. For example, on Monday, August 14, 2023, reports from the *San Diego Union-Tribune* and from *MedTech Dive* highlighted the focus of the SEC investigation and Illumina's ongoing dispute with antitrust regulators.
- 244. The market reacted severely to these revelations, with the price of Illumina common stock declining approximately 5.4%, from a closing price of \$185.12 on August 10, 2023, to a closing price of \$175.14 on August 14, 2023.

# H. Icahn Files a Complaint Confirming Defendants' Undisclosed "Personal Stake" in the GRAIL Acquisition

245. Just weeks after being elected to Illumina's Board and gaining access to internal Board documents and privileged information concerning the GRAIL acquisition, Carl Icahn's nominee and then-newly elected director of the Board, Andrew Teno, concluded that members of Illumina's Board had breached their fiduciary duties and could not be trusted to make decisions for the Company because they were "poisoned by their personal stake" in the deal.

246. Armed with this knowledge, Icahn sued certain members of Illumina's Board of Directors, filing a public version of the complaint after market close on October 20, 2023. The complaint was verified by Icahn Partners LP's Chief Operating Officer, who swore in his accompanying affidavit and verification that the "facts alleged" in the complaint—which were based on extensive citations to internal and privileged Illumina Board documents—were "true and correct." As Illumina explained in moving to strike the complaint, it contained 47 paragraphs of "direct quotes from and/or descriptions of privileged memoranda and advice provided to [Illumina] by its outside counsel" related to the GRAIL acquisition. In a submission related to Illumina's motion, Teno testified that his review of some of these materials made him "extremely concerned" about the conflict posed by the Illumina leadership's "personal stake" in the deal, and prompted the lawsuit.

247. While large portions of the public complaint are redacted and unavailable to the public, the complaint asserted that "[t]he conflicted directors" were "poisoned by their personal stake in the matter," could not be "entrusted" with "matters of vital importance to Illumina," and lied about the Company's reasons for closing the acquisition. Among other things, the complaint sought an order seeking "disclosure of material facts surrounding the acquisition," as Illumina shareholders were "entitled to know the truth about Defendants' misconduct" and have their fate

- 248. At an investor conference the same day the complaint was filed, Icahn rebuked Defendants' conduct, remarking: "Throughout my long, long career as an activist, I have never found it necessary, until today, to sue a board of directors in this manner," and that he had "never seen one as bad as this, and I've been around a long time."
- 249. The following Monday, October 23, 2023, during mid-day trading, *Bloomberg* published a detailed article highlighting Icahn's allegations that "'[t]he conflicted directors, poisoned by their personal stake in the matter, cannot be entrusted' with the company's next move." Similarly, *Law360* reported on Icahn's allegations that the individual defendants named in the lawsuit "wrongfully 'entrenched themselves' on the board and 'orchestrated Illumina's widely reported crusade and obsessive quest to complete Illumina's acquisition of Grail." These reports continued into October 24, when, for example, *MedTech Dive* reported that Icahn was seeking to remove individuals from Illumina's Board due to their "bad faith pursuit of their 'holy grail' acquisition."
- 250. Following this news, the price of Illumina common stock declined in a statistically significant manner by nearly 3%, from a closing price of \$119.64 on October 20, 2023, to a closing price of \$116.10 on October 24, 2023.

### I. Illumina Announces Nearly \$1 Billion Impairment Due to GRAIL

251. Shortly after market close on November 9, 2023, Illumina issued an earnings release in which the Company announced that it would be taking an \$821 million impairment due to GRAIL. Specifically, as part of its annual impairment test, Illumina concluded in the third quarter of 2023 that GRAIL's "carrying value exceeded its estimated fair value." As a result, the Company "recorded \$712 million of goodwill impairment related to our GRAIL reporting unit," as well as \$109 million intangible asset impairment.

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252. This impairment followed just a year after Illumina took a massive \$3.9 billion impairment related to GRAIL during the third quarter of fiscal year 2022. At the time of the prior write-down, Defendants downplayed it, with Goswami explaining that the "reassessment of GRAIL's book value was really more of an accounting requirement, triggered by some of the regulatory decisions coming out of Europe" and that "[t]he underlying . . . performance of GRAIL in terms of how it's progressing on its clinical results and signing up customers really has not changed" and "in fact has improved a little bit over the last few quarters." The November 2023 write-down, by contrast, had no such exculpatory explanation. Rather, Illumina wrote down GRAIL due in part "to a decrease in projected cash flows"—i.e., because GRAIL would generate less revenue.

253. Analysts immediately reacted to the news of the new impairment. For "took Morgan Stanley Illumina \$821M example, reported that an goodwill/intangible impairment charge related to GRAIL in 3Q, following the \$3.9B charge taken in the same period last year." Likewise, Leerink Partners noted that Illumina had "recognized a \$821 million for GRAIL, which follows a \$3.9B impairment in 3Q22." For its part, Canaccord discussed a potential divestment of GRAIL, stating that the price would likely be "below \$3 billion" but that "Illumina may not have much leverage in this situation"—thus suggesting that, even with the additional write-down, GRAIL was still overvalued.

254. Once again, the market reacted severely to these revelations, and the price of Illumina common stock declined 13.3%, from a closing price of \$106.98 on November 9, 2023, to a closing price of \$92.79 on November 13, 2023—its lowest trading price in a decade.

255. The net result of the two impairments was that, within approximately two years of the acquisition closing, Illumina had reduced its valuation of GRAIL by well over 50%. In a report published after the latest impairment was announced, Barclays had harsh words, lamenting that GRAIL "burns >\$600m of cash per year

and has fallen well short of mgmt's targets over the past two years," there was a lack of needed clinical data about the "test accuracy," and concluding that they would "remain on sidelines until we get clarity on what happens with GRAIL." For its part, RBC Capital reflected on how Illumina's investors had been burned by the GRAIL acquisition: "Inventing a time machine and convincing his predecessor to forget about GRAIL would have been a good way to gain investor confidence; but yesterday afternoon [deSouza's replacement] Mr. Thaysen did the next best thing: he confirmed the GRAIL divestiture process has begun."

#### IX. POST-CLASS PERIOD DEVELOPMENTS

256. Events occurring after the end of the Class Period have further confirmed that Defendants knew or recklessly disregarded the truth about GRAIL during the Class Period—and that, in reality, GRAIL was worth a fraction of what Illumina paid to acquire it.

#### A. GRAIL Cannot Be Sold After Illumina Commits to Divestiture

- 257. On December 15, 2023, the U.S. Court of Appeals for the Fifth Circuit issued its decision in the matter of *Illumina v. the Federal Trade Commission*, upholding the prior decision of the FTC to enjoin the GRAIL acquisition.
- 258. On December 17, 2023, Illumina announced that it had elected not to pursue further appeals of the Fifth Circuit's decision and that it would divest GRAIL through a third-party sale or capital markets transaction, consistent with the European Commission's divestiture order, with the goal of finalizing the terms by the end of the second quarter of 2024. Under the European Commission's order, Illumina is required to capitalize GRAIL with two and a half years of funding because GRAIL will be divested through a capital-markets transaction.
- 259. The market reacted with relief in response to the announcement, with one reporter calling the decision "the final chapter in one of the most disastrous attempted mergers in biotech history." Likewise, Piper Sandler analysts remarked, "Finally!" Recounting the history of the acquisition, the analysts noted that the deal

had never won over investors, and that Illumina already had "operating losses on standalone GRAIL of >\$1B, had a fine of \$476M, and written down \$3.9B." Though analysts viewed the divestment as positive news, this troubled history was reflected in analysts' predictions of GRAIL's ultimate sale price; Canaccord and RBC Capital analysts predicted that GRAIL would sell for approximately \$3 billion or even less—well below the more than \$8 billion deal reached between Illumina and GRAIL.

260. The reality was even worse for Illumina investors than these analysts' grim assessment. Since Illumina's announcement that it would be divesting from GRAIL, newly appointed CFO Goswami left Illumina, and Illumina was unable to find any buyer to purchase GRAIL. On April 9, 2024, Illumina announced that Goswami would be leaving the company just 14 months after becoming its permanent CFO. The Company announced that he would be taking on an advisory role through June 30 "to support two new executive management team appointments." Ankur Dhingra was announced as Goswami's replacement, making him Illumina's third CFO in the span of two years.

261. On May 6, 2024, Illumina publicly filed its Form 10 registration statement in connection with its intended divestiture of GRAIL, having previously submitted a confidential version of the registration statement to the SEC the previous December, and disclosed that GRAIL would be hosting a Capital Markets Day on May 13, 2024, further indicating that Illumina did not have a buyer for a third-party sale of GRAIL. Analysts at Canaccord remarked that they "expect bidders are not plentiful."

262. These doubts about Illumina's ability to sell off GRAIL were confirmed on June 3, 2024, when Illumina announced that its Board of Directors had approved the spin-off of GRAIL. GRAIL is scheduled to spin off from Illumina on June 24, 2024, and applied to list on NASDAQ as "GRAL." Illumina further announced that beginning on or about June 12, 2024, GRAIL common stock would trade on a "when-issued" basis on NASDAQ (i.e., when securities have been announced but

not yet issued). On Friday, June 21, 2024, when-issued trading of GRAIL common stock ends, and on Tuesday, June 25, 2024, GRAIL common stock will begin trading "regular way" on NASDAQ under the ticker symbol "GRAL."

263. Based on GRAIL's "when-issued" trading since mid-June 2024, it has a market capitalization of under \$500 million. In other words, GRAIL is now valued at around 6% of what Illumina paid, an extraordinary fact that defies any legitimate justification. Moreover, not only was GRAIL worth a mere fraction of what Illumina paid, there is a significant possibility that Illumina will have to continue spending \$1 billion annually to fund GRAIL's operations as part of the divestiture process, on top of a nearly \$500 million fine from EU, and the destruction to Illumina's business caused by Defendants fraud.

## B. The FDA Takes Action to Ensure the Safety and Effectiveness of Laboratory Developed Tests

264. On April 24, 2024, the FDA announced a final rule amending the FDA's regulations to ensure the safety and effectiveness of LDTs like Galleri, which had previously been announced in September 2023. The FDA's new rule makes explicit that cancer tests like GRAIL, including those that are offered as LDTs, are "devices" under the Federal Food, Drug, and Cosmetic Act. Accordingly, LDTs will be required to comply with more stringent device requirements, including premarket review, quality system requirements, adverse event reporting, establishment registration and device listing, labeling requirements, and investigational use requirements. Notably, in proposing the rule, the FDA explicitly cited the dangers posed by Galleri and the "serious questions" that the test posed, pointing to an oncologist's experience with the false test results from the Arizona first responders testing round noted above.

265. The FDA's announcement of the final rule, and the reasons for the issuing of the rule, challenged Defendants' repeated statements about the clinical validity of GRAIL's Galleri test. In announcing the final rule, the FDA made clear

that the rule was issued due to "numerous examples of potentially inaccurate, unsafe, ineffective or poor quality" In Vitro Diagnostics—i.e., test-tube diagnostic tests like Galleri—"offered as LDTs that caused or may cause patient harm, including tests used to select cancer treatment . . . and identify a patient's risk of cancer." The final rule thus provides "greater oversight of the safety and effectiveness of LDTs," without which "patients may be more likely to initiate unnecessary treatment, or delay or forego proper treatment based on inaccurate test results or tests promoted with false or misleading claims."

266. As FDA Commissioner Robert M. Califf, M.D. explained, "The agency cannot stand by while Americans continue to rely on results of these tests without assurance that they work. The final rule announced today aims to provide crucial oversight of these tests to help ensure that important health care decisions are made based on test results that patients and health care providers can trust."

### C. NHS Postpones Rollout of Galleri Based on Data from the First Year of the NHS-Galleri Trial

267. Contrary to Defendants' statements that NHS study data would support FDA approval in 2024 and broad-based reimbursement shortly thereafter, the NHS study, to date, has done nothing of the sort. On May 29, 2024, the NHS announced that it would not be taking up an option to roll out the NHS Galleri trial to 1 million people, based on a data "snapshot" of selected first year results. The NHS's data "snapshot" review of trial results was first disclosed in a March 2024 blog post by GRAIL.

268. The NHS reported that it "has reviewed preliminary data from the first year of the NHS-Galleri trial and *did not find them compelling enough to justify proceeding straight away with a large-scale pilot programme of the test in NHS clinical practice*, while we await the final results of the trial." Instead, the NHS will "wait to see final results" of the NHS Galleri trial, which are expected in 2026, before deciding whether to proceed with the rollout.

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269. The announcement cast further doubt on Galleri's clinical validity. In an article published by *Genome Web*, an analyst at Canaccord noted that investors had been "banking on" the NHS Galleri trial "to help boost Galleri sales and accelerate regulatory approval in the US." GRAIL did not respond to questions from *Genome Web* about "when it submitted the data snapshot to NHS and when NHS informed it that it would not be accelerating Galleri implementation."

270. On May 29, 2024, GRAIL further filed an amended Form 10 registration statement, disclosing the NHS's decision. In an article published by *Endpoints News* the next day, Nephron analyst Jack Meehan said that the news did not bode well for Illumina and GRAIL: "Not only does this dampen the short-term commercial prospects for the test, but as Grail's disclosure notes, there could be broader implications into the value of the test in the full study."

## D. Illumina Insiders Land Plush Jobs with ARCH Ventures-Backed Companies

271. Although the news for Illumina's investors has continued to worsen, since the closing of the GRAIL acquisition, departed Illumina and GRAIL Executive Defendants have landed lucrative positions at companies backed by ARCH Ventures, suffering no consequences for causing the massive value destruction of Illumina stock and pocketing millions of dollars from their insider stakes. That executives and directors from both Illumina and GRAIL have joined new ARCH Ventures-backed companies further betrays the conflicts that drove the GRAIL acquisition.

272. GRAIL founder and former GRAIL director and Illumina CMO Klausner; former GRAIL CEO Bishop; former GRAIL director Hal Barron; and former Illumina director Frances Arnold—who approved the GRAIL acquisition and closing—have each landed jobs at Altos Labs. Altos Labs is an ARCH Ventures-backed anti-aging startup seeking to develop "life extension" therapies that can halt or reverse the human aging process. Altos Labs was founded by Klausner and

Bishop together, and they now serve as Board Co-Chairs. Klausner serves as Chief Scientist of the company, while Bishop serves as President. Hal Barron, a former director at GRAIL, is currently the CEO of Altos Labs, while Illumina Board member Frances Arnold serves as a director. With funds needed to launch the new start-up, on August 18, 2021, the architects closed the GRAIL acquisition just months after Altos Labs had filed for incorporation in the US and the UK, reaping millions of dollars. In January 2022, just months after the company was officially incorporated, Altos Labs finally announced its launch with \$3 billion in venture funding—with ARCH Ventures calling Altos its largest investment ever, undoubtedly fueled by the profits from GRAIL.

273. For their part, Defendant deSouza and Defendant Aravanis have taken on roles at another ARCH Ventures-backed company, Moonwalk Biosciences, which was co-founded by Defendant Aravanis, the former CTO of Illumina, after his departure. The startup was launched in 2024 with \$57 million in financing from backers including ARCH Ventures.

#### X. ADDITIONAL ALLEGATIONS OF SCIENTER

- 274. Numerous facts establish that Defendants acted with scienter when they made false and misleading statements to investors as alleged above and herein. These facts are set forth above and summarized below.
- 275. *First*, Defendants were well aware of the projections that Illumina and its Board considered in connection with the acquisition, but nevertheless issued a misleading Form S-4 touting far rosier projections while holding back the more pertinent, darker projections. In its S-4 for the GRAIL acquisition, Illumina included a "fairness opinion" from Morgan Stanley that purportedly justified the price of the deal based on two sets of assumptions—one supposedly conservative, the other less so—provided by GRAIL management. But, undisclosed to investors, Illumina's internal "Deal Model" prepared in connection with the decision to acquire GRAIL projected GRAIL's revenues as just a small fraction of the revenues from the more

conservative set of GRAIL assumptions publicly detailed in the S-4. As has become clear through filings in derivative actions in Delaware after the Class Period, Illumina management's internal projections valued GRAIL at only \$3.3 billion to \$11.9 billion—billions of dollars lower that the valuations publicly discussed by GRAIL in its public SEC filings, which ranged from \$11.1 billion to \$43.95 billion.

276. *Second*, the Executive Defendants' and other Illumina and GRAIL senior managers' testimony in the FTC proceedings, the findings of the FTC and the Fifth Circuit Court of Appeals on the basis of that testimony, and the accounts of well-placed former employees, all confirm that Defendants knew their statements were misleading. Specifically, that record shows that Defendants' statements about Illumina's ability to "accelerate" Galleri's commercialization, FDA approval and adoption, statements about Illumina needing to acquire GRAIL to effect such acceleration, and assertions about Galleri not requiring any further tests to be successful were knowingly false and misleading when made.

277. At the very beginning of the Class Period, Defendants stated that "the reason" Illumina was acquiring GRAIL was "because we have very clear line of sight into how we can accelerate the plan that they are on today" and "we can only do that when they're part of Illumina." Defendants repeated and expanded on these representations throughout the Class Period—explaining, for example, that "[i]n reuniting the two organizations, Illumina will leverage its global scale of manufacturing and clinical capabilities, as well as its global regulatory and reimbursement expertise, to bring early-stage, multi-cancer testing to patients more quickly and more affordably, resulting in more lives being saved" and that the transaction "would accelerate the adoption of a breakthrough multi-cancer early detection blood test."

278. But when required to substantiate their acceleration claims in the FTC trial, Defendants could not muster *any* evidence to support that claim. As the Fifth Circuit explained after reviewing the extensive trial record, "substantial evidence"

showed that "Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved." Defendants themselves argued before the FTC that they were "unable to substantiate [their acceleration] claims" because the companies were being held separate—ignoring that they had asserted unequivocally that they had "very clear line of sight into how we can accelerate the plan" for GRAIL *before* they closed the merger.

279. Similarly, testimony and other evidence from the FTC trial confirms that Defendants knew of or, at minimum, recklessly disregarded that their statements that Illumina needed to acquire GRAIL to accelerate Galleri's widespread adoption were false and misleading. During the FTC proceedings, GRAIL executives admitted that Illumina had not provided any estimates of how much it expected to accelerate Galleri's FDA approval when the transaction was announced and that they could not quantify the acceleration themselves nearly a year later. Defendant Febbo testified that Illumina had not identified any "specific areas where [Illumina could] help [GRAIL] accelerate" Galleri's FDA approval and would not be able to do so until the companies actually combined. The only evidence of any "acceleration" was Dr. Febbo's uncreditable testimony concerning a "feeling" that the acquisition would "shift the availability of Galleri . . . forward by a year"—baseless assertions the FTC and the Fifth Circuit flatly rejected.

280. *Third*, Defendants' testimony, as well as the accounts of well-placed former employees, confirm that Defendants knew or recklessly disregarded that Defendants' public timelines for commercialization and assurances that additional studies were not "necessary" or "essential" for the successful commercialization of Galleri were false and misleading when made. To start, during the FTC trial, GRAIL and Illumina executives uniformly admitted that, to achieve commercialization of Galleri, GRAIL needed FDA PMA approval and that such approval would take years. Defendant Bishop, then-GRAIL CEO, testified that FDA approval "is very necessary for getting American citizens access to our test." Defendant Ofman,

President at GRAIL, testified that developers of MCED tests need FDA approval for their tests to gain widespread commercialization and reimbursement. Defendant deSouza and Defendant Ofman both further testified that FDA approval is necessary for Medicare coverage of MCED testing, while Defendant Bishop acknowledged that FDA approval would likely be a requirement for an MCED test to receive broadbased reimbursement from payers.

- 281. Moreover, numerous GRAIL executives testified during the FTC trial that the FDA would impose significant additional requirements to commercialization. Notably, Defendant Ofman testified that "the FDA has many additional requirements in terms of quality, manufacturing, inspections" for PMA when compared with LDT standards, while Defendant Bishop testified that PMA has "an entirely different set of requirements" than an LDT.
- 282. Numerous well-placed former employees confirmed these facts. As FE2, a former GRAIL Director of Key Accounts explained, GRAIL's commercial plan—which involved seeking reimbursement from hospital systems and other healthcare networks—was "preposterous" and based on "dreams and magic" because such providers required detailed clinical data based on patient outcomes and FDA approval before they would consider paying for a test like Galleri. Similarly, FE3, a former Galleri Sales Consultant, reported that Defendants were "overstating what [Galleri] can do when they didn't have the data," that "everything" concerning GRAIL's prospects was based on "a hypothetical," and there were no "real-world studies completed" that were needed in order for Galleri to be successfully commercialized.
- 283. *Fourth*, Defendants' decision to obtain an extraordinarily expensive (and unprecedented) insurance policy specifically to cover shareholder claims arising out of the acquisition—and their patently dishonest statements justifying such coverage—strongly suggest that they knew their statements about the reasons for closing the transaction and defying Illumina's regulators were false and their

conduct was wrongful. Specifically, on August 18, 2021, the same day the GRAIL acquisition closed, Illumina's Board of Directors obtained \$300 million in D&O insurance—which covered them and Illumina's senior management, and not the Company, and so could not be used to protect Illumina from any gun-jumping penalties—at an annual premium of up to \$100 million.

284. Unknown to investors, a year before the GRAIL acquisition closed, on August 5, 2020, Illumina's Board received a report recommending an increase to Illumina's D&O liability insurance coverage. At the time, the Board unanimously agreed to purchase D&O insurance with \$150 million coverage, at an annual premium of up to \$3.8 million with a retention of \$10 million—reflecting an increase of \$30 million in coverage from the Company's then-existing D&O insurance policy—to bring Illumina's coverage in line with its peers.

285. The following year, in August 2021, just prior to closing the GRAIL acquisition, the Board's Audit Committee specifically discussed "possible changes" to the D&O insurance "relating to matters relating to [the GRAIL acquisition]" at two separate meetings. On August 4, 2021, the "independent members of the Board" unanimously approved the purchase of D&O insurance with up to \$300 million in coverage at an annual premium of up to \$100 million—adding double the Company's then-current coverage for a premium more than 25 times what the Company had paid the year before. This special insurance covered Illumina's directors and officers for "any and all claims against any of them arising out of or related to" the GRAIL acquisition, including "any determinations or decisions in connection with regulatory approvals, rulings or other actions."

286. On August 13, 2021, Illumina's Board and management met to discuss the GRAIL acquisition, D&O insurance, and a "Competition and Antitrust Update and Review," and, during the following two days, the Board met with management again to discuss the risks of closing the GRAIL acquisition. These numerous discussions further demonstrate that Defendants thoroughly understood that their

conduction in connection with the GRAIL acquisition would give rise to personal liability for the Board and senior management.

287. This extraordinary insurance policy cannot be squared with Defendant deSouza's statements to investors that there was no U.S. "legal impediment" to closing the transaction, and that Illumina believed the European Commission had no jurisdiction over the merger—and is particularly striking evidence of scienter given that deSouza was personally involved in obtaining this insurance, yet did not breathe a word of it while making these confident statements about Illumina's legal position.

Rather than disclose the insurance terms or the extraordinary risks Illumina was inviting, Defendants buried the disclosure of this policy in the hopes that investors and the public would not notice. Specifically, on November 5, 2021, months after the date of the insurance agreement and the close of the GRAIL acquisition, Illumina attached an exhibit titled "Form of Insurance Matters Agreement" to its quarterly report, publicly disclosing for the first time the existence of the insurance agreement. Despite its public disclosure, the insurance agreement does not include any information about the extraordinary premium the Company paid for it—a key fact of which Defendants were already well aware. Illumina's failure to timely file the insurance agreement at the time of the GRAIL acquisition, and omission of the key pricing term, demonstrates that Illumina was trying to avoid drawing attention to it.

289. Moreover, when Carl Icahn called attention to the existence of the policy (while still not knowing the premium) in an open letter to shareholders in March 2023, Defendants issued a thoroughly dishonest response—stating that such insurance and "corporate indemnification are standard for Delaware companies," "[a]ll major U.S. public companies, including Illumina, regularly review their D&O insurance to reflect appropriate coverage," and that "it is not uncommon for a company buying another business to increase insurance limits during the acquisition

process." Nowhere did they disclose or acknowledge the fact that they had *doubled* the Company's insurance at an unprecedented, exorbitant cost.

290. *Fifth*, Defendants' actions in failing to timely provide necessary information to the European Commission and then closing the transaction in defiance of the Commission's standstill obligation—and their statements that there was no "legal impediment" to closing the deal in the United States, when the FTC had withdrawn its motion seeking a preliminary injunction precisely because of the European Commission's standstill obligation—is further powerful evidence of fraudulent intent. Even though Illumina and GRAIL's merger agreement expired in September 2021 (i.e., a month after Defendants ultimately closed the GRAIL acquisition), the merger agreement explicitly gave each the ability to extend the expiration date of the agreement until December 20, 2021 in the event the antitrust laws of any jurisdiction had "the effect of enjoining, restraining, prohibiting or otherwise preventing the consummation of the" merger.

291. When the European Commission opened an "in-depth investigation into [the] proposed acquisition of GRAIL by Illumina" on July 22, 2021, it explicitly stated that it would reach a decision on the transaction by *November 29, 2021*. Thus, under the terms of the merger agreement, Illumina could have obtained clearance from the Commission well before the agreement expired simply by unilaterally exercising the merger agreement's extension provision. Instead, Illumina and GRAIL declined to "provide essential information for the Commission's assessment," and, as a result, the Commission stopped the clock on its investigation on August 11, 2021—just a week before Illumina announced that it had gone ahead with the acquisition. That Defendants closed the merger while refusing to produce documents its regulator had requested is highly suspicious, has no innocent explanation, and strongly supports scienter.

292. Further, for these reasons, Defendant deSouza's statement that Illumina closed the acquisition when it did to avoid being "locked into a situation where the

deal terms [would] expire before there is a chance for full review" and "the clock [would have] just [ran] out" was misleading and made no sense. Had Defendants simply complied with the Commission's information requests and utilized the merger agreement's explicit terms, they would have obtained a full review comfortably before the agreement expired.

293. *Sixth*, Defendants were personally motivated to carry out the GRAIL acquisition and surrounding fraud, as it enabled them to secretly reap hundreds of millions of dollars in proceeds through their undisclosed financial interests in the form of GRAIL's missing equity and Milky Way, Defendant Klausner's investment vehicle that he used to exploit his inside knowledge of the GRAIL acquisition. As detailed above, the missing equity at the time of the close of the GRAIL acquisition totaled over \$830 million. Despite calls from Carl Icahn to conduct an "unbiased investigation" into the missing equity, which had been raised by an analyst in April 2023, to date, Illumina has not conducted an independent forensic investigation into these allegations. This secret benefit to Illumina insiders provided a powerful motive to carry out the GRAIL acquisition. Defendants possessed no other reasons to close the deal—and a powerful, uncontroverted legal obligation not to close.

294. Defendant Klausner's investment in GRAIL at the exact same time Illumina was working to acquire it also provides powerful evidence of fraudulent intent. Specifically, before Milky Way invested \$125 million in GRAIL's Series D fundraising round, which closed on May 6, 2020, Defendant deSouza and Illumina's management were making plans to acquire GRAIL. In April 2020, deSouza engineered a series of substantial personnel changes—elevating Defendant Aravanis from GRAIL to serve as Illumina's CTO, and transitioning Illumina's then-CTO to serve on GRAIL's Board—to help facilitate the acquisition. All of these changes were overseen or approved by Defendant Klausner, who sat on GRAIL's Board and was involved in them. That Defendant Klausner had advance inside information pertaining to Illumina's acquisition of GRAIL when he invested another \$125

million in GRAIL's Series D round—an investment that doubled in value when the acquisition was announced just months later—demonstrates a compelling inference of scienter.

295. Defendants' carefully-crafted responses to investors and analysts' questions regarding Illumina insiders' undisclosed interests in GRAIL support, rather than refute, that insiders benefitted from the deal. Defendant Thompson's response indirectly confirms that the directors held interests in GRAIL. In his May 18, 2023 letter to shareholders, Defendant Thompson stated that "no executive officers of Illumina held GRAIL shares at the signing or closing of the GRAIL acquisition (including indirect ownership interests such as through trusts, LP or GP stakes in investment vehicles, or through derivative securities)." This proposition tellingly omitted Illumina directors. Put differently, directors could have (and did) held GRAIL shares "at the signing or closing of the GRAIL acquisition (including indirect ownership interests such as through trusts, LP or GP stakes in investment vehicles, or through derivative securities)." Likewise, Illumina's May 1, 2023 response did not provide any disclosure or explanation for the missing equity, nor did it mention Defendant Klausner's massive stake in GRAIL.

296. The personal financial motives of Illumina's Board and senior management were also confirmed by then-outside director Andrew Teno, who was elected to the Board in June 2023 by shareholder vote. Defendants' self-interest was so evident in Illumina's own books and records that, immediately after Teno gained access to internal Board materials and privileged communications relating to the transaction, he and Icahn determined that Illumina's Board had been "poisoned by their personal stake" in the GRAIL acquisition. In briefing in the same proceeding, Icahn noted that Defendants "created the need for disclosure by voluntarily affirming, in 2023, that Illumina's officers had no 'indirect ownership interests such as through trusts, LP or GP stakes in investment vehicles, or through derivative securities,' while conspicuously omitting the same representation regarding indirect

interests in GRAIL with respect to Illumina's directors." Based on the privileged information Teno received, Icahn concluded that the Board's misconduct was exceptionally egregious and disloyal. He stated: "Throughout my long, long career as an activist, I have never found it necessary, until today, to sue a board of directors in this manner."

based on a mountain of evidence drawn from Illumina board materials—that Illumina had made "inadequate, partial, and misleading disclosures concerning the GRAIL acquisition." He also demanded that Illumina shareholders be provided with "the truth about Defendants' misconduct" and have their fortunes determined by "a Board compromised of faithful fiduciaries untainted by prior misdeeds, conflicts, and definite personal liability." Other investors who were granted access to internal Board materials and minutes reached similar conclusions, finding that Illumina's directors acted with "bad faith and intentional, reckless, or disloyal misconduct" and that Illumina's public statements describing their reasons the Company approved the transaction were "false and/or materially misleading" when made.

298. Lead Plaintiffs and other experienced financial journalists have likewise concluded that Illumina insiders received a significant financial benefit for closing the acquisition—concluding, for example, that Illumina insiders must have made hundreds of millions of dollars "from splitting-off and subsequently reacquiring GRAIL." And when Carl Icahn put these questions directly to Illumina management and demanded an accounting and independent investigation, Illumina issued materially false and misleading statements denying any conflict, refused to conduct any investigation, and sought to keep evidence of its misconduct under seal.

299. Moreover, since at least July 2023, the SEC has been conducting an investigation into the GRAIL acquisition covering "statements and disclosures concerning GRAIL" and "the conduct and compensation of certain members of Illumina and GRAIL management."

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300. *Seventh*, the complex and purposeful accounting fraud alleged herein could only have been carried out by Illumina and GRAIL's most senior executives. Throughout the Class Period, Defendants engaged in a series of machinations designed to conceal the benefits that Illumina insiders obtained through the GRAIL acquisition. As detailed above, Defendants failed to disclose the existence of 70 million shares of GRAIL equity, which represented approximately 20.6% of GRAIL's fully diluted common shares as of April 3, 2016—a stake that was worth approximately \$830 million at the time of the GRAIL acquisition.

301. Further, pursuant to the accounting scheme, Illumina management undertook a series of steps to conceal their secret financial interests in GRAIL after spinning it out in 2016, which is also highly indicative of scienter. Specifically, in 2017, Illumina reduced its equity stake in GRAIL to just below a key regulatory threshold in order to achieve an accounting treatment that would require virtually no disclosure to investors of Illumina insiders' secret stake in GRAIL. Notably, Illumina accomplished this equity reduction by having GRAIL repurchase a significant portion of Illumina's equity stake at a time when Illumina had no need for any such funding—and when GRAIL desperately needed it. Lead Plaintiffs have not been able to identify any other examples of a strategic investor like Illumina diverting hundreds of millions of dollars of capital from a high-profile biotech startup like GRAIL to repurchase the investor's shares. Further, Illumina made a series of false disclosures and omissions in connection with these accounting machinations—including omitting Jay Flatley's service on the GRAIL Board as an "observer," and failing to conduct the appropriate "significant influence" test required by the GAAP when Ronaghi joined the GRAIL Board in 2020.

302. That Defendants engaged in numerous accounting maneuvers in violation of GAAP to conceal the financial benefits received by Illumina insiders through the GRAIL acquisition is highly indicative of fraudulent intent at the Company's highest levels.

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303. **Eighth**, when analysts and investors raised questions about Illumina insiders holding hidden equity interests in GRAIL, Defendants concocted a series of carefully worded and misleading explanations. As detailed above, Defendant Thompson's statement that "no director who oversaw any part of the GRAIL transaction has ever owned any equity interest in GRAIL"—implicitly concedes that directors who did not fall within Thompson's definition of "oversaw" did own an equity interest in GRAIL. Similarly, Thompson's statement that "no executive officers of Illumina held GRAIL shares at the signing or closing of the GRAIL acquisition," including through "indirect ownership," failed to include Illumina directors, and again implicitly concedes that Illumina directors did hold GRAIL shares at the signing or closing of the GRAIL acquisition. And Defendants' assertion that "none of Illumina's directors . . . has ever held any equity interests in GRAIL" leaves open the possibility that such insiders or their affiliates indirectly held such interests. Moreover, notwithstanding the seriousness of the accounting allegations, the SEC's ongoing investigation, and Icahn's request for a full examination by an independent law firm and a public airing of any findings, Illumina has refused to conduct any such investigation.

304. *Ninth*, certain of the Executive Defendants engaged in highly suspicious insider sales that betray their false statements about GRAIL's value and the supposed benefits of Galleri. For example, Defendant Aravanis offloaded his personal holdings in Illumina shares over the course of just several months at the very same time he was touting Galleri's ability "save lives." Specifically, soon after the acquisition closed on August 18, 2021 and Defendant Aravanis was awarded Illumina shares in exchange for his GRAIL holdings, he sold out of every single Illumina share he received in the acquisition in October and November—reaping \$5 million in insider proceeds. The timing of these sales is highly indicative of scienter.

305. *Tenth*, the over \$8 billion GRAIL acquisition was the single most important transaction in either Illumina or GRAIL's histories and was thus of

paramount importance to both Defendants and the investing public. It was a subject of intense market scrutiny and concern, and a topic on which Defendants made numerous public statements during the Class Period. Given the importance of the GRAIL acquisition and its impact on the value of Illumina's stock, analysts were intensely focused on the acquisition throughout the Class Period, repeatedly asking about the transaction itself, GRAIL's Galleri test and its clinical trials, and the antitrust proceedings before the FTC and European Commission. Defendants, who were Illumina and GRAIL's highest-ranking executives, made a litany of statements about these subjects (including in response to direct analyst questions), and were well aware that analysts were relying on the veracity of their statements.

306. These false and misleading statements concerned matters about which Defendants professed to have intimate knowledge, and thus there is a strong inference that Defendants knew the true facts, or, at minimum, were severely reckless.

307. Defendants' intimate knowledge about the subjects of their false statements is confirmed by their extensive testimony about the GRAIL acquisition in the FTC proceedings. In that testimony, Defendants demonstrated knowledge of detailed information concerning the transaction, the history of GRAIL's formation and spinoff, GRAIL's Galleri test and MCED tests more generally, the regulatory approval process for MCED tests, GRAIL's dependence on Illumina's NGS sequencers, and the Galleri test's commercialization, regulatory approval, and payor reimbursement.

308. Defendants' intimate knowledge about the subjects of their false statements is also confirmed by Illumina's access to and review of GRAIL's interactions with the FDA as well as Galleri's clinical data. Specifically, the merger agreement between GRAIL and Illumina provided the Illumina Defendants with unrestricted access to GRAIL's FDA file, including "all correspondence, presubmissions, submissions and other communications with the FDA since January 1,

2018," as well as the Galleri data generated by GRAIL. In an effort to reassure analysts and investors about the value of the merger and Galleri's purported "efficacy," Defendant deSouza touted Illumina's access to sensitive interim trial data, stating on March 2, 2021, that "we've had a chance to . . . look at that interim PATHFINDER data." Defendants also repeatedly provided investors with key information on Galleri's FDA approval timeline and key details about Grail's interactions with the FDA, further demonstrating their intimate knowledge about the subjects of their false statements. For example, in a presentation to the FTC, Illumina also held itself out as being at the "vanguard" of "guiding the FDA through educational sessions as it seeks to achieve the most challenging of approvals."

309. *Eleventh*, Defendant deSouza has a history of making false statements, including in court proceedings, and hiding assets from those to whom he owes fiduciary duties, supporting an inference of scienter. Specifically, a California judge overseeing Defendant deSouza's divorce proceedings, in which deSouza was accused of hiding assets and breaching his fiduciary duties, found that deSouza's "credibility [was] suspect" and his testimony was "not to be trusted." In that proceeding, deSouza denied the existence of restrictive stock awards that he received during his marriage, a claim the judge found "hard to believe" given that "Francis is far too sophisticated and experienced to not remember one, let alone three RSAs." Instead, the court found that "Francis purposefully obfuscated this issue" and that "Francis's testimony without documentary backup is not to be trusted." In those proceedings, deSouza failed to report significant stockholdings he had received from Illumina—supporting the plausible inference that he concealed his true financial interests in the GRAIL acquisition from investors here.

310. In addition, Defendant deSouza has previously used intermediaries to conceal his financial transactions in violation of a court order. In the divorce proceeding, the court found that deSouza violated his fiduciary duties and an automatic temporary restraining order prohibiting him from transferring his property

when he sent \$45,000 to a bitcoin exchange to purchase bitcoins (which he never received), \$99,451 to a friend and colleague to purchase bitcoins on his behalf, and a further \$44,940 to a different associate to purchase bitcoins on his behalf. As the California court ruled, in doing so, deSouza "violated the automatic restraining order and his fiduciary duties."

- 311. *Twelfth*, the circumstances surrounding the numerous "resignations" of Illumina senior executives further strengthen the scienter inference. While some executive turnover at a major publicly traded company can be expected, the massive departure of Illumina's senior executives is extraordinary. Of Illumina's eight named executives at the time Defendant deSouza was announced as Flatley's replacement, seven promptly departed—with only General Counsel Dadswell remaining.
- 312. In light of the extensive GAAP violations committed by Illumina, the turnover at the role of the Company's chief accounting positions is particularly notable and supportive of an inference of scienter. Since the beginning of the Class Period, Illumina has replaced its CFO or Chief Accounting Officer at least three times, with CFO Samad suddenly "resigning" in June 2022, Chief Accounting Officer Jose Torres unexpectedly "resigning" in September 2022, and Samad's replacement Goswami suddenly "resigning" after the Class Period, in April 2024. The departures further corroborate that they knew about the accounting violations alleged herein.
- 313. In addition, the chief architects of the GRAIL acquisition—including Defendant deSouza, Defendant Aravanis, and Defendant Thompson—have similarly been forced out of their roles. Analysts expressed concern about the sudden announcement of these departures, as well as skepticism about their purported reasons. For example, after Defendant deSouza's resignation, analysts at Barclays viewed the announcement as "the biggest surprise given the seemingly successful battle against the recent activist campaign," as well as the timing of the

announcement after a "recent slew of product launches." And while some analysts were not shocked by deSouza's departure, they nonetheless called the "specific details"—including the immediacy of the departure—"a bit unexpected."

- 314. Analysts' suspicions about deSouza's departure were internally confirmed by those inside the Company. For example, FE3 reported that GRAIL employees were asked to sign arbitration agreements just days after Defendant deSouza's resignation—an unusual request that had never been made before, and evidence that Defendants sought to conceal their misconduct by silencing insiders who knew the truth about GRAIL.
- 315. The departures of Defendants deSouza, Samad, and Aravanis, as well as Goswami, cannot be explained by innocent reasons. In leaving when they did, they abandoned their prominent roles at Illumina just as GRAIL was purportedly poised to become a multi-billion-dollar revenue generator. The stronger inference is that these Defendants were forced to leave the Company because they had committed wrongdoing in connection with the failed GRAIL acquisition.
- 316. Last, there are numerous facts that corroborate that Defendants and their affiliates secretly financially benefitted from the undisclosed \$830 million in missing GRAIL equity, including the following: First, the sophisticated accounting maneuvers orchestrated by Defendants allowed them to avoid disclosure of related party transactions that would have exposed Illumina insiders' concealed interests in GRAIL. There is no other plausible justification for Illumina to undertake these accounting maneuvers. There is also no other plausible justification for Defendants' other conduct, including GRAIL's spending of hundreds of millions of capital it needed for Galleri's research and development to repurchase shares from Illumina, GRAIL's strategic investor that had no need for cash. Second, when Illumina was directly questioned about its leadership's financial interests in GRAIL, Defendant Thompson issued a non-denial—conceding in a carefully worded response that Illumina directors who did not oversee the GRAIL transaction could have held

interests in GRAIL, and further that Illumina directors could have held such investments *indirectly through other investment vehicles*. Third, there is no other plausible justification for Illumina to defy its own regulators by closing the acquisition unless doing so financially benefitted Illumina insiders. The decision to close boggled analysts and investors, risked destroying Illumina's relationships with its regulators for years to come, and none of Defendants' purported justifications for closing make any sense at all. Defendant deSouza's representation that Illumina needed to close to prevent regulators from "running out the clock" is flatly refuted by the terms of the merger agreement, which enabled Illumina to "stop the clock" in this very circumstance. Fourth, Defendants secured a \$300 million insurance policy, with a \$100 million premium, specifically to insure Illumina's senior leadership for their acquisition-related misconduct—an unprecedented policy that came at an extraordinary cost and can only be explained as evidence of knowing misconduct. Fifth, newly installed Board director Andrew Teno quickly determined based on privileged and confidential Illumina documents that Illumina's Board was selfinterested and had been "poisoned by their personal stake" in the GRAIL deal, that their purported reasons for closing were false, and that investors had not been told "the truth about Defendants' misconduct." Sixth, as was recently revealed in the Delaware 220 books and records action, Defendant deSouza and another unnamed director engaged in numerous "unauthorized" communications with GRAIL Board members and GRAIL's bankers before and following the announcement of the acquisition. Specifically, according to a February 8, 2021 director assessment, there were "multiple streams of unauthorized communications between an Illumina board member and GRAIL board members and bankers"—communications that would have only been carried out through improper channels because Defendants wanted them to remain secret.

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## XI. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

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317. Throughout the Class Period, Defendants made a series of materially false and misleading statements and omissions that were disseminated to investors through calls, public filings, press releases and other Company statements, and news and media outlets. All of Defendants' statements about Illumina's acquisition of GRAIL were materially misleading because they omitted to disclose the highly material fact that Defendants were secretly enriched by the transaction, and stood to personally pocket hundreds of millions of dollars in undisclosed profits. Defendants' statements and omissions were also materially false and misleading for the independent reason that they were contrary to the true facts. Those statements principally fall into five categories: (1) the reported valuation of and financial projections for GRAIL; (2) Illumina's ability to "accelerate" the Galleri test's commercialization, regulatory approval, and payor reimbursement; (3) the clinical evidence purportedly supporting Galleri's effectiveness, its prospects for FDA approval, and the test's ability to "save lives"; (4) Illumina's reported accounting treatment for the GRAIL asset and the justifications for and risks of purchasing and closing the GRAIL acquisition; and (5) Illumina's characterizations of Illumina and GRAIL's decision and ability to close the GRAIL in the face of the EU standstill and FTC proceeding.

- A. During and After the Announcement of the GRAIL Acquisition, Defendants State that Acquiring GRAIL Created Value and Was Necessary to "Accelerate" Galleri's Adoption and "Save Lives"
- 318. On September 21, 2020, Illumina issued a press release announcing that Illumina and GRAIL had entered into a merger agreement whereby Illumina would acquire GRAIL for \$8 billion in cash and stock. The press release listed, among the "Strategic Benefits" of the deal, that it would "Accelerate[] Adoption of NGS-Based Early Multi-Cancer Detection Test to Reach More Patients Faster" by "levera[ging] its global scale, manufacturing and clinical capabilities to support

GRAIL's commercialization efforts, realize the total addressable market potential and drive significant growth in the clinical value chain." In the press release, Defendant Bishop further stated: "Combining forces with Illumina enables broader and faster adoption of GRAIL's innovative, multi-cancer early detection blood test, enhancing patient access and expanding global reach."

319. On a conference call that same day to discuss the transaction, Defendants made additional representations about Illumina's ability to "accelerate" the adoption, commercialization, and payor reimbursement of the Galleri test by acquiring GRAIL. Specifically, on the call, Defendant deSouza stated:

Now as they stand poised to bring products to market in 2021, we believe this is the right time to bring the GRAIL team into Illumina so that we can help to commercialize and accelerate adoption. . . . [T]he reason to acquire them is because we have very clear line of sight into how we can accelerate the plan that they are on today. And we can only do that when they're part of Illumina.

320. Also on the same call, Defendant Bishop stated:

[B]y joining forces with Illumina, we'll achieve scale faster preventing more late-stage cancer diagnosis. . . With Illumina's international footprint and expertise across market access, regulatory, government affairs and manufacturing, we'll accelerate our ability to realize our mission and goals of improved patient outcomes.

321. The statements in ¶¶318-20 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendants to state that acquiring GRAIL would "[a]ccelerate[]" the adoption of MCED tests, that "[c]ombining forces with Illumina" would enable "broader and faster adoption" of Galleri, and that two companies "joining forces" would "achieve scale faster preventing more late-stage cancer diagnosis" and "accelerate" the ability to realize "improved patient outcomes." It was also materially false and misleading for Defendant deSouza to state that Defendants "ha[d] a very clear line of sight into how we can accelerate the plan that they are on today," and that this acceleration can only happen "when they're part of Illumina."

322. In truth, as Illumina and GRAIL management would admit during an FTC trial that focused on Illumina's representation that the acquisition would "accelerate" Galleri's adoption, and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, there was nothing at all supporting the false statement that the combination would "accelerate" Galleri adoption. Rather, as the Fifth Circuit explained, "Illumina [did] not establish[] that such acceleration would actually occur, much less show[] how it would be achieved"—including because "Illumina's own financial modeling of the merger did not assume that Galleri's widespread commercialization would be accelerated," the "modeling" did not "account for the costs that would be associated with achieving any such acceleration," and, "Illumina [] failed to demonstrate that its claimed 'regulatory expertise' was superior to that which GRAIL already possessed."

323. It was also materially false and misleading for Defendants to state that Illumina would leverage "international footprint and expertise across market access, regulatory, government affairs and manufacturing" to accelerate Galleri's commercialization. Such statements concerning Illumina's manufacturing and clinical capabilities were unsubstantiated because, as the Fifth Circuit determined, Illumina did not possess "regulatory expertise" that was "superior to that which GRAIL already possessed," because Illumina had "only ever obtained pre-market approval for one Class III NGS-based diagnostic test" (i.e., the same type of diagnostic test as Galleri) whose approval was based upon a "third party sponsored" clinical study. Further, as the Fifth Circuit determined, there was no evidence that the merger would "lead to 'significant supply chain and operational efficiencies.'"

324. During the FTC trial, Defendants' only evidence to support the statement that the acquisition would accelerate Galleri's adoption was "the unsupported and vague assertions of management personnel"—specifically, Defendant Febbo's "feel[ing]"—which was belied by the extensive evidentiary

record. Defendants *admitted* that they could not substantiate that any "acceleration" would occur, blaming the fact that integration planning for the two companies was paused pending the European Commission's review—an admission that shows that Defendants' prior statements touting "acceleration" were without basis.

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325. In the same press release and during the same September 21, 2020 investor conference announcing the acquisition, Defendants also made false statements about Galleri's clinical effectiveness. Specifically, Defendant deSouza pointed to "the exceptional progress in developing the technology and clinical data required to launch [Galleri]," telling investors that "the results [GRAIL is] demonstrating from their large-scale clinical studies have put to bed a lot of the questions that we had" and that, therefore, "[GRAIL's] value has been demonstrated." Defendants further stated that Illumina could "leverage its global manufacturing clinical capabilities GRAIL's scale, and to support commercialization efforts."

326. The statements in ¶325 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendants to state that GRAIL had made "exceptional progress in developing the technology and clinical data required to launch" Galleri, that "the results [GRAIL is] demonstrating from their large-scale clinical studies" "demonstrated" GRAIL's "value," and that Illumina could "leverage its global scale, manufacturing and clinical capabilities to support GRAIL's commercialization efforts." In truth, as the FDA informed Defendants before the start of the Class Period, the clinical data for Galleri developed to date was "insufficient," and that even the clinical trials GRAIL proposed to run to seek FDA approval would not establish its effectiveness because those trials did not, for example, "directly confirm the results of [the] test," nor "assess how the test results impacted patient treatment decisions," and thus were "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test," as required to demonstrate the test's "value" and obtain FDA

approval. It was further misleading to state that Galleri's clinical test results had "put to bed the questions that we had" because, in truth, those test results did not measure patient treatment decisions, and were thus unable to demonstrate effectiveness and thus the potential for FDA approval, commercial viability, or value. Further, such statements concerning Illumina's manufacturing and clinical capabilities were unsubstantiated because, as the Fifth Circuit determined, there was no evidence that the merger would "lead to 'significant supply chain and operational efficiencies."

327. On September 24, 2020, Defendant deSouza represented Illumina at an investor event hosted by investment banking firm Cowen called Cowen's Liquid Biopsy Summit. During that event, in response to why Illumina had decided to acquire GRAIL when it did, Defendant deSouza stated:

So let's talk about the why now question. And we really do believe that we're in an inflection point in the early detection of cancer market and we're in a place where the binary risk about will the product work or not is largely behind us. . . . [I]t was really in the last year, through the data that GRAIL started to publish from its large-scale clinical studies at ASCO, at ESMO, the peer-reviewed journal that they published earlier this year that gave us comfort to realize, well, *I think they've cracked the code. Their technology works, it's been tested in very large numbers, and the data has been peer-reviewed. And so there will be a product that works, and the GRAIL team is ahead.* So that made us start to shift our thinking to say we've identified, A, that the binary risk seems to be behind us now, that there is a product that meets the characteristics that would be successful. And then, two, that GRAIL has the right approach and it's differentiated.

And so we started looking at it more seriously. And with GRAIL getting to commercialize its products next year, we realized that we could really accelerate the development of this market if we acquired GRAIL now. And so, that's sort of the why now. They have a product. It's demonstrated that the binary risk is largely retired, and that if we get involved now, we can accelerate the development of what's going to be the largest genomic application we've ever seen.

328. The statements identified in ¶327 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that GRAIL's "technology works" and was a "product that works" based on Galleri having been "tested in very large numbers" because, as

the FDA informed GRAIL before the Class Period, the clinical studies that GRAIL conducted and planned to conduct were not even designed to demonstrate whether Galleri in fact "work[ed]." In truth, the clinical studies conducted on GRAIL by that time, and those GRAIL planned to undertake, would not "directly confirm the results of [its] test nor will [GRAIL] assess how the test results impacted patient treatment decisions," and thus were "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test." For these same reasons, it was false and misleading to state that the "binary risk" for Galleri was "largely retired" because, in truth, there was no clinical evidence demonstrating that Galleri worked or could even be considered for approval by the FDA.

- 329. It was also materially false and misleading to state that Illumina "can accelerate the development of what's going to be the largest genomic application we've ever seen." In truth, as the Fifth Circuit ruled (and as noted above), at the time this statement was made, "Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved," and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.
- 330. On the same call, in response to another question about the decision to acquire GRAIL for \$8 billion, Defendant deSouza stated:

[A]s we did the financial analysis, moving from selling platforms to GRAIL and participating in the revenue stream to owning GRAIL is significantly value-accretive to Illumina shareholders compared to the previous model. And so, we ran those models in many different ways. We've put in conservative assumptions. But in terms of value to Illumina shareholders, owning it creates significantly more value."

331. The statements identified in ¶330 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that "owning GRAIL" was "significantly value-accretive" and "create[d] significantly more value," and that Defendants had used "conservative assumptions" in their models. In truth, the GRAIL acquisition was

not "significantly value-accretive," nor did it "create[] significantly more value," including because Illumina management-prepared slide decks reviewed by Illumina's Board in April 2020 showed that the GRAIL acquisition would only generate revenues of ">\$8B by 2030."

332. On November 25, 2020, Illumina filed a registration statement with the SEC on Form S-4, which was signed by Defendants deSouza, Samad, and Thompson, among others. In the registration statement, Defendants described the "[b]ackground" of the GRAIL acquisition, stating in part as follows:

Beginning in late June 2020, GRAIL commenced initial preparations for a potential IPO.

On July 31, 2020, GRAIL confidentially submitted its draft registration statement on Form S-1 with the U.S. Securities and Exchange Commission (the "SEC"). On the same day, Illumina's Chief Executive Officer met with GRAIL's Chief Executive Officer and noted that Illumina wanted to explore a potential acquisition of GRAIL. GRAIL's Chief Executive Officer asked that Illumina's Chief Executive Officer provide him with a proposal with respect to such an acquisition.

333. The statements identified in ¶332 were misleading because they omitted material facts. Specifically, while the background of the merger discussion creates the impression that Illumina's consideration of GRAIL was initiated on July 31, 2020, that description omitted the highly material facts that (1) Illumina's Board of Directors had already begun discussions concerning an acquisition of GRAIL on April 28, 2020, and that "management" (i.e., Defendant deSouza) recommended "further due diligence into GRAIL as a potential acquisition target"; (2) management's due diligence had begun before that time and before Illumina disclosed that GRAIL's then-Chief Scientific Officer, Defendant Aravanis, would serve as Illumina's CTO, and that Illumina's Senior Vice President of Entrepreneurial Development, Mostafa Ronaghi, would join GRAIL's Board as a director on May 4, 2020; (3) GRAIL director Defendant Klausner knew of these facts and had invested \$125 million in GRAIL's final fundraising round while in possession of these highly material facts; and (4) "unauthorized" communications

between an Illumina director and GRAIL board members and bankers were occurring around this time, as revealed in post-Class Period documents produced in related litigation.

334. In the same registration statement, Illumina provided a fairness opinion offered by Morgan Stanley on behalf of GRAIL based on two forecasts "prepared by GRAIL management." Specifically, the S-4 publicly presented two sets of GRAIL financial forecasts for fiscal years 2021 through 2030 based on two scenarios ("Case A" and "Case B") reflecting, respectively, lower and higher internal targets. As Illumina stated in the Form S-4, under the lower "Case A" scenario, GRAIL would generate \$14.4 billion in revenues by 2030, while under "Case B," GRAIL's revenues would approach \$24 billion by that time:

	Fiscal year ended December 31,							-		
(In millions) GRAIL Forecasts:	2021E	<u>2022E</u>	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
GRAIL Forecasis:  GRAIL Total Revenue –										
Management Case A										
Estimate	\$ 19	\$ 119	\$ 462	\$ 892	\$ 1,704	\$ 3,916	\$ 6,625	\$ 9,884	\$ 12,129 \$	14,387
GRAIL Total Revenue –										
Management Case B										
Estimate	56	327	1,042	2,142	4,075	9,570	13,629	17,747	21,277	23,980
GRAIL Operating Profit				,						
(Loss) – Management Case A Estimate	(427)	(586	(576)	(454	(110)	876	1,943	3,339	4,015	4,460
GRAIL Operating Profit	(427)	(380	(370)	(434	(110)	870	1,943	3,339	4,013	4,400
(Loss) – Management				,						
Case B Estimate	(436)	(589)	(427)	(37	920	3,683	5,630	7,493	8,846	9,305
Unlevered Free Cash	( /	( )	( ,	(		- ,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	.,	-,-	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Flow:										
GRAIL Unlevered Free										
Cash Flow – Case A										
Estimate	(424)	(541)	(566)	(453	(156)	714	1,650	2,464	3,048	3,440
GRAIL Unlevered Free Cash Flow – Case B										
Estimate	(433)	(541)	(431)	(87	719	2,713	4,137	5,634	6,776	7,268

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The S-4 also represented that, using these two sets of financial forecasts, Morgan Stanley valued GRAIL at \$11.15 billion (the lowest valuation under Case A) to \$43.95 billion (the highest valuation under Case B):

Forecast Scenario	Equity Value Range				
	(\$ in millions)				
Case A	\$11,150-				
	\$17,450				
Case B	\$28,200-				
	\$43.950				

336. Further, Illumina stated that these projections and valuations "were based on estimates, assumptions and judgments made by GRAIL management." For Case A and Case B, those assumptions included "growth in the number of health systems and employers offering GRAIL's products, that new products such as DAC and MRD would be successfully launched and that broad reimbursement would be achieved in calendar 2025, which management forecasted would significantly increase the acceptance of GRAIL's product." For Case B, the forecasts assumed "broader acceptance of GRAIL's products across health systems, employers and more significant coverage after broad reimbursement is achieved."

337. The statements identified in ¶¶334-36 above were materially false and misleading and omitted material facts. It was materially misleading for Defendants to provide the projections noted above to Illumina shareholders while withholding the far more pessimistic projections and valuations that Illumina's management prepared and its Board reviewed. Those concealed projections that Illumina management prepared and Illumina's Board reviewed in April 2020 showed that the GRAIL acquisition would only generate revenues of ">\$8B by 2030" (i.e., just about *half* the revenues Illumina publicly reported to investors in its conservative Case A scenario and *one-third to one-fourth* of the revenues projected in its more optimistic Case B forecast). It was also materially misleading for Defendants to publish the valuation range in the Form S-4 while withholding the far more pessimistic valuation range that Illumina's Board reviewed. Specifically, in April 2020, Illumina's Board considered and reviewed a discounted cash flow analysis that valued GRAIL between \$3.3 billion and \$11.9 billion, barely approaching the lowest range of Illumina's publicly reported valuations of \$11 billion to \$17.45 billion under the more conservative Case A scenario.

338. It was also materially false and misleading for Defendants to state that the Case A and Case B projections "were based on estimates, assumptions and judgments made by GRAIL management," including "growth in the number of health systems and employers offering GRAIL's products . . . and that broad reimbursement would be achieved in calendar 2025, which management forecasted would significantly increase the acceptance of GRAIL's product," and that the Case B projections assumed "broader acceptance of GRAIL's products across health systems, employers and more significant coverage after broad reimbursement is achieved." In truth, Defendants knew that these "assumptions" and "judgements" were baseless. As Illumina and GRAIL executives would later admit in testimony before the FTC and as reported by well-placed former employees, GRAIL's hospital system and healthcare network customers overwhelmingly required detailed clinical data and FDA approval that Galleri did not have and could not have by 2025, and GRAIL's commercial plans were based on "dreams and magic," totally unrealistic, and unachievable.

339. On March 2, 2021, Defendant deSouza represented Illumina at the Cowen & Co. Health Care Conference. At the conference, an analyst asked, "And then in terms of the studies you're going to need to do . . . I think the assumption is there's going to have to be some prospective randomized studies done that are probably pretty sizable on the tens of thousands of patients, if not well above 100,000 patients, to support FDA approval and then broader CMS reimbursement. . . . But those types of studies, should we expect that those could be or will be initiated in 2022 or is that not necessarily the case?" In response, deSouza stated:

[W]e don't believe additional studies are necessary for Galleri to be successful. . . . And so, we don't think that any studies are essential

from a performance perspective but also from a launch perspective.

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[GRAIL's] intent is to do an FDA submission in 2023[.]

The statements identified in ¶339 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that "additional studies" were not "necessary for Galleri to be successful," that further studies were not "essential from a performance perspective but also from a launch perspective," and that GRAIL would "do an FDA submission in 2023," because, as the FDA informed GRAIL before the Class Period, the clinical studies that GRAIL conducted and planned to conduct were not even designed to demonstrate whether Galleri was effective, and thus could not support FDA approval. In truth, the clinical studies conducted on GRAIL by that time, and those GRAIL planned to undertake, would not "directly confirm the results of [its] test nor will [GRAIL] assess how the test results impacted patient treatment decisions," and thus were "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test." That is because none of the Galleri studies to date measured the impact on treatment decisions, none of the planned studies for GRAIL did so in a sufficiently powered manner, and there was a total absence of the kind of clinical evidence necessary to show whether Galleri was effective as needed to support FDA approval, commercialization, and payor reimbursement. Rather, GRAIL's real-world experiences, including the screenings conducted by the San Francisco Firefighters Cancer Prevention Foundation, reflected the extraordinary risks of errors and inaccuracies inherent in Galleri that can harm patients.

341. Soon after Illumina announced the acquisition, antitrust authorities in the United States and Europe began investigating the deal because it threatened GRAIL's competitors who relied upon Illumina technology for their own tests. On

March 30, 2021, the FTC sued to block the acquisition. In response, Defendants made a series of false and misleading statements intended to assuage investors' concerns about the acquisition and to justify Illumina's actions in pursuing the deal.

342. On March 30, 2021, the day the FTC sued to block the deal, Illumina stated in a press release: "In reuniting the two organizations [Illumina and GRAIL], Illumina will leverage its global scale of manufacturing and clinical capabilities, as well as its global regulatory and reimbursement expertise, to bring early-stage, multi-cancer testing to patients more quickly and more affordably, resulting in more lives being saved." Illumina further stated: "Illumina will pursue its right to proceed with the transaction, the impact of which would accelerate the adoption of a breakthrough multi-cancer early detection blood test."

343. In the same press release, Defendant Bishop stated: "Combining GRAIL's innovative multi-cancer early detection test with Illumina's experience and scale will enable more patients in both the United States and worldwide to garner access to GRAIL's test faster."

344. The statements identified in ¶¶342-43 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendants to state that, through the GRAIL acquisition, Illumina would "leverage its global scale of manufacturing and clinical capabilities, as well as its global regulatory and reimbursement expertise, to bring early-stage, multi-cancer testing to patients more quickly and more affordably, resulting in more lives being saved," "accelerate the adoption" of Galleri, and "enable more patients" to "garner access to GRAIL's test faster." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to

achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.

345. The acquisition would also not "result[] in more lives being saved," because, in truth, Defendants had no evidence to support this claim. Further, as the FDA informed Defendants before the start of the Class Period, the clinical data for Galleri developed to date was "insufficient," and that even the clinical trials GRAIL proposed to run to seek FDA approval would not establish its effectiveness because those trials did not, for example, "directly confirm the results of [the] test," nor "assess how the test results impacted patient treatment decisions," as required to demonstrate the test's effectiveness as would be needed to be considered for FDA approval. Rather, at the time this statement was made, and as reported by well-placed former employees, Defendants were "overstating what [Galleri] can do when they didn't have the data."

346. It was also materially false and misleading for Defendants to state that Illumina would leverage "global scale of manufacturing and clinical capabilities, as well as its global regulatory and reimbursement expertise." Such statements concerning Illumina's manufacturing and clinical capabilities were unsubstantiated because, as the Fifth Circuit determined, Illumina did not possess "regulatory expertise" that was "superior to that which GRAIL already possessed," because Illumina had "only ever obtained pre-market approval for one Class III NGS-based diagnostic test" (i.e., the same type of diagnostic test as Galleri) whose approval was based upon a "third party sponsored" clinical study. Further, as the Fifth Circuit determined, there was no evidence that the merger would "lead to 'significant supply chain and operational efficiencies."

347. On April 6, 2021, Defendant deSouza gave an interview on CNBC concerning Illumina's results for the first quarter of 2021. Defendant deSouza stated: "By doing this acquisition we can accelerate patient access to [the Galleri] test and also drive accelerated reimbursement."

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348. The statement identified in ¶347 above was materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that, that Illumina was "doing [the GRAIL] acquisition" to "accelerate patient access to [the Galleri] test and also drive accelerated reimbursement." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.

349. On April 6, 2021, SVB hosted Defendants Aravanis and Febbo at a virtual fireside meeting as part of SVB's Second Annual Liquid Biopsy and Oncology Diagnostics Summit. During the meeting, Defendants Aravanis and Febbo discussed the GRAIL acquisition, with SVB reporting that the two members of senior management "emphasized the importance of bringing early cancer detection technology to the market as soon as possible to save lives," that launching Galleri as an LDT would generate "robust 'real world' clinical data which can be used in future FDA submissions," and that the "current plan is for GRAIL to submit a single-site PMA for approval in 2023 with a dossier of clinical evidence including STRIVE, PATHFINDER, CCGA, SUMMIT, and real-world data from early commercialization efforts."

350. The statements identified in ¶349 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendants Aravanis and Febbo to state that launching GRAIL as an LDT would generate "robust 'real world' clinical data" which could be used in "future FDA submissions," and that GRAIL's plan was to "submit a single-site PMA for approval in 2023 with a dossier of clinical evidence" because, as the FDA informed GRAIL

before the Class Period, the clinical studies that GRAIL conducted and planned to conduct were not even designed to demonstrate whether Galleri was effective as necessary to be considered for FDA approval. In truth, the clinical studies conducted on GRAIL by that time, and those GRAIL planned to undertake, would not "directly confirm the results of [its] test nor will [GRAIL] assess how the test results impacted patient treatment decisions," and thus were "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test." That is because none of the Galleri studies measured whether the test appropriately measured patient treatment decisions in an appropriate patient population, in a sufficiently powered manner as needed to support FDA approval, commercialization, and payor reimbursement.

351. It was also materially false and misleading for Defendants Aravanis and Febbo to state that the acquisition would "save lives" because, in truth, and as the FDA informed Defendants before the start of the Class Period and Defendant Bishop admitted at trial, the clinical data for Galleri developed to date was "insufficient," and even the clinical trials GRAIL proposed to run to seek FDA approval would not establish its effectiveness because those trials did not, for example, "directly confirm the results of [the] test" or "assess how the test results impacted patient treatment decisions," and thus were "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test" as required to obtain FDA approval. Rather, at the time this statement was made, and as reported by well-placed former employees, Defendants were "overstating what [Galleri] can do when they didn't have the data."

352. On April 20, 2021, Illumina issued a press release in which Defendant deSouza stated: "Reuniting GRAIL and Illumina will allow us to bring GRAIL's breakthrough early detection multi-cancer test to patients across the world faster and consequently save lives."

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353. The statement identified in ¶352 above was materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that, by merging GRAIL and Illumina, Illumina would bring Galleri to "patients across the world faster." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.

354. It was also materially false and misleading for Defendant deSouza to state that acceleration would "consequently save lives" because, in truth, and as the FDA informed Defendants before the start of the Class Period, the clinical data for Galleri developed to date was "insufficient," and even the clinical trials GRAIL proposed to run to seek FDA approval would not establish its effectiveness because those trials did not, for example, "directly confirm the results of [the] test" or "assess how the test results impacted patient treatment decisions," and thus were "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test" as required to demonstrate the true effectiveness and obtain FDA approval. Rather, at the time this statement was made, and as reported by well-placed former employees, Defendants were "overstating what [Galleri] can do when they didn't have the data."

355. On May 6, 2021, Defendant deSouza published an opinion piece titled "FTC Imperils a Cancer Breakthrough" in the *Wall Street Journal*. Defendant deSouza wrote:

The Federal Trade Commission is jeopardizing our chance to save more lives from cancer. . . . We announced last year our intent to reunite with GRAIL to make this cancer-screening test widely available, accessible and affordable, accelerating the test's broad adoption and saving tens of thousands of lives.

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356. The statements identified in ¶355 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that Illumina's acquisition of GRAIL could "make this cancer-screening test widely available, accessible and affordable, accelerating the test's broad adoption." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.

357. It was also materially false and misleading for Defendant deSouza to state that acceleration would "sav[e] tens of thousands of lives" because, in truth, and as the FDA informed Defendants before the start of the Class Period, the clinical data for Galleri developed to date was "insufficient," and even the clinical trials GRAIL proposed to run to seek FDA approval would not establish its effectiveness because those trials did not, for example, "directly confirm the results of [the] test" or "assess how the test results impacted patient treatment decisions," and thus were "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test" as required to demonstrate the test's true effectiveness and obtain FDA approval. Rather, at the time this statement was made, and as reported by well-placed former employees, Defendants were "overstating what [Galleri] can do when they didn't have the data."

358. On July 22, 2021, Illumina issued a press release affirming its commitment to re-acquire GRAIL as the European Commission opened an in-depth investigation into the acquisition, entering its second phase. In the press release, Defendant deSouza stated:

When people have access to early cancer detection, lives will be saved. If this acquisition does not proceed, GRAIL's European roll-out will be

slower and the cost will be measured in the unnecessary loss of life. Reuniting GRAIL with Illumina will accelerate availability of the GRAIL test by many years in the [European Economic Area] and globally, saving tens of thousands of lives, and leading to significant health care cost savings.

359. The statements identified in ¶358 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that the acquisition "[would] accelerate availability of the GRAIL test" and "lead[] to significant health care cost savings." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.

360. It was also materially false and misleading for Defendant deSouza to state that acceleration would "sav[e] tens of thousands of lives." In truth, and as the FDA informed Defendants before the start of the Class Period, the clinical data for Galleri developed to date was "insufficient," and even the clinical trials GRAIL proposed to run to seek FDA approval would not establish its effectiveness because those trials did not, for example, "directly confirm the results of [the] test" or "assess how the test results impacted patient treatment decisions," and thus were "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test" as required to demonstrate the test's actual effectiveness and obtain FDA approval. Rather, at the time this statement was made, and as reported by well-placed former employees, Defendants were "overstating what [Galleri] can do when they didn't have the data."

361. On August 5, 2021, Illumina held a conference call with analysts and investors to discuss the Company's earnings and operations for the second quarter of 2021. On that call, in response to an analyst question about why Illumina

remained committed to the GRAIL acquisition, Defendant deSouza stated: "We continue to believe that this deal will result in the savings of tens of thousands of lives that would not be saved if we didn't buy GRAIL, simply because we can accelerate the business. So to answer the question, we are committed to working through this deal."

362. The statements identified in ¶361 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that Illumina's acquisition of GRAIL "[would] result in the savings of tens of thousands of lives that would not be saved if [Illumina] didn't buy GRAIL" because Illumina would "accelerate the business." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.

363. It was also materially false and misleading for Defendant deSouza to state that acceleration would "result in the savings of tens of thousands of lives" because, in truth, Defendants lacked any clinical evidence to support this statement. Further, as the FDA informed Defendants before the start of the Class Period, the clinical data for Galleri developed to date was "insufficient," and even the clinical trials GRAIL proposed to run to seek FDA approval would not establish its effectiveness because those trials did not, for example, "directly confirm the results of [the] test" or "assess how the test results impacted patient treatment decisions," and thus were "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test" as required to demonstrate the test's actual effectiveness. Rather, at the time this statement was made, and as reported by well-

placed former employees, Defendants were "overstating what [Galleri] can do when they didn't have the data."

- B. Defendants Continued to Falsely State that the GRAIL Acquisition Was Needed to "Accelerate" Galleri's Adoption and "Save Lives" After Closing the Transaction in Defiance of Illumina's Regulators
- 364. On August 18, 2021, Illumina issued a press release announcing that it had closed the transaction and acquired GRAIL. In the press release, Illumina described the "reasons to reunite the two companies," including, in part:
  - The deal will save lives. Cancer kills around 10 million people annually worldwide and 600,000 people in the US alone. Cancers responsible for nearly 71% of cancer deaths have no recommended early detection screening, and most cancers are detected when chances of survival are lower. Illumina feels there is a moral obligation to have the deal decided by a thoughtful and full review by the EU regulators and the US courts. This can only be done if Illumina acquires GRAIL now. Otherwise, the company is locked into a situation where the deal terms will expire before there is a chance for full review; the clock will just run out.
  - Right now, the Galleri test is available but costs \$950 because it is not covered by insurance. Reuniting the two companies is the fastest way to make the test broadly available and affordable. Illumina's expertise in market development and access has resulted in coverage of genomic testing for over 1 billion people around the world already. This experience will help lead to coverage and reimbursement for the Galleri test.
- 365. In the same press release, Defendant Bishop stated, "The merger with Illumina will get the Galleri test to people far faster."
- 366. On a conference call that same day to discuss the GRAIL transaction, Defendants made additional representations about Illumina's "acceleration" and the lives that would be saved by the acquisition. During the call, Defendant deSouza stated, "The stakes here are high, because simply put, *this deal saves lives*, and we feel a moral obligation to ensure that the deal has a full review. . . . [W]ith Illumina's

acceleration, the Galleri test can conservatively save 10,000 additional lives in the U.S. and additional lives in the E.U. over the next nine years."

367. The statements identified in ¶¶364-66 above were materially false and misleading and omitted material facts. It was materially false and misleading for Illumina to state that Illumina's acquisition of GRAIL "[would] save lives," that "[t]his [could] only be done if Illumina acquires GRAIL now," and the deal would "save 10,000 additional lives in the U.S. and additional lives in the E.U. over the next nine years." In truth, and as the FDA informed Defendants before the start of the Class Period, the clinical data for Galleri developed to date was "insufficient," and that even the clinical trials GRAIL proposed to run to seek FDA approval would not establish its effectiveness because those trials did not, for example, "directly confirm the results of [the] test," nor "assess how the test results impacted patient treatment decisions," as required to demonstrate the test's true effectiveness. Rather, at the time this statement was made, and as reported by well-placed former employees, Defendants were "overstating what [Galleri] can do when they didn't have the data."

368. It was also materially false and misleading for Defendants to state that the acquisition was "the fastest way to make the test broadly available and affordable" and would "get the Galleri test to people far faster." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so. It was further materially false and misleading for Defendant deSouza to state that the acquisition was "the fastest way to make the test broadly available and affordable" because, as Illumina and GRAIL executives would later admit in testimony before the FTC and as reported

by well-placed former employees, GRAIL's hospital system and healthcare network customers overwhelmingly required detailed clinical data and FDA approval that Galleri did not have, and GRAIL's commercial plans were merely based on "dreams and magic."

369. On August 19 and 20, 2021, in an effort to quell investor concerns about Illumina's closing of the transaction, Defendant deSouza gave a series of interviews to the news media and analysts. In an interview on podcast Masters of Scale on August 19, Defendant deSouza was asked, "Now, this deal with GRAIL has put you in conflict with a different part of the government, with the FTC, the Federal Trade Commission, as well as with European regulators. Can you explain to us how you find yourself in this situation?" In response, deSouza stated:

What we want to do is bring the GRAIL test to market as fast as possible to people around the U.S. and around the world. GRAIL has a terrific technology, and Illumina, we have the commercial presence in over 140 countries around the world. We have the teams that can work on reimbursement and regulatory approval, and so we can dramatically accelerate getting this test into the hands of people whose lives it could save.

- 370. The statement in ¶369 above was materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that Illumina acquired GRAIL to "dramatically accelerate getting this test into the hands of people whose lives it could save." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.
- 371. On September 13, 2021, Defendant deSouza represented Illumina at the Morgan Stanley Global Healthcare Conference. In response to an analyst's question

about the GRAIL acquisition and its "key considerations," Defendant deSouza stated:

In addition to the considerations around shareholder value and making sure we're doing the move that long term maximizes shareholder value, we also felt a moral obligation to close the deal because the – potentially life savings, the savings life associated with doing this deal are so substantial. By accelerating GRAIL in terms of its global distribution and the accessibility of the tests globally, we will save many thousands of lives by getting this test into the hands of more people and making it more affordable than GRAIL would do on their own. And so, there was a moral element here, too, by saying in addition to creating long-term shareholder value, we have an obligation to have this deal reviewed and get to a decision because of the life-saving potential of doing this deal. And so all those considerations came together and that's how we made the decision.

- 372. The statements identified in ¶371 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that the acquisition would "accelerat[e] GRAIL in terms of its global distribution and the accessibility of the tests globally," and "save many thousands of lives by getting this test into the hands of more people and making it more affordable than GRAIL would do on their own." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.
- 373. On February 8, 2022, in an interview with *Medtech Insight*, Defendant Febbo stated: "We feel very strongly that *this acquisition will speed the test [Galleri] to market and make it more accessible more broadly, more quickly, and save lives."*
- 374. On November 8, 2022, in an interview on the Harry Glorikian Show, Defendant Febbo stated: "So we have incredible commercial kind of—commercial

capability, support capability, regulatory capability and reimbursement experience to help bring this test globally."

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375. The statements identified in ¶¶373-74 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant Febbo to state that the acquisition would "speed the test [Galleri] to market and make it more accessible more broadly [and] more quickly," and "save lives." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.

376. It was also materially false and misleading for Defendant Febbo to state Illumina had "incredible commercial capability, support capability, regulatory capability and reimbursement experience to help bring this test globally." Such statements concerning Illumina's commercial, support, and regulatory capabilities were unsubstantiated and false because, as the Fifth Circuit determined, Illumina did not possess "regulatory expertise" that was "superior to that which GRAIL already possessed" because Illumina had "only ever obtained pre-market approval for one Class III NGS-based diagnostic test" and that experience was largely irrelevant because the approval was based upon a "third party sponsored" clinical study. It was further false and misleading to suggest that Illumina's "commercial capability, support capability, regulatory and reimbursement experience" would accelerate Galleri's adoption because, as the most senior executive at Illumina who would have had responsibility for Galleri's commercial, regulatory and reimbursement strategy testified, Illumina did not have the appropriate experiences, resources, or funding to pursue Galleri's commercial adoption—and did not even have the level of expertise or experience GRAIL already had itself.

377. On November 29, 2022, Defendant Aravanis represented Illumina at the Evercore ISI HealthCONx Conference. At that conference, Defendant Aravanis stated in response to a question about the NHS-Galleri trial: "So, *it'll be an exciting piece of clinical evidence for GRAIL*, not just in the UK, but also in the U.S., right? So, you can imagine how useful that will be if successful in adoption, in just – in discussions with regulators about approval and so on."

378. The statements identified in ¶377 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant Aravanis to state that the NHS-Galleri trial would be "an exciting piece of clinical evidence for GRAIL," and that the study would be "useful" in "discussions with regulators about approval and so on," including because the FDA told GRAIL that there was "no way" that GRAIL could get approval for the Galleri test based on the NHS-Galleri trial, including due to significant differences in population characteristics, screening, and treatment practices between the U.S. and the U.K.

379. On January 10, 2023, Defendant deSouza represented Illumina at the JPMorgan Healthcare Conference. During the conference, deSouza stated that "GRAIL is making progress towards reimbursement, with 300,000 participants across multiple studies and a final FDA submission expected in 2024/2025," and that the "exciting momentum" from these studies had "translated into an expected GRAIL revenue CAGR of 60% to 90% over the next five years."

380. The statements identified in ¶379 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that GRAIL was "making progress towards reimbursement" and "a final FDA submission" was "expected in 2024/2025" because, as the FDA informed GRAIL before the Class Period, the clinical studies that GRAIL conducted and planned to conduct were not even designed to demonstrate whether Galleri was effective, as was needed to support FDA approval.

In truth, the clinical studies conducted on GRAIL by that time, and those GRAIL planned to undertake, would not "directly confirm the results of [its] test nor will [GRAIL] assess how the test results impacted patient treatment decisions," and thus were "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test." That is because none of the Galleri studies to date appropriately measured the test's effectiveness, none of the planned studies for GRAIL did so in a sufficiently powered manner, and there was a total absence of the kind of clinical evidence necessary to support FDA approval, commercialization, and payor reimbursement.

381. On January 20, 2023, Defendant deSouza gave an interview on CNBC. Defendant deSouza stated:

I think the GRAIL test is very important in terms of the impact it's going to have. *Illumina can really accelerate GRAIL*. So it's a startup. Again, we founded it, go through the trials, we had to raise more money and then we bought it back. GRAIL, on its own, we'll make a difference, but with Illumina, we can make the test available much more broadly than this startup could on its own. . . . *So what we want to do is make that test available more broadly, more affordably, more quickly than [GRAIL] could on its own*.

382. The statements identified in ¶381 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that "Illumina can really accelerate GRAIL." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.

383. On February 7, 2023, Illumina held a conference call with analysts and investors to discuss the Company's earnings and operations for the third quarter of 2020. During that call, in response to an analyst question about FDA approval,

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Defendant deSouza stated that GRAIL had "been working... with the FDA for a number of years on designing the studies that will be part of the ultimate submission," and was "making good progress." deSouza further stated that GRAIL had "been talking to the FDA about submitting data from the NHS trial as part of the FDA submission. Now that's really powerful because that's a very large trial. And so that continues to add to the bolus of evidence that GRAIL was able to get and submit into the FDA." As a result, deSouza stated, Illumina was "starting to see the benefits of that good working relationship between GRAIL and the FDA."

384. The statements identified in ¶383 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that GRAIL was "making good progress," had "been talking to the FDA about submitting data from the NHS trial as part of the FDA submission" a "powerful" trial that would "add to the bolus of evidence" supporting GRAIL's FDA submission, and Illumina was "starting to see the benefits of that good working relationship between GRAIL and the FDA." As the FDA informed GRAIL before the Class Period, the clinical studies that GRAIL conducted and planned to conduct were not even designed to demonstrate whether Galleri was effective, as was required for consideration for FDA approval. In truth, the clinical studies conducted on GRAIL by that time, and those GRAIL planned to undertake, would not "directly confirm the results of [its] test nor will [GRAIL] assess how the test results impacted patient treatment decisions," and thus were "not appropriately designed to evaluate the benefits and risks associated with the use of the Galleri test." Further, the NHS-Galleri Trial would likewise not support FDA approval because, in truth, the FDA told GRAIL that there was "no way" that GRAIL could get approval for the Galleri test based on the NHS-Galleri trial, including because of the significant differences in population characteristics, screening, and treatment practices between the U.S. and the U.K. do not permit valid comparisons between study outcomes in the two countries.

385. On March 28, 2023, Defendant Ofman discussed Galleri on a video presentation that was featured on GRAIL's website. In that presentation, Defendant Ofman represented that "Our Galleri multi-detection test can *identify 50 different cancers with a single blood draw*. And we can do that with a very low false positive rate, and a very high accuracy to predict in the body any cancer signal is found, and that *allows physicians to make an efficient and rapid diagnosis*."

386. The statement identified in ¶385 above was materially false and misleading. It was materially false and misleading for Defendant Ofman to state that Galleri could "identify 50 different cancers with a single blood draw" and that enable physicians to make "an efficient and rapid diagnosis" because, in truth, Galleri could not detect "more than 50 types of cancers" and there was no clinical evidence that Galleri would result in an "efficient" or "rapid" diagnosis of cancer. Rather, as the FDA informed Defendants before the start of the Class Period, the clinical data for Galleri developed to date was "insufficient" to establish Galleri's effectiveness as a diagnostic tool, and that even the clinical trials GRAIL proposed to run to seek FDA approval would not establish its effectiveness because those trials did not, for example, "directly confirm the results of [the] test" nor "assess how the test results impacted patient treatment decisions." Further, record evidence in the FTC proceeding demonstrated that there was "simply no clinical evidence that Galleri can provide early detection of 50+ cancers in an asymptomatic population," and Defendants' expert conceded that Galleri "has been clinically shown to detect only seven types of Stage I through Stage III cancer in an asymptomatic population"—not the 50 cancers represented by Defendant Ofman.

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C. In Response to Analyst Inquiries, Defendants Continue to Misrepresent GRAIL's Value, the Reasons for the Acquisition, and Illumina's Accounting

387. After the closing of the deal, analysts increasingly raised questions about GRAIL's value, Defendants' reasons for closing the acquisition in light of the standstill obligation imposed by the European Commission, and Illumina's accounting. In addition, on March 24, 2023, activist investor Carl Icahn issued an open letter to Illumina's shareholders calling attention to and questioning the D&O policy Illumina obtained for its Board immediately prior to the GRAIL acquisition.

388. In response to these inquiries, on March 24, 2023, Illumina issued a press release, which was also filed with the SEC on Form DEFA14A. In the press release, in response to Icahn's questions concerning the D&O insurance policy, Illumina stated that "D&O insurance and corporate indemnification are standard for Delaware companies," "[a]ll major U.S. public companies, including Illumina, regularly review their D&O insurance to reflect appropriate coverage," and that "it is not uncommon for a company buying another business to increase insurance limits during the acquisition process."

389. The statements identified in ¶388 above were materially misleading and omitted material facts. It was materially misleading to state that "D&O insurance and corporate indemnification are standard for Delaware companies," "[a]ll major U.S. public companies, including Illumina, regularly review their D&O insurance to reflect appropriate coverage," and that "it is not uncommon for a company buying another business to increase insurance limits during the acquisition process" while omitting the fact that the insurance policy was highly unusual, including because it involved an unprecedented premium of \$100 million on \$300 million of coverage, doubling the Company's D&O insurance from the year before at 25 times the cost.

390. In the press release, Illumina also stated: "The Board takes its fiduciary duties seriously and exercises considered and deliberate judgement [sic] with independent advice. Illumina steadfastly follows appropriate risk management

and disclosure practices. Illumina's disclosures are full, transparent and timely, consistent with SEC and other disclosure requirements."

391. The statements identified in ¶390 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendants to state that Illumina's Board "[took] its fiduciary duties seriously," Illumina "steadfastly follow[ed] appropriate risk management and disclosure practices," and Illumina's "disclosures were full, transparent and timely." Defendants' description statements omitted the highly material fact that in August 2021 (i.e., just prior to the close of the GRAIL acquisition), the Board unanimously approved the purchase of D&O insurance—that covered Illumina's directors and officers for claims arising out of the GRAIL acquisition—with up to \$300 million in coverage at an annual premium of up to \$100 million, doubling the Company's then-coverage for a premium that was over 25 times what the Company had paid the Under this special insurance, Illumina's directors and officers are vear before. covered for "any and all claims against any of them arising out of or relating to" the GRAIL acquisition including "any determinations or decisions in connection with regulatory approvals, rulings or other actions."

392. In the face of analyst questions and the proxy contest, Defendant deSouza continued to publicly defend the acquisition and its rationale. For example, on April 26, 2023, Defendant deSouza gave an interview on CNBC to defend the deal. During the interview, in response to the interviewer remarking, "This one [the Galleri test] *really works*," Defendant deSouza stated:

This one does and so, you know, the first 12-month revenue ramp for GRAIL has been the first test of any cancer screening test in history...

The reason why we think it makes sense at Illumina is that we can accelerate bringing this test to more people, more quickly, more affordably than GRAIL can do on their own... we have teams that are experts in bringing reimbursements for tests. And so what we can do is make this test more available to people who can't afford the \$950 test and roll it out more quickly."

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393. On the same day, Defendant deSouza also gave an interview on Bloomberg TV. During the interview, Defendant deSouza stated: "[The Galleri test] is a proven technology. There are large studies that show the efficacy of GRAIL as well as the performance metrics around GRAIL."

394. On the same day, Defendant deSouza also gave an interview on FOX Business. During the interview, Defendant deSouza stated:

We also have the opportunity at Illumina to significantly accelerate the ramp of GRAIL.... We at Illumina can accelerate that ramp because GRAIL has only plans to roll it out, the test out in the U.S. and the U.K. until 2030. We operate in 150 countries. I have talked personally to ministers of health that have expressed interest in rolling this test out in Europe, in Asia, in the Middle East, so we can accelerate this test and create significant shareholder value in doing this.

395. The statements identified in ¶¶392-94 above were materially false and misleading and omitted material facts. It was materially false and misleading for Defendant deSouza to state that Illumina acquired GRAIL to "accelerate bringing this test to more people, more quickly, more affordably than GRAIL could do on their own," "make this test more available to people who can't afford the \$950 test and roll it out more quickly," "significantly accelerate the ramp of GRAIL," and "create significant shareholder value." In truth, as Illumina and GRAIL management would admit during the FTC trial and as confirmed by the FTC and the Fifth Circuit Court of Appeals after reviewing the full evidentiary record in that case, Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved, and had not modeled any acceleration, planned any steps to achieve any acceleration, and did not have the relevant expertise, experience, or resources to do so.

396. On April 28, 2023, activist investor Carl Icahn published an open letter to Illumina shareholders, questioning the GRAIL acquisition and requesting that the Board "bring in an outside – and demonstrably independent – law firm and forensic accounting team to investigate and address these questions publicly." In response,

just before the market closed on May 1, 2023, Illumina issued a press release, which was also filed with the SEC on Form DEFA14A, stating:

None of Illumina's directors involved in either the decision to sign or the decision to close the GRAIL acquisition – including our former CEO and Executive Chairman Jay Flatley, our current CEO Francis deSouza and each of Illumina's current directors – has ever held any equity interest in GRAIL. At the time of Illumina's various investment rounds in GRAIL, no individuals at Illumina were investors in GRAIL. Illumina's employees, executive officers and Board members were not permitted to participate in GRAIL investment rounds and did not otherwise receive any GRAIL equity. Illumina, Inc. was the founder of GRAIL and individuals employed by Illumina moved to GRAIL as part of the spin-out in 2016. Those who moved to GRAIL terminated their relationship with Illumina at the time of transition and directors and employees who remained at Illumina could not receive any GRAIL equity.

397. On May 18, 2023, in response to activist investor Carl Icahn's questions about Illumina insiders' financial interests in the GRAIL transaction, Defendant Thompson stated:

On conflicts of interest, there is an important question I would like to put to bed: "Did any Illumina directors have a financial interest in GRAIL at the time of the acquisition?" This question is not a matter of interpretation or explanation. The answer is simply no. As we have said before, no director who oversaw any part of the GRAIL transaction has ever owned any equity interest in GRAIL — that includes Jay Flatley, Francis deSouza, myself, and any member of the Board now or at the time of acquisition. In addition, no executive officers of Illumina held GRAIL shares at the signing or closing of the GRAIL acquisition (including indirect ownership interests such as through trusts, LP or GP stakes in investment vehicles, or through derivative securities), other than Alex Aravanis, who Illumina had hired from GRAIL, and Mostafa Ronaghi, Illumina's former CTO, who received GRAIL shares upon joining GRAIL's Board in May 2020. The economic interests and relationships of these individuals with GRAIL were fully disclosed to, and known by, Illumina and its Board, and, consistent with good corporate governance practices, both were recused from any decisions to sign and close the GRAIL acquisition.

398. The statements identified in ¶¶396-97 above were materially false and misleading and omitted material facts. Rather than lack "any financial interest in GRAIL at the time of the acquisition," in truth, Illumina directors and management had a massive undisclosed financial interest in GRAIL that motivated Illumina's acquisition and closing of the transaction. In reality, as a newly installed Illumina director uncovered after gaining access to privileged and confidential internal

Illumina Board materials, Defendants were in fact personally motivated to close the GRAIL acquisition and Illumina's remaining directors were conflicted because they were "poisoned by their personal stake" in the deal, Illumina misrepresented the Company's reasons for closing the acquisition, and investors had not been told "the truth about Defendants' misconduct."

399. Defendants' statements disclaiming that any Illumina directors, employees, executive officers held any equity interests in GRAIL and did not receive GRAIL equity were also materially false and misleading because they omitted the highly material facts that (1) there were approximately 70 million GRAIL shares worth over \$830 million at the close of the GRAIL transaction held by Illumina's senior leadership and their affiliates, the existence of which was not publicly disclosed by Defendants; (2) Illumina had, for years prior to and throughout the Class Period, improperly accounted for GRAIL as a "cost method" (as opposed to "equity method") investment in violation of GAAP; (3) Illumina engaged in such accounting violations specifically in order to avoid public disclosure of Illumina insiders' secret financial interest in GRAIL; (4) Defendant Klausner invested \$125 million in GRAIL's final fundraising round while in possession of material facts concerning Illumina's reacquisition of GRAIL and was able to make over \$100 million in virtually risk-free profits by investing with this unique access to material nonpublic information.

## D. Defendants Treated GRAIL as a Deconsolidated Variable Interest Entity in Violation of GAAP

400. On October 30, 2020, Illumina filed its quarterly report on Form 10-Q for the third quarter of 2020. The Form 10-Q reported that Illumina treated GRAIL as a deconsolidated "[variable interest entity] for which we have concluded that we are not the primary beneficiary and, therefore, we do not consolidate GRAIL in our consolidated financial statements." Attached to the Form 10-Q were certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") signed by

Defendants deSouza and Samad attesting to the accuracy of Illumina's financial reporting and the disclosure of all fraud. The Form 10-K filed on February 17, 2021; the Form 10-Q filed on April 28, 2021; the Form 10-Q filed on August 6, 2021; and the Form 10-Q filed on November 5, 2021 made identical or substantively identical statements and appended identical SOX certifications.

401. The statements identified in ¶400 above were materially false and misleading and omitted material facts. It was materially false and misleading to state that Illumina treated GRAIL as a deconsolidated VIE "for which we have concluded that we are not the primary beneficiary and, therefore, we do not consolidate GRAIL in our consolidated financial statements" and for Defendants deSouza and Samad to certify that Illumina's quarterly and annual reports fairly presented, in all material respects, "the financial condition, results of operations and cash flows" of Illumina. In truth, despite "continuously monitoring" the accounting treatment of GRAIL before the close of the acquisition as a deconsolidated variable interest entity, Illumina improperly accounted for GRAIL under the cost method in violation of GAAP given the "significant influence" that Illumina could and did exert over GRAIL through material intra-entity transactions, technological dependence, the interchange of managerial personal, and representation on GRAIL's board of directors.

#### XII. LOSS CAUSATION

- 402. The fraud alleged herein was the proximate cause of the economic loss suffered by Plaintiffs and the Class. There was a causal connection between the alleged fraud and the loss (i.e., stock price declines) described herein. *See, e.g., Mineworkers' Pension Scheme v. First Solar Inc.*, 881 F.3d 750 (9th Cir. 2018).
- 403. During the Class Period, Plaintiffs and the Class members purchased or otherwise acquired Illumina common stock at artificially inflated prices, and were damaged thereby when the price of Illumina common stock declined in response to the partial disclosures. Throughout the Class Period, the price of Illumina common

stock was artificially inflated and/or maintained as a result of Defendants' materially false and misleading statements and omissions. The price of Illumina common stock significantly declined, causing investors to suffer losses, in response to a series of partial disclosures concerning or connected to the facts misrepresented or concealed by Defendants, which disclosures are described more fully above in Section VIII. Throughout the disclosure period, Defendants mitigated Illumina's stock price declines by making additional false assurances concerning the alleged fraud, as described herein.

404. As the result of the disclosures described herein, Illumina common stock declined from a Class Period high of \$555.77 per share to a closing price of \$98.37 per share on November 10, 2023, a decline of 82.3%. Each of these disclosures was associated with a statistically significant "abnormal" decline, meaning that it was not explained by broader market or industry price declines.

Date <sup>11</sup>	Disclosure Summary	Closing Price	% Change
8/19/2021	Illumina announces the closing of the GRAIL acquisition.		-7.9%
11/23/2021	Clinicians in <i>Diagnostics</i> article question Galleri's validity and whether "this test could become a viable pan-cancer clinical screening tool."	\$365.74	-3%
5/6/2022	Illumina reports a revenue miss due to GRAIL and reveals information raising questions about the timeline for Galleri's commercial adoption and clinical validity.	\$249.05	-14.63%
6/10/2022	Illumina announces the departure of Defendant Samad. <i>The New York Times</i> reports on the high expense and low clinical validity of MCED tests.	\$204.19	-9%

<sup>&</sup>lt;sup>11</sup> The date(s) in parentheses refer to the date(s) of stock price decline caused by the corrective event.

Date <sup>11</sup>	Disclosure Summary	Closing Price	% Change
8/12/2022	Illumina reports results showing that GRAIL missed analyst estimates.	\$208.33	-8.4%
6/27/2023	STAT reports that Illumina's headcount reduction would consist of 10% of Illumina's R&D workforce.	\$184.43	-4.4%
8/11/2023 (8/14/2023)	Illumina discloses that it is the target of an SEC investigation.	\$175.14	-5.4%
10/24/2023	News media report on an Icahn shareholder derivative complaint alleging Defendants' "Personal Stake" in the GRAIL acquisition.	\$116.10	-2.96%
11/10/2023 (11/13/2023)	Illumina announces that it will be taking an \$821 million write down related to GRAIL.	\$92.79	-13.26%

405. It was entirely foreseeable that Defendants' materially false and misleading statements and omissions discussed herein would artificially inflate or maintain the existing artificial inflation of the price of Illumina common stock. It was also foreseeable to Defendants that the disclosures described above would cause the price of Company stock to fall as the artificial inflation caused and maintained by Defendants' misstatements and omissions was removed. Thus, the stock price declines described above were directly and proximately caused by Defendants' materially false and misleading statements and omissions.

#### XIII. THE PRESUMPTION OF RELIANCE

406. Lead Plaintiffs are entitled to a presumption of reliance on Defendants' material misrepresentations and omissions, deceptive devices, and fraudulent scheme pursuant to the fraud-on-the-market doctrine because, among other things, during the Class Period:

- (i) The Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (ii) The misrepresentations and omissions were material;

- (iii) Illumina's common stock was actively traded in an efficient market on the NASDAQ;
- (iv) Illumina's common stock traded at high weekly volumes;
- (v) As a regulated issuer, Illumina filed periodic public reports with the SEC;
- (vi) Illumina was eligible to file registration statements with the SEC on Form S-3, its equivalent;
- (vii) Illumina regularly communicated with public investors by means of established market communication mechanisms, including through regular dissemination 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;
- (viii) The market reacted promptly to public information disseminated by Illumina;
- (ix) Illumina common stock was covered by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective firms. These reports were publicly available and entered the public marketplace; The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of Illumina common stock; and
- (x) Without knowledge of the misrepresented or omitted material facts alleged herein, Lead Plaintiffs and other members of the Class purchased or acquired Illumina common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed.
- 407. Additionally, Lead Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because certain of the claims asserted herein against Defendants are predicated upon omissions of material fact which there was a duty to disclose.
- 408. Accordingly, Lead Plaintiffs and other members of the Class relied, and are entitled to have relied, upon the integrity of the market prices for Illumina's common stock, and are entitled to a presumption of reliance on Defendants' materially false and misleading statements and omissions, deceptive devices, and fraudulent scheme during the Class Period.

#### XIV. CLASS ACTION ALLEGATIONS

- 409. Plaintiffs bring this action as a class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of all persons or entities that purchased or otherwise acquired Illumina common stock between September 21, 2020, and November 9, 2023, inclusive, and who were damaged thereby (the "Class Period").
- 410. 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 class members. During the Class Period, Illumina had more than 150 million shares of common stock outstanding, owned by many thousands of investors.
- 411. 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 that may affect individual Class members include: (a) whether Defendants violated the federal securities laws; (b) whether Defendants omitted and 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 the price of Illumina common stock was artificially inflated; (e) whether Defendants' conduct caused the members of the Class to sustain damages; and (f) the extent of damages sustained by Class members and the appropriate measure of damages.
- 412. Plaintiffs' claims are typical of those of the Class because Plaintiffs and the Class sustained damages from Defendants' wrongful conduct.
- 413. Plaintiffs will adequately protect the interests of the Class and have retained counsel experienced in class-action securities litigation. Plaintiffs have no interests that conflict with those of the Class.

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414. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

#### XV. THE INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

- 415. The statutory safe harbor applicable to forward-looking statements under certain circumstances does not apply to any of the false or misleading statements pleaded in this Complaint. The statements complained of herein were: (i) historical statements or statements of purportedly current facts and conditions at the time the statements were made; (ii) mixed statements of present and/or historical facts and future intent; and/or (iii) omitted to state material current or historical facts necessary to make the statements not misleading.
- 416. Further, to the extent that any of the false or misleading statements alleged herein could be construed as forward-looking, the statements were not accompanied by any meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements. Given the then-existing facts contradicting the Defendants' statements, any generalized risk disclosures made by the Defendants were not sufficient to insulate them from liability for their materially false and misleading statements.
- 417. Further, to the extent that any of the false or misleading statements alleged herein could be construed as forward-looking, the statements were not accompanied by any meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements. Given the then-existing facts contradicting the Defendants' statements, any generalized risk disclosures made by the Defendants were not sufficient to insulate them from liability for their materially false and misleading statements.
- 418. Alternatively, to the extent the statutory safe harbor otherwise would apply to any forward-looking statements pleaded herein, the Defendants are liable for those false and misleading forward-looking statements because at the time each of those statements was made, the speaker knew the statement was false or

misleading, did not actually believe the statements, had no reasonable basis for the statements, and were aware of undisclosed facts tending to seriously undermine the statements' accuracy. XVI. CLAIMS FOR RELIEF COUNT I – VIOLATION OF SECTION 10(B) OF THE EXCHANGE ACT AND SEC RULE 10B-5(B) PROMULGATED THEREUNDER (AGAINST DEFENDANTS ILLUMINA, GRAIL, DESOUZA, SAMAD, FEBBO, ARAVANIS, THOMPSON, BISHOP, AND OFMAN)

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## 419. Lead Plaintiffs repeat, incorporate, and reallege each and every allegation set forth above as if fully set forth herein.

- 420. This count is asserted on behalf of Lead Plaintiffs and all members of the Class against Defendants Illumina, GRAIL, deSouza, Samad, Febbo, Aravanis, Thompson, Bishop, and Ofman for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5(b) promulgated thereunder, 17 C.F.R. § 240.10b-5.
- 421. During the Class Period, Defendants Illumina, GRAIL, deSouza, Aravanis, Samad, Febbo, Thompson, Bishop, and Ofman made the false statements specified above, which they knew or, at minimum, were severely reckless in not knowing, were misleading in that they contained misrepresentations and omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.
- 422. Defendants Illumina, GRAIL, deSouza, Samad, Febbo, Aravanis, Thompson, Bishop, and Ofman violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they made untrue statements of material fact and/or disseminated and/or approved and/or omitted to state material facts necessary to make the false or misleading statements specified above not misleading.
- 423. Defendants Illumina, GRAIL, deSouza, Samad, Febbo, Aravanis, Thompson, Bishop, and Ofman individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails made various untrue and/or misleading statements of material facts 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, and made the above statements and omissions intentionally or with severe recklessness.

- 424. Defendants Illumina, GRAIL, deSouza, Samad, Febbo, Aravanis, Thompson, Bishop, and Ofman are liable for all materially false or misleading statements made during the Class Period, as alleged above.
- 425. As described above, Defendants Illumina, GRAIL, deSouza, Samad, Febbo, Aravanis, Thompson, Bishop, and Ofman acted with scienter throughout the Class Period, in that they acted either with intent to deceive, manipulate, or defraud, or with severe recklessness. The misrepresentations and omissions of material facts set forth herein, which presented a danger of misleading buyers or sellers of Illumina common stock, were either known to Defendants Illumina, GRAIL, deSouza, Samad, Febbo, Aravanis, Thompson, Bishop, and Ofman or were so obvious that they should have been aware of them.
- 426. Lead Plaintiffs and the Class have suffered damages in that, in direct reliance on the integrity of market prices, they paid artificially inflated prices for Illumina common stock, which inflation was removed from its price when the true facts became known.
- 427. Defendants Illumina, GRAIL, deSouza, Samad, Febbo, Aravanis, Thompson, Bishop, and Ofman's wrongful conduct, as alleged above, directly and proximately caused the damages suffered by Lead Plaintiffs and other Class members. Had Defendants Illumina, GRAIL, deSouza, Samad, Febbo, Aravanis, Thompson, Bishop, and Ofman disclosed complete, accurate, and truthful information concerning these matters during the Class Period, Lead Plaintiffs and other Class members would not have purchased or otherwise acquired Illumina common stock or would not have purchased or otherwise acquired these securities at the artificially inflated prices that they paid. It was also foreseeable to Defendants Illumina, GRAIL, deSouza, Samad, Febbo, Aravanis, Thompson, Bishop, and

Ofman that misrepresenting and concealing these material facts from the public would artificially inflate the price of Illumina's securities and that the ultimate disclosure of this information, or the materialization of the risks concealed by the Defendants Illumina, GRAIL, deSouza, Samad, Febbo, Aravanis, Thompson, Bishop, and Ofman's material misstatements and omissions, would cause the price of Illumina common stock to decline.

- 428. Accordingly, as a result of their purchases of Illumina common stock during the Class Period, Lead Plaintiffs and the Class suffered economic loss and damages under the federal securities laws.
- 429. By virtue of the foregoing, Defendants Illumina, GRAIL, deSouza, Samad, Febbo, Aravanis, Thompson, Bishop, and Ofman violated Section 10(b) of the Exchange Act and Rule 10b-5, promulgated thereunder.
- 430. This claim is timely within the applicable statute of limitations and repose.

#### COUNT II – VIOLATION OF SECTION 10(B) OF THE EXCHANGE ACT AND SEC RULE 10B-5(A) AND (C) PROMULGATED THEREUNDER (AGAINST ALL DEFENDANTS)

- 431. Lead Plaintiffs repeat, incorporate, and reallege each and every allegation set forth above as if fully set forth herein.
- 432. This count is asserted on behalf of all members of the Class against Defendants Illumina, GRAIL, deSouza, Thompson, Samad, Febbo, Aravanis, Bishop, Ofman, and Klausner for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5(a) and (c) promulgated thereunder, 17 C.F.R. § 240.10b-5.
- 433. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) in that they: (1) employed devices, schemes, and artifices to defraud; and (2) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon Plaintiffs and others similarly situated in connection with their

purchases of Illumina common stock during the Class Period in an effort to maintain artificially high market prices for Illumina common stock.

- 434. Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, employed devices, schemes, and artifices to defraud and engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Plaintiffs and the Class in connection with the purchase and sale of Illumina common stock; which did: (i) deceive the investing public, including Plaintiffs and the Class, regarding, among other things, the Galleri test's capabilities and readiness for commercialization and Defendants' personal financial motives for acquiring GRAIL; (ii) artificially inflate and maintain the market price of Illumina common stock; and (iii) cause Plaintiffs and other members of the Class to purchase Illumina common stock at artificially inflated prices and suffer losses when the true facts became known.
- 435. As part of their scheme to defraud investors in violation of Rule 10b-5(a) and (c), Defendants engaged in the following course of business conduct, as described by, among things, pleadings and evidence filed in connection with related litigation involving Illumina and GRAIL, including *In re Matter of Illumina*, *Inc. and GRAIL, Inc.*, FTC Docket No. 9401, *Icahn, Omaha, Roseville*, and *Pavers*; and the accounts of former employees described above. For example, Defendants engaged in the following deceptive activities:
  - i. Concealing evidence of GRAIL's missing equity by applying the cost method of accounting rather than the equity method of accounting in violation of GAAP and disseminating false statements to do so;
  - ii. Garnering illicit profits by using Defendants' knowledge of Illumina's acquisition of GRAIL while "investing" tens of millions in GRAIL and concealing evidence of Defendant Klausner and Milky Way's purchase of GRAIL equity;
  - iii. Purchasing \$300 million in D&O insurance at a \$100 million premium specifically to provide against personal liability for completing the GRAIL acquisition while knowing that completion of the deal was illegal and then misrepresenting the

nature of the policy and its import when questioned by investors;

- iv. Disseminating false statements over-valuing GRAIL with knowledge that Galleri's commercial prospects and FDA approval were unsubstantiated; and
- v. Selling Galleri as an LDT so as to avoid FDA enforcement and facilitate Defendants' ability to make unsubstantiated medical claims concerning its supposed clinical effectiveness to customers and to conceal those facts from investors.
- 436. These deceptive acts were part of a course of conduct that operated as a fraud and deceit upon Plaintiffs and others similarly situated in connection with their purchases of Illumina common stock during the Class Period in an effort to maintain artificially high market prices for Illumina common stock.
- 437. As described above, Defendants Illumina, GRAIL, deSouza, Aravanis, Samad, Febbo, Thompson, Bishop, Ofman, and Klausner acted with scienter throughout the Class Period, in that they either acted either with intent to deceive, manipulate, or defraud, or with severe recklessness. Defendants engaged in this misconduct to conceal Illumina's true condition from the investing public and to support the artificially inflated prices of the Company's common stock.
- 438. Plaintiffs and the Class have suffered damages in that, in direct reliance on the integrity of market prices, they paid artificially inflated prices for Illumina common stock, which artificial inflation was removed from the stock when true facts became known. Plaintiffs and the Class would not have purchased Illumina common stock at the prices they paid, or at all, had they been aware that the market prices for Illumina common stock had been artificially inflated by Defendants' fraudulent course of conduct.
- 439. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages attributable to the fraud alleged herein in connection with their respective purchases of the Company's common stock during the Class Period.
- 440. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c), promulgated thereunder.

441. This claim is timely within the applicable statute of limitations and repose.

# COUNT III – VIOLATION OF SECTION 20(a) OF THE EXCHANGE ACT (AGAINST THE ILLUMINA EXECUTIVE DEFENDANTS AND THE GRAIL EXECUTIVE DEFENDANTS)

- 442. Lead Plaintiffs repeat, incorporate, and reallege each and every allegation set forth above as if fully set forth herein.
- 443. This count is asserted on behalf of all members of the Class against the Illumina Executive Defendants and the GRAIL Executive Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).
- 444. *Illumina*. The Illumina Executive Defendants acted as controlling persons of Illumina within the meaning of Section 20(a) of the Exchange Act, as alleged herein.
- 445. By reason of their high-level positions of control and authority as Illumina's most senior officers, the Illumina Executive Defendants had the authority to influence and control, and did influence and control, the decision-making and activities of Illumina and its employees, and to cause Illumina to engage in the wrongful conduct complained of herein. The Illumina Executive Defendants were able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by Illumina during the Class Period, thereby causing the dissemination of the materially false and misleading statements and omissions of material facts as alleged herein.
- 446. The Illumina Executive Defendants communicated with investors or the public on behalf of Illumina during the Class Period. The Illumina Executive Defendants were provided with, or had unlimited access to, copies of the Company's press releases, public filings, and other statements alleged by Lead Plaintiffs to be misleading prior to and/or shortly after these statements were made and had the ability to prevent the issuance of the statements or to cause the statements to be corrected. Therefore, the Illumina Executive Defendants were able to influence and

control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by Illumina during the Class Period, thereby causing the dissemination of the materially false and misleading statements and omissions of material facts as alleged herein.

- 447. Illumina violated Section 10(b) of the Exchange Act by virtue of the acts and omissions of its top executives, including the Illumina Executive Defendants, as alleged in this Complaint.
- 448. By virtue of their positions as controlling persons of Illumina and as a result of their own aforementioned conduct, the Illumina Executive Defendants are liable pursuant to Section 20(a) of the Exchange Act to Lead Plaintiffs and the other members of the Class who purchased or otherwise acquired Illumina common stock during the Class Period. As detailed above, during the respective times, these Defendants served as officers, directors, and/or senior personnel of Illumina and/or GRAIL.
- 449. *GRAIL*. The GRAIL Executive Defendants acted as controlling persons of GRAIL within the meaning of Section 20(a) of the Exchange Act, as alleged herein.
- 450. By reason of their high-level positions of control and authority as GRAIL's most senior officers, the GRAIL Executive Defendants had the authority to influence and control, and did influence and control, the decision-making and activities of GRAIL and its employees, and to cause GRAIL to engage in the wrongful conduct complained of herein. The GRAIL Executive Defendants were able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by GRAIL during the Class Period, thereby causing the dissemination of the materially false and misleading statements and omissions of material facts as alleged herein.
- 451. The GRAIL Executive Defendants communicated with investors or the public on behalf of GRAIL during the Class Period. The GRAIL Executive

Defendants were provided with, or had unlimited access to, copies of GRAIL's press releases, public filings, and other statements alleged by Lead Plaintiffs to be misleading prior to and/or shortly after these statements were made and had the ability to prevent the issuance of the statements or to cause the statements to be corrected. Therefore, the GRAIL Executive Defendants were able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by GRAIL during the Class Period, thereby causing the dissemination of the materially false and misleading statements and omissions of material facts as alleged herein.

- 452. GRAIL violated Section 10(b) of the Exchange Act by virtue of the acts and omissions of its top executives, including the GRAIL Executive Defendants, as alleged in this Complaint.
- 453. By virtue of their positions as controlling persons of GRAIL and as a result of their own aforementioned conduct, the GRAIL Executive Defendants are liable pursuant to Section 20(a) of the Exchange Act to Lead Plaintiffs and the other members of the Class who purchased or otherwise acquired Illumina common stock during the Class Period. As detailed above, during the respective times, these Defendants served as officers, directors, and/or senior personnel of GRAIL.
- 454. As a direct and proximate result of the Illumina Executive Defendants and GRAIL Executive Defendants' conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their purchases or acquisitions of Illumina common stock.
- 455. This claim is timely within the applicable statutes of limitations and repose.

#### XVII.PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment as follows:

A. Determining that this Action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

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1	B.	Awarding compensate	ory or rescissory damages in favor of Plaintiffs
2	and other	Class members against	all Defendants, jointly and severally, for all
3	damages su	ustained as a result of Def	fendants' wrongdoing, in an amount to be proven
4	at trial, inc	luding interest;	
5	C.	Awarding Plaintiffs ar	nd the Class their reasonable costs and expenses
6	incurred in	this action, including at	torneys' fees and expert fees; and
7	D.	Awarding any equitable	le, injunctive, or other further relief that the Court
8	may deem	just and proper.	
9	XVIII.	JURY TRIAL DEMA	AND
10	Plair	ntiffs demand a trial by j	ury.
11	Dated: Jun	ne 21, 2024	Respectfully submitted,
12			BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP
13			/s/ John Rizio-Hamilton
14			Jonathan D. Uslaner (Bar No. 256898)
15			(jonathanu@blbglaw.com) 2121 Avenue of the Stars, Suite 2575
16			Los Angeles, CA 90067 Tel: (310) 819-3470
17			Tel. (310) 819-3470
18			-and-
19			John Rizio-Hamilton
20			(johnr@blbglaw.com) Michael D. Blatchley
21			(michaelb@blbglaw.com) Alec Coquin
22			(alec.coquin@blbglaw.com)
23			Michael Mathai (michael.mathai@blbglaw.com
24			Emily A. Tu
25			(emily.tu@blbglaw.com) 1251 Avenue of the Americas
26			New York, NY 10020 Tel: (212) 554-1400
27			Fax: (212) 554-1444
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## Appendix A

## **Chart of Defendants and Relevant Non-Parties**

Name	<u>Illumina/GRAIL</u> Tenure and Role	Other Relevant Roles	Connections to Other Key Players		
	Illumina Executives				
Defendant Francis A. deSouza	Illumina:     President (2013-2016)     Director (2014-2023)     CEO (2016-2023)	IBM:  • Technical Staff (1990-1992)  Symantec:  • President (2006-2011)  Moonwalk Biosciences, Inc. (backed by ARCH Ventures):  • Advisor (2024-present)	IBM, Symantec:  Thompson  Moonwalk Biosciences:  Aravanis  ARCH Ventures:  Aravanis  Flatley  Arnold  Epstein  Gottlieb  Bishop  Klausner  Nelsen  Foster  Freidman  Barron  Baselga  Golumbeski  Rastetter  Ho		
Defendant John W. Thompson	Illumina:	<u>IBM</u> :	<ul><li>IBM, Symantec:</li><li>deSouza</li></ul>		
Defendant Sam A. Samad	Illumina: • CFO (2017-2022)				

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<u>Name</u>	Illumina/GRAIL Tenure and Role	Other Relevant Roles	Connections to Other Key Players	
Defendant Phillip G. Febbo	Illumina: • CMO (2018-2023)	Veracyte:  • Chief Scientific Officer, CMO	Veracyte:  • Epstein	
Defendant Alexander M. Aravanis	Illumina:  Senior Director, R&D (2013-2016)  CTO, Senior Vice President, Head of R&D (2020-2023)  GRAIL:  Co-founder, Chief Scientific Officer, Head of R&D (2016-2020)	Moonwalk Biosciences, Inc. (backed by ARCH Ventures):  • Co-founder and CEO (2023-present)	Moonwalk Biosciences:  deSouza  ARCH Ventures: deSouza Flatley Arnold Epstein Gottlieb Bishop Klausner Nelsen Foster Freidman Barron Baselga Golumbeski Rastetter Ho	
Joydeep Goswami	<ul> <li>Illumina:</li> <li>Senior Vice President, Corporate Development &amp; Strategic Planning (2019-2021)</li> <li>Chief Strategy Officer (2021-2022)</li> <li>CFO (2022-2024)</li> </ul>			
	Illumina Board of Directors			
Jay T. Flatley	<u>Illumina</u> : ■ President (1999-2013)	Denali Therapeutics (backed by ARCH Ventures):	Juno Therapeutics:  Bishop	

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<u>Name</u>	Illumina/GRAIL Tenure and Role	Other Relevant Roles	Connections to Other Key Players
	<ul> <li>CEO (1999-2016)</li> <li>Executive Board Chair (2016-2020)</li> <li>Board Chair (2020-2021)</li> </ul>	<ul> <li>Director</li> <li>Cellanome: <ul> <li>Board Chair</li> </ul> </li> <li>Juno Therapeutics (backed by ARCH Ventures): <ul> <li>Director</li> </ul> </li> </ul>	<ul> <li>Klausner</li> <li>Barron</li> <li>Baselga</li> <li>Cellanome: <ul> <li>Ronaghi</li> </ul> </li> <li>ARCH Ventures: <ul> <li>deSouza</li> <li>Aravanis</li> <li>Arnold</li> <li>Epstein</li> <li>Gottlieb</li> <li>Bishop</li> <li>Klausner</li> <li>Nelsen</li> <li>Foster</li> <li>Freidman</li> <li>Barron</li> <li>Baselga</li> <li>Golumbeski</li> <li>Rastetter</li> <li>Ho</li> </ul> </li> </ul>
Frances Arnold	Illumina:  • Director (2016-GRAIL acquisition)	Altos Labs (backed by ARCH Ventures):  • Director National Resilience (backed by ARCH Ventures):  • Director  Generate Biomedicines (backed by ARCH Ventures):  • Director	Altos Labs:      Bishop     Klausner     Barron  National Resilience:     Gottlieb     Nelsen     Foster

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<u>Name</u>	Illumina/GRAIL  Tenure and Role	Other Relevant Roles	Connections to Other Key Players
			ARCH Ventures:  deSouza Aravanis Flatley Epstein Gottlieb Bishop Klausner Nelsen Foster Freidman Barron Baselga Golumbeski Rastetter Ho
Robert S. Epstein	Illumina:  • Director (2016-GRAIL acquisition)	Fate Therapeutics (backed by ARCH Ventures):  • Director  Mindstrong Health (backed by ARCH Ventures):  • Director  Veracyte:  • Board Chair  Merck:  • CMO	Fate Therapeutics:  Rastetter  Mindstrong Health:  Klausner  Veracyte:  Febbo  Merck:  Dorsa  ARCH Ventures:  deSouza Aravanis

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<u>Name</u>	Illumina/GRAIL Tenure and Role	Other Relevant Roles	Connections to Other Key Players
			<ul> <li>Flatley</li> <li>Arnold</li> <li>Gottlieb</li> <li>Bishop</li> <li>Klausner</li> <li>Nelsen</li> <li>Foster</li> <li>Freidman</li> <li>Barron</li> <li>Baselga</li> <li>Golumbeski</li> <li>Rastetter</li> <li>Ho</li> </ul>
Philip W. Schiller	Illumina:  • Director (2016-GRAIL acquisition)		
Susan E. Siegel	Illumina:  • Director (2019-GRAIL acquisition)		
Caroline D. Dorsa	Illumina:  • Director (2017-GRAIL acquisition)	<ul> <li>Merck:         <ul> <li>Vice President and Treasurer</li> <li>Executive Director of U.S.</li></ul></li></ul>	Merck: • Epstein
Gary S. Guthart	Illumina:  • Director (2017-GRAIL acquisition)		

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Name    Scott Gottlieb   Tenure and Role   Other Relevant Roles   Other Key F	<u>Players</u>
Scott Gottlieb    Illumina:   • Director (2020-GRAIL acquisition)   Mational Resilience (backed by ARCH Ventures):   • Director   • Director   • Nelsen     • Foster	
Defendant Hans Bishop  GRAIL:  CEO (2019-2021)  Defendant Hans Bishop  GRAIL:  CEO (2019-2021)  Defendant Hans Bishop  ARCH Ventures):  Founder, President, CEO  Altos Labs (backed by ARCH Ventures):  Founder, President, Board Co-Chair  Sana Biotechnology (backed by ARCH Ventures):  Barron  Baselga  Altos Labs:  Arnold  Klausner  Barron  Barron  Barron  Barron  Sana Biotechnology  Nelsen  Lyell Immunopharma (backed by ARCH Ventures):  Director  Director  ARCH Ventures:  Altos Labs:  Nelsen  Klausner  Nelsen  Klausner  Nelsen  Klausner  Nelsen  ARCH Ventures:  ARCH Ventures:  ARCH Ventures:  ARCH Ventures:  ARCH Ventures:  Fitaley	<u>y</u> :

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<u>Name</u>	Illumina/GRAIL Tenure and Role	Other Relevant Roles	Connections to Other Key Players
			<ul> <li>Epstein</li> <li>Klausner</li> <li>Nelsen</li> <li>Foster</li> <li>Freidman</li> <li>Barron</li> <li>Baselga</li> <li>Golumbeski</li> <li>Rastetter</li> <li>Ho</li> </ul>
Defendant Joshua J. Ofman	<ul> <li>GRAIL:</li> <li>Chief of Corporate Strategy and External Affairs (2019-2020)</li> <li>CMO and Head of External Affairs (2020-2021)</li> <li>President and CMO (2021-2022)</li> <li>President (2022-present)</li> </ul>		
Gautam Kollu	<ul> <li>Illumina:</li> <li>Vice President, Commercial Operations and Product Strategy (2013-2014)</li> <li>Head of Market Development (2014-2017)</li> <li>Global Head, Market Development (2017-2019)</li> <li>GRAIL:</li> <li>Chief Commercial Officer (2019-2022)</li> </ul>	Genentech:  • Senior Manager, Market Development and Launch Team Leader	Genentech:  • Barron
Satnam Alag	<ul> <li>Illumina:</li> <li>Vice President of Software Engineering, Enterprise Informatics (2013-2020)</li> </ul>		

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	Illumina/GRAIL		<b>Connections to</b>
<u>Name</u>	Tenure and Role	Other Relevant Roles	Other Key Players
	GRAIL:  • Senior Vice President of Software Engineering and Chief Security Officer (2020-present)		
	GRAIL Board	of Directors	
Defendant Richard D. Klausner	Illumina:  Senior Vice President and CMO (2013-2014)  Chief Opportunity Officer (2014-2016)  GRAIL:  Co-founder and Director (2016-GRAIL acquisition)	Milky Way Investments Group:  Founder, Managing Partner  Juno Therapeutics (backed by ARCH Ventures):  Founder, Director  Altos Labs (backed by ARCH Ventures):  Chief Scientist  Lyell Immunopharma (backed by ARCH Ventures):  Founder, Board Chair  LifeMine Therapeutics (backed by ARCH Ventures):  Co-founder, Board Chair Sonoma Biotherapeutics (backed by ARCH Ventures):  Board Chair  Mindstrong Health (backed by ARCH Ventures):  Executive Chair	Juno Therapeutics:      Bishop     Flatley     Barron     Baselga  Altos Labs:     Arnold     Bishop     Barron  Lyell Immunopharma:     Bishop     Nelsen     Friedman  Mindstrong Health:     Epstein  ARCH Ventures:     deSouza     Aravanis     Flatley     Arnold     Gottlieb     Epstein  Bishop

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Name	<u>Illumina/GRAIL</u> Tenure and Role	Other Relevant Roles	Connections to Other Key Players
<u>rume</u>	Tenare and Rote	Other Relevant Roles	<ul> <li>Nelsen</li> <li>Foster</li> <li>Freidman</li> <li>Barron</li> <li>Baselga</li> <li>Golumbeski</li> <li>Rastetter</li> <li>Ho</li> </ul>
Mostafa Ronaghi	<ul> <li>Illumina:</li> <li>Senior Vice President and CTO (2008-2020)</li> <li>Senior Vice President of Entrepreneurial Development (2020-2021)</li> <li>GRAIL:</li> <li>Co-founder, Director (2020-GRAIL acquisition)</li> </ul>	Cellanome:  Co-founder, Executive Board Member	<u>Cellanome</u> : • Flatley
Robert Nelsen	GRAIL:  • Director (2016-GRAIL acquisition)	ARCH Ventures (investor in GRAIL Series A and B):  • Co-founder, Managing Director  National Resilience (backed by ARCH Ventures):  • Co-founder, Board Chair  Sana Biotechnology (backed by ARCH Ventures):  • Director  Lyell Immunopharma (backed by ARCH Ventures):  • Director	ARCH Ventures:  deSouza Aravanis Flatley Arnold Gottlieb Epstein Bishop Klausner Foster Freidman Barron Baselga Golumbeski

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Name	Illumina/GRAIL Tenure and Role	Other Relevant Roles	Connections to Other Key Players
		Sage Therapeutics:  • Director	<ul> <li>Rastetter</li> <li>Ho</li> <li>National Resilience:</li> <li>Arnold</li> <li>Gottlieb</li> <li>Foster</li> <li>Sana Biotechnology:</li> <li>Bishop</li> <li>Lyell Immunopharma:</li> <li>Bishop</li> <li>Klausner</li> <li>Friedman</li> </ul>
Kaye Foster	GRAIL:  • Director (2017-GRAIL acquisition)	ARCH Ventures (investor in GRAIL Series A and B):  • Venture Partner  Agios Pharmaceuticals (backed by ARCH Ventures):  • Director  National Resilience (backed by ARCH Ventures):  • Director	Sage Therapeutics:  Golumbeski  ARCH Ventures:  deSouza Aravanis Flatley Arnold Gottlieb Epstein Bishop Klausner Nelsen Freidman Barron Baselga Golumbeski

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<u>Name</u>	Illumina/GRAIL Tenure and Role	Other Relevant Roles	Connections to Other Key Players
Catherine Friedman	GRAIL:  • Board Chair (2017-GRAIL acquisition)	Lyell Immunopharma (backed by ARCH Ventures):  • Director  Revolution Healthcare Acquisition Corp. (backed by ARCH Ventures):  • Director	Rastetter Ho  Agios Pharmaceuticals: Ho  National Resilience: Arnold Gottlieb Nelsen  Lyell Immunopharma: Klausner Nelsen Bishop  ARCH Ventures: deSouza Aravanis Flatley Arnold Gottlieb Epstein Bishop Klausner Bishop Klausner Bishop Klausner Bishop Klausner Rastetter Barron Baselga Golumbeski Rastetter Ho
Hal V. Barron	GRAIL:	Altos Labs (backed by ARCH Ventures):	Altos Labs:

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Name	<u>Illumina/GRAIL</u> Tenure and Role	Other Relevant Roles	Connections to Other Key Players
	• Director (2018-GRAIL acquisition)	Co-founder, CEO, Co-Chair  Juno Therapeutics (backed by ARCH Ventures):     Non-Executive Director, Chair of Science & Technology Committee  Genentech:     Senior Vice President of Development, CMO	<ul> <li>Arnold</li> <li>Bishop</li> <li>Klausner</li> </ul> Juno Therapeutics: <ul> <li>Flatley</li> <li>Bishop</li> <li>Klausner</li> <li>Baselga</li> </ul> Genentech: <ul> <li>Kollu</li> </ul> ARCH Ventures: <ul> <li>deSouza</li> <li>Aravanis</li> <li>Flatley</li> <li>Arnold</li> <li>Gottlieb</li> <li>Epstein</li> <li>Bishop</li> <li>Klausner</li> <li>Nelsen</li> <li>Foster</li> <li>Friedman</li> <li>Baselga</li> <li>Golumbeski</li> <li>Rastetter</li> <li>Ho</li> </ul>

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Name	Illumina/GRAIL Tenure and Role	Other Relevant Roles	Connections to Other Key Players
José Baselga <sup>1</sup> George Golumbeski	Tenure and Role  GRAIL:  Chair Scientific Advisory Board (2016-2021)  Director (2017-2018)  GRAIL:  President, Head of Corporate Development, Director (2018-2019)	<ul> <li>Other Relevant Roles</li> <li>Juno Therapeutics (backed by ARCH Ventures):         <ul> <li>Chair of Clinical Advisory Board</li> </ul> </li> <li>ARCH Ventures (investor in GRAIL Series A and B):         <ul> <li>Partner</li> </ul> </li> <li>Sage Therapeutics (backed by ARCH Ventures):         <ul> <li>Director</li> </ul> </li> <li>MorphoSys AG (backed by ARCH Ventures):         <ul> <li>Deputy Chairman of the Supervisory Board</li> </ul> </li> </ul>	Juno Therapeutics:  Flatley Bishop Klausner Barron  ARCH Ventures: deSouza Aravanis Flatley Arnold Gottlieb Epstein Bishop Klausner Bishop Klausner Bishop Klausner Bishop Klausner Rateura
			Sage Therapeutics:  Nelsen
William H. Rastetter	Illumina:	Fate Therapeutics (backed by ARCH Ventures):  • Board Chair	Fate Therapeutics:  • Epstein

<sup>&</sup>lt;sup>1</sup> Dr. Baselga is deceased. In 2018, Dr. Baselga resigned from his role as CMO of Memorial Sloan Kettering Cancer Center amid reports that he had failed to disclose millions of dollars in payments from health care companies in dozens of research articles.

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<u>Name</u>	Illumina/GRAIL Tenure and Role	Other Relevant Roles	Connections to Other Key Players
	GRAIL:  CEO (2017)  Board Chair (2017-2018)		
Xiangmin (Min) Cui	GRAIL:  • Director (2017-GRAIL acquisition)	Decheng Capital (investor in GRAIL Series B):  • Founder, Managing Director	
Maykin Ho	GRAIL:  • Director (2019-GRAIL acquisition)	Neumore Therapeutics (backed by ARCH Ventures):  • Director  Agios Pharmaceuticals (backed by ARCH Ventures):  • Director	Agios Pharmaceuticals:  Foster  ARCH Ventures:  deSouza Aravanis Flatley Arnold Gottlieb Epstein Bishop Klausner Nelsen Foster Friedman Barron Baselga Golumbeski Rastetter

## Appendix B

#### **Lead Plaintiffs' Accounting Analysis**

#### A. Executive Summary

After presenting relevant background information concerning Illumina's investments in GRAIL, Lead Plaintiffs' analysis first evaluates the propriety of Illumina's accounting treatment of GRAIL as a deconsolidated variable interest entity ("VIE") under ASC 323-10-15-6. The analysis concludes that Illumina failed to properly consider dispositive indicators of "significant influence" and thereby improperly accounted for GRAIL under the equity accounting method. Illumina's improper treatment of GRAIL as a deconsolidated VIE created a disclosure void that enabled Illumina to not disclose Defendants' equity interests in Grail.

Lead Plaintiffs' analysis next quantifies the GRAIL equity interest that fall within the disclosure void created by Illumina's improper accounting for GRAIL as a deconsolidated VIE. Based on Lead Plaintiffs' review of Illumina and Grail's filings with the SEC as well as corporate records filed by GRAIL, Lead Plaintiffs' analysis concludes that 70,000,000 shares of GRAIL equity of unknown share class are not accounted for by public disclosures and fall within the disclosure void.

Last, Lead Plaintiffs calculate the value of the 70,000,000 shares as of the time of the announcement of the merger between GRAIL and Illumina, concluding that the 70,000,000 shares of unknown origin that fall within the disclosure void were valued at \$837,550,000.

#### **B.** Background Information

GRAIL was founded in January 2016 by Illumina and unrelated third-party investors. During that same month, GRAIL raised \$120 million from a Series A convertible preferred share offering, which included \$40 million from Illumina, and entered into a long-term supply agreement with Illumina that encompassed perpetual licenses, employees and discounted supply terms in exchange for 112.5 million shares of GRAIL's Class B common stock. For the three months ended April 3, 2016, Illumina disclosed it owned 90% of GRAIL's common stock and 52% of GRAIL's equity. Consistent with its common stock holdings, Illumina would absorb 90% of GRAIL's losses. Illumina accounted for its investment in GRAIL as a consolidated VIE.

On June 23, 2016, GRAIL issued 97.5 million shares of Series A-1 convertible preferred stock to Illumina in exchange for 97.5 million shares of GRAIL's Class B common stock. This transaction effectively reclassified the vast majority (86.7%) of the GRAIL Class B common stock received for the long-term supply agreement as convertible preferred stock. As of the end of the second quarter, July 3, 2016, Illumina disclosed it owned approximately 50% of GRAIL's common stock and continued to own 52% of GRAIL's equity. Consistent with its common stock holdings, Illumina would now absorb 50% of GRAIL's losses going forward. Illumina continued to account for its investment in GRAIL as a consolidated VIE.

Illumina's 10-K filing for the year ended January 1, 2017 disclosed no other changes to its investment in GRAIL. It continued to own 50% of GRAIL common stock, 52% of its equity, absorb 50% of its losses and continued to account for its investment in GRAIL as a consolidated VIE.

On February 28, 2017, GRAIL completed the initial close of its Series B, which raised over \$900 million. Concurrent with the financing, GRAIL repurchased 35 million shares of Series A preferred stock and 34 million of Series A-1 preferred stock from Illumina for an aggregate purchase price of \$278 million. As a result of this transaction, Illumina owned 5 million shares of Series A preferred stock and approximately 78 million Class A common shares. Illumina's ownership in GRAIL was reduced from approximately 52% to approximately 19%. At this time, Illumina no longer had a controlling financial interest in GRAIL and it deconsolidated GRAIL's financial statements and recorded its investment in GRAIL based upon its cost of \$159 million under the "cost method" accounting treatment.

As a result of deconsolidating GRAIL, Illumina's required reporting and disclosures of its investment in GRAIL were substantially reduced. Illumina's 10-Q and 10-K filings for 2017, 2018 and 2019 make no meaningful disclosures about Illumina's investment in GRAIL.

The next public substantive SEC filings concerning GRAIL were GRAIL's initial public offering filings during August and September 2020, with the final S-1

filing of September 9, 2020 marking the last of GRAIL's disclosures related to its planned initial public offering.

Illumina significantly increased the amount of information it disclosed about GRAIL commencing with its Agreement and Plan of Merger filing on September 20, 2020 with the SEC, and began including additional information concerning GRAIL in its 10-Q and 10-K fillings, commencing with the quarter ended September 27, 2020.

The combination of these GRAIL and Illumina SEC filings provided some additional information about GRAIL's ownership interests; however, that information was limited due to the Jumpstart Our Business Startups Act of 2012 (JOBS Act), which permitted reporting of only two years of audited financial statements and reduced disclosures regarding executive compensation.

On August 18, 2021, Illumina acquired GRAIL for cash and other consideration valued at more than \$8 billion and began accounting for GRAIL as a wholly owned subsidiary. Approximately eighteen months later, Illumina recognized a \$3.9 billion goodwill impairment on the GRAIL acquisition, which was reported in Illumina's 10-K filing for the year ended January 1, 2023. Less than a year after that, on December 17, 2023, Illumina announced its decision to divest GRAIL.

### C. Illumina's Reporting of Its Ownership Interest in GRAIL Violated GAAP

Lead Plaintiffs' analysis establishes that Illumina violated ASC 323 and ASC 323-10-15-6 when it improperly accounted for its investment in GRAIL using the fair value method. Illumina incorrectly deemed that it did not have the ability to exercise significant influence over GRAIL's operating and financial policies, despite the fact GRAIL was dependent upon access to Illumina's resources to operate its business, and evidence of Illumina's ability to exercise significant influence under the ASC 323-10-15-6 proscribed indicators. Illumina, based upon its ability to exercise significant influence over GRAIL, should have accounted for its GRAIL investment using the equity method. Finally, because Illumina failed to use the equity method, it had the ability to omit disclosures about related parties that were required under the equity method.

### D. ASC 323-10-15-6 Required Illumina to Use Cost Method Accounting for GRAIL

Lead Plaintiffs' analysis entailed review of applicable accounting standards for application of the equity method and the fair value method of accounting for investments, including Accounting Standards Codification ("ASC") 323 on equity method accounting, and ASC 323-10-15-6, which sets forth indicators of significant influence. The review also considered Ernst and Young ("EY") and Price Waterhouse Coopers' ("PwC") guidance on accounting for equity method

investments and joint ventures and SEC filings of comparable companies that accounted for investments with less than 20% ownership using the equity method. EY and PwC served as auditors for Illumina and GRAIL, respectively.

The analysis focused on Illumina's decision to use the fair value (cost) method, and not the alternative equity method, to account for its investment in GRAIL after Illumina's ownership fell below 20%. The accounting standards state that an investor (Illumina) should account for its investment in an investee (GRAIL) using the equity method if the investor's ownership of the investee is between 50% and 20%, while the investor should use the fair value (cost) method to account for investments where its ownership of the investee is below 20%.

The accounting standards allow for circumstances where the equity method is not to be used when the ownership is between 50% and 20%, and where the equity method is to be used when the ownership is less than 20%. If predominant evidence exists that an investor with 50% to 20% ownership is unable to exercise significant influence, then the equity method cannot be used. If the ability to exercise significant influence can be demonstrated, then an investor with less than 20% must use the equity method to account for its investment.

Illumina's accounting for its investment in GRAIL was in compliance with ASC-323-10-15-6 until its ownership interest fell below 20% on February 28, 2017,

which lowered Illumina's ownership of GRAIL from 52% to 19% according to Illumina's public disclosures.

The applicable accounting standards (ASC 323-10-15-6) required Illumina to address the issue of whether it had the ability to exercise significant influence over GRAIL to determine how to account for its GRAIL investment. If an investor can exercise significant influence and owns between 50% to 20% of the investee, it must use the equity method. If an investor owns less than 20%, but it can be demonstrated that it exercises significant influence over the investee, then the investor must also use the equity method. The equity method requires Illumina insiders to make disclosures about their financial interests and transactions involving GRAIL that the fair value method does not.

ASC 323-10-15-6 provides a list of indicators that should be evaluated to determine whether an investor has the ability to exercise significant influence. Those indicators include:

- Representation on the board of directors
- Participation in policy-making decisions
- Material intra-entity transactions
- Interchange of managerial personnel
- Technological dependency
- Extent of ownership by an investor in relationship to the concentration of other shareholders

EY's guide on equity method accounting notes "A presumption exists that when an investor owns less than 20% of the voting stock of an investee, the investor does not have significant influence over the investee. In this situation, the investor considers whether the facts and circumstances demonstrate that it has significant influence over the operating and financial policies of an investee." Under ASC 323-10-15-6, if the investor does have significant influence, it must use the equity method to account for the investee, otherwise it must use the fair value (cost) accounting method.

The determination of whether Illumina demonstrated it has significant influence over GRAIL must consider the facts and circumstances that are unique to this situation. Specifically, GRAIL's substantial dependence upon Illumina's resources to conduct its business operations, the fact that the Executive Chairman of Illumina (the strategic investor that spun out GRAIL) had observer rights on GRAIL's board of directors, the material inter-entity transactions that were created by Illumina's long-term supply agreement with GRAIL, and the technological dependency created by GRAIL's continuing reliance upon Illumina's proprietary products, supplies and intellectual property.

#### E. Illumina Failed to Comply With ASC 323-10-15-6

Based upon Lead Plaintiffs' analysis, Illumina did not properly report its investment in GRAIL from 2017 through 2021, when it accounted for GRAIL as a

fair value investment. That accounting treatment was not in compliance with applicable accounting standards as consideration of the relevant factors from ASC 323-10-15-6 demonstrates that Illumina had the ability to exercise significant influence over GRAIL throughout this period. As such, Illumina should have accounted for its GRAIL holdings as an equity method investment. In 2022, this issue was no longer relevant as Illumina acquired 100% of GRAIL's stock, discontinued accounting for it as an investment, and reported it as a wholly-owned subsidiary.

## 1. Numerous Facts Confirm that Illumina Exerted "Significant Influence" Over GRAIL

Lead Plaintiffs' finding of improper accounting is predicated upon the level of GRAIL's dependence upon Illumina for critical aspects of its operations and financing. This extraordinary dependence has existed from GRAIL's inception. As noted in Illumina's 10-Q from April 3, 2016:

Additionally, the Company and GRAIL executed a long-term supply agreement in which the Company contributed certain perpetual licenses, employees, and discounted supply terms in exchange for 112.5 million shares of GRAIL's Class B Common Stock.

Illumina, Form 10-Q for the period ended April 3, 2016 (May 9, 2016), at 12.

GRAIL's founding relied almost entirely upon Illumina's intellectual property, Illumina employees with specialized technical knowledge, access to Illumina's research and development resources, access to Illumina's proprietary products and

supplies, assignment of key joint development agreements with third parties (including assays and data), and access to confidential information.

As explained in more detail below, GRAIL's principal product, Galleri, is entirely dependent on Illumina technology, which illustrates Illumina's significant influence over GRAIL's operations and finances. The significant influence exists irrespective of the Illumina's ownership interest in GRAIL. Under ASC 323-10-15-6, extensive corporate dependency cannot be mitigated by select efforts to create an impression of investee independence.

Once Illumina's ownership in GRAIL fell to 19% on February 28, 2017, Illumina noted that it no longer had a controlling financial interest in GRAIL, withdrew from its board position, amended its long-term supply agreement (with certain perpetual licenses), and accounted for GRAIL using the fair value (cost) accounting method for investments. Although Illumina did not explicitly disclose that it no longer had significant influence over GRAIL, it indirectly disclosed that it reached this determination in its 2017 10-K filing.

The equity method is used to account for investments in which we have the ability to exercise significant influence, but not control, over the investee. Such investments are recorded within other assets, and the share of net income or losses of equity investments is recognized on a one quarter lag in other income (expense), net.

Illumina, Form 10-K for the period ended December 31, 2017 (Feb. 13, 2018), at 49.

In addition to the significant influence Illumina is able to exercise due to GRAIL's dependence upon Illumina's resources for GRAIL to operate, the ASC 323-10-15-6 list of indictors of significant influence further support the finding of significant influence. Lead Plaintiffs' analysis also relied on EY and PwC guidance on accounting for equity method investments and joint ventures, which provide additional detail on the ASC's list of indicators of significant control, in making this determination.

## 2. Board Observer Rights and Membership Support Illumina's "Significant Influence" Over GRAIL

The EY and PwC guides on accounting for equity method investments and joint ventures cite examples of how to address board observer rights in determining significant influence. The EY guide uses the following example:

When evaluating all facts and circumstances to determine whether an investor has the ability to exercise significant influence over an investee, how should the ability to appoint an observer seat on the board be considered?

As discussed in ASC 323-10-15-6, representation on the board of directors may indicate that an investor has the ability to exercise significant influence over an investee's operating and financial policies. In some cases, an investor may negotiate for an "observer" seat on the board of directors that allows the investor to observe board meetings but does not give the investor the ability to vote. Judgment will be necessary based upon the facts and circumstances in determining whether the investor has significant influence when it has a board observer seat. Factors to be considered in making this judgment include:

- Background information about how the investor obtained an "observer" seat rather than a voting seat
- Role of the observer seat, including whether the board observer has an ability to actively participate in discussions
- Observer rights on board committees
- Size of the board (see Question 3.1 for more guidance) and size of the investor's holding relative to other investors
- Any unique expertise or role that the investor holds relative to other board members, which may indicate a higher degree of influence

All facts and circumstances, including other indicators referenced in ASC 323-10-15-6, should be considered when determining whether an investor has significant influence.

Ernst & Young, Financial reporting developments, A comprehensive guide, Equity method investments and joint ventures (July 2023), at 22.

In this instance, the Illumina board observer was Jay Flatley, its Executive Chairman, the highest-ranking board member at Illumina, the Company upon which GRAIL is dependent upon to operate. Mr. Flatley was CEO of Illumina from October 1999 through July 2016, which encompassed the period during the development of GRAIL's technology and the creation of GRAIL as a separate entity. Mr. Flatley's past history with GRAIL, his current position at Illumina, and his involvement at the highest level of GRAIL's decision-making demonstrates Illumina's significant influence.

The significant role that Mr. Flatley played in GRAIL's operations is disclosed in the GRAIL S-1 of September 9, 2020 (at F-38), which notes that he was

Chairman of GRAIL's board of directors from January 2016 to February 2017. It also discloses that Mr. Flatley was then the executive chairman of the board of directors of Illumina, and notes that Illumina is a major supplier of the GRAIL's reagents and capital equipment.

Based upon these factors, Illumina's board observer role meets ASC 323-10-15-6 criteria of significant influence. While Illumina disclosed that it relinquished its GRAIL board seat in its 2017 10-K, it failed to contemporaneously disclose that it was given board observer rights, or the fact that it filled the board observer position with its Executive Chairman.

In addition to the significant influence exercised by Mr. Flatley in his board observer role, Illumina further expanded its significant influence over GRAIL in May 2020, the period leading up to GRAIL's aborted initial public offering and subsequent acquisition by Illumina. As noted in the GRAIL S-1 of September 9. 2020:

Beginning May 4, 2020, Mostafa Ronaghi has served as a member of the Company's board of directors. Mr. Ronaghi was also the Chief Technology Officer of Illumina, Inc. (Illumina) through May 2020 and is currently the Senior Vice President of Entrepreneurial Development of Illumina. Illumina is a principal owner of the Company and is a major supplier of the Company's reagents and capital equipment.

GRAIL, Form S-1 (Sept. 9, 2020), at F-65.

The addition of Mostafa Ronaghi, Illumina's Chief Technology Officer and Senior Vice President of Entrepreneurial Development, to GRAIL's board of

directors, provides further corroborating evidence that supports Lead Plaintiffs' determination of Illumina's ability to exercise significant influence over GRAIL, which required Illumina to report its investment in GRAIL using equity method accounting. In this instance, Illumina is not exercising significant influence solely through board observer rights, but also through Illumina's actual representation on GRAIL's board of directors, which ASC 323-10-15-6 cites as one of the indicators of significant influence. As a director appointed by Illumina, Ronaghi had the ability to vote on critical corporate decisions surrounding the merger, further establishing Illumina's significant influence over GRAIL.

## 3. Material Intra-Entity Transactions Support Illumina's "Significant Influence" Over GRAIL

The PwC guide on equity method accounting provides guidance (which is not included in the EY guide) on the determination of significant influence derived from material intra-entity transactions.

However, the sale or purchase of highly specialized goods or services may provide the investor with significant influence. Consideration should be given to the investee's ability to source goods or services from alternative providers, considering any significant cost barriers associated with such alternatives.

PricewaterhouseCoopers, *Equity method investments and joint ventures* (partially updated May 2024), at 2-10.

Many of GRAIL's critical operating functions rely upon access to Illumina's proprietary products where no alternative supplier exists. The following are excerpts

from GRAIL LLC Information Statement (Exhibit 99.1), dated May 6, 2024, related to its Registration Statement for Illumina's divestiture of GRAIL:

We rely on Illumina as a sole supplier for our next-generation sequencers and associated reagents, Madison Industries ("Madison") (who acquired our blood collection tube manufacturer Streck, Inc. in 2023) as a sole supplier of our blood collection tubes, and Twist Bioscience Corporation ("Twist") as a sole supplier of our DNA panels. Additionally, we rely on a limited number of suppliers for some of our laboratory instruments and reagents, and we may not be able to immediately find replacements if necessary.

GRAIL, Form 10, Information Statement, Ex. 99-1 (May 6, 2024), at 11.

Our current suppliers, including Illumina, Madison, or Twist, may also discontinue or substantially change the specification of products that we utilize or intend to utilize in our products and future products. While we believe other suppliers exist that are capable of supplying and servicing the equipment and materials necessary for our products and laboratory operations, including certain instruments, components, consumables, and reagents, qualifying, contracting with, validating, and transitioning to any such new suppliers could temporarily result in interruptions in or otherwise affect our ability to manufacture and commercialize products or the performance specifications of our laboratory operations and sample processing or, if we receive FDA authorization for our current or future products, could require that we revalidate such products or submit such changes for regulatory authorization by the FDA.

GRAIL, Form 10, Information Statement, Ex. 99-1 (May 6, 2024), at 46.

The Illumina long-term supply agreement does not give GRAIL perpetual access to these products and supplies, require Illumina to continue to produce them, or provide exclusive rights to any Illumina products or supplies. This supply arrangement, in conjunction with GRAIL's substantial dependency on Illumina's

products, supplies, and research and development resources, meets ASC 323-10-15-6's criteria of significant influence.

### 4. Technological Dependency Supports Illumina's "Significant Influence" Over GRAIL

The PwC guide on equity method accounting provides guidance (which is not included in the EY guide) on the determination of significant influence derived from technological dependency.

Additionally, the nature of the technology should be considered. For instance, a time-limited license rather than a perpetual one gives the investor the discretion to choose not to renew the license and may serve as an indication that the investor has significant influence compared to a scenario in which the investee holds a perpetual license for the same technology.

PricewaterhouseCoopers, *Equity method investments and joint ventures* (partially updated May 2024), at 2-10.

GRAIL was founded as a spinoff of Illumina's technology, its operations remain highly dependent upon Illumina's technology, and the development of GRAIL's own intellectual property involves Illumina's technology. The following are excerpts from GRAIL LLC Information Statement (Exhibit 99.1), dated May 6, 2024 (page 80), related to its Registration Statement for Illumina's divestiture of GRAIL:

We have agreements with Illumina and license agreements with others that provide rights to certain technologies related to assays used in our products. We may need to obtain additional licenses from others to advance our research or allow commercialization of our products or technology, either globally or in certain geographies, without infringing

the intellectual property of third parties. It is possible that we may be unable to obtain such additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology or to develop or license replacement technology, any of which may not be feasible on a technical or commercial basis. If we are unable to obtain or maintain applicable licenses, we may be unable to commercialize certain of our products, either globally or in certain geographies, or continue to utilize our technology, which could harm our business, financial condition, results of operations, and growth prospects.

GRAIL, Form 10, Information Statement, Ex. 99-1 (May 6, 2024), at 80.

In addition, the PwC guide highlights that, in evaluating technological dependency, the existence of a perpetual license should be considered as a mitigating factor of significant influence.

Illumina's 2016 10-K disclosed that Illumina's long-term supply agreement provided GRAIL with certain perpetual licenses. The same disclosure in Illumina's 2017 10-K omitted the reference to perpetual licenses. No publicly available copy of the original supply agreement exists. The amended copy of the supply agreement contains no specifically identified perpetual licenses. As such, it appears that, as Illumina reduced its ownership of GRAIL to 19%, it took steps (eliminating the perpetual licenses) to increase its ability to exercise significant influence.

Based upon these facts and circumstances, GRAIL's dependency on Illumina technology meets ASC 323-10-15-6 criteria of significant influence.

## 5. GRAIL's Categorization of Illumina as a Related Party Supports Illumina's "Significant Influence" Over GRAIL

Finally, GRAIL treated Illumina as a related party and made disclosures required of related party transactions. The accounting rules that govern the determination of related parties and related party transactions are set forth in ASC 850-10-20, which like the ASC 323 rules for equity method accounting, require the determination of control and significant influence. Specifically, ASC 850-10-20 includes the following criteria in the definition of related parties:

- a. Affiliates of the entity
- b. Entities for which investments in their equity securities would be required, absent the election of the fair value option under the Fair Value Option Subsection of Section 825-10-15, to be accounted for by the equity method by the investing entity
- c. Trusts for the benefit of employees, such as pension and profitsharing trusts that are managed by or under the trusteeship of management
- d. Principal owners of the entity and members of their immediate families
- e. Management of the entity and members of their immediate families
- f. Other parties with which the entity may deal if one party controls or can significantly influence the management or operating policies of the other to an extent that one of the transacting parties might be prevented from fully pursuing its own separate interests
- g. Other parties that can significantly influence the management or operating policies of the transacting parties or that have an ownership interest in one of the transacting parties and can

significantly influence the other to an extent that one or more of the transacting parties might be prevented from fully pursuing its own separate interests.

ASC 850-10-20.

The definition of principal owner, as set forth in ASC 850-10-20, is "Owners of record or known beneficial owners of more than 10% of the voting interest of the entity."

Since Illumina owns more than 10% of GRAIL, it meets the definition of a principal owner. However, GRAIL's related party disclosures in its S-1 filing of September 9, 2020 do not reference Illumina's ownership interest, but focus on the aspects of the business relationship where Illumina has the ability to exercise significant influence over GRAIL.

Specifically, the GRAIL related party disclosures note Jay Flatley's role as Chairman of GRAIL's board of directors from January 2016 to February 2017 (GRAIL, Form S-1 (Sept. 9, 2020), at F-38), the fact that Illumina is a major supplier of GRAIL's reagents and capital equipment (*id.*), Illumina's supply agreement with GRAIL (*id.*), and the addition of Mostafa Ronaghi, Illumina's Chief Technology Officer and Senior Vice President of Entrepreneurial Development, to GRAIL's board of directors (*id.* at F-65).

As previously noted, the GRAIL S-1 dated September 9, 2020 makes disclosures, outside of its related party footnotes, about its supply agreement with Illumina that describe Illumina's ability to use the supply agreement to exercise

significant influence over GRAIL. Therefore, the treatment of Illumina as a related party and the disclosures within the GRAIL S-1 regarding its business relationship with and dependency on Illumina support Lead Plaintiffs' findings of Illumina's ability to exercise significant influence over GRAIL's finances and operations.

## 6. Other Public Companies' Accounting of Similar Investor and Investee Relationships Corroborate that Illumina Violated GAAP

Other public companies' use of the equity method of accounting for investments where an investor had less than a 20% ownership interest in an investee but where the investee was highly dependent upon the investor further support that Illumina's accounting treatment of GRAIL was improper. For example, Coca-Cola's relationship with its bottlers and other beverage companies that are dependent upon its formula, distribution network, or share a similar dependency between investor and investee as Illumina and GRAIL did here. The Coca-Cola 2023 10-K has the following disclosure of its equity method investments:

The Company's equity method investments include, but are not limited to, our ownership interests in CCEP; Monster; AC Bebidas, S. de R.L. de C.V.; Coca-Cola FEMSA, S.A.B. de C.V.; Coca-Cola HBC AG; and Coca-Cola Bottlers Japan Holdings Inc. As of December 31, 2023, we owned 19%, 20%, 20%, 28%, 21% and 18%, respectively, of these companies' outstanding shares.

The Coca-Cola Company, Form 10-K for the fiscal year ended December 31, 2023 (Feb. 20, 2024), at 84.

Two of the six equity method investments had ownership interests less than 20%. Moreover, Coca-Cola did not use the fair value (cost) method of accounting

for any of its investments. It thus appears that Coca-Cola determined that it can exercise significant influence over every one of its investments despite owning less than 20% of at least two of those investees.

Similarly, Exxon/Mobil's relationship with other oil companies that utilize its drilling, refining and distribution resources, represents a business relationship that has a similar dependency between investor and investee as Illumina and GRAIL did here. The Exxon/Mobil 2023 10-K discloses that it has 35 investments that it accounts for using the equity method. There were three equity method investments where Exxon/Mobil's ownership interest was 10% or less, including one where it owned 7%.

Lead Plaintiffs' analysis supports the conclusion that comparable companies, defined as investors with highly dependent investees, use the equity method to account for investments with less than a 20% ownership, as the ability to exercise significant influence goes hand in hand with high levels of dependency.

#### 7. All Relevant Factors Support a Finding of "Significant Influence"

The relevant accounting standards and PwC's guidance note that all relevant factors should be considered when determining how to account for investments with 20% or less ownership. In this case, there are several factors that are unique to Illumina's investment in GRAIL. In 2016, GRAIL was spun off from Illumina,

which was done to accelerate the development of a multi-cancer early detection test.

The initial decision on the FTC antitrust case against Illumina noted:

GRAIL required a substantial amount of capital to conduct its foundational clinical trials. [¶37]. Illumina decided to bring in outside investors to spread the risk while ensuring that GRAIL had the capital it needed to move from concept through clinical trials. [¶38]. In February 2017, Illumina completed a capital raising campaign in connection with which Illumina reduced its stake in GRAIL to less than 20%. [¶40]. Illumina thereafter reduced its equity stake in GRAIL to approximately 12% of GRAIL's outstanding shares on a fully diluted basis. *Id*.

Initial Decision, *In the Matter of Illumina, Inc. & GRAIL, Inc.*, Docket No. 9401 (Sept. 9, 2022).

In February 2017, GRAIL used \$278 million of the \$900 million of the capital it raised to repurchase shares from Illumina to bring Illumina's ownership down to exactly 19%, which is just below the 20% threshold for equity method accounting. Lead Plaintiffs' research could find no other examples where a strategic investor of a high profile biotech start-up diverted hundreds of millions of dollars of capital from technology development to a share repurchase. In this case, the transaction occurred roughly a year after GRAIL's founding, when GRAIL was rapidly ramping up its research and development efforts and in need of funds.

Moreover, evidence in Illumina's 2017 10-K supports the conclusion that the \$278 million of share repurchase proceeds were not needed or used to meet an Illumina funding need, as no such funding need existed. During 2017, Illumina generated \$875 million of operating cash flow from \$2.75 billion in revenue. As a

result of the share repurchase, Illumina gave up 14% of its equity ownership in GRAIL, one of the most heralded start-ups, in exchange for \$278 million of cash it did not need. As a reference point, the 14% equity ownership Illumina sold back to GRAIL in 2017 would have been worth approximately \$1.1 billion five years later when Illumina acquired GRAIL in 2022.

#### Lead Plaintiffs' GRAIL Equity Analysis

By treating and reporting its ownership interest in GRAIL on a cost method accounting basis, Illumina was ostensibly able to avoid publicly disclosing certain information concerning executive compensation and related party transactions. Specifically, as a result of deconsolidating GRAIL, Illumina's required reporting and disclosures of its investment in GRAIL were substantially reduced and Illumina's 10-Q and 10-K filings for 2017, 2018 and 2019 make no meaningful disclosures about Illumina's investment in GRAIL.

Not only did Illumina violate GAAP when reporting its ownership interests in GRAIL and avoid public disclosure of insider interests, Illumina also failed to disclose or publicly account for a substantial portion of GRAIL equity valued at approximately \$835 million.

Specifically, the following presents detailed information on the GRAIL equity ownership interests supporting this figure based upon the Illumina and Grail disclosures in the relevant SEC filings and the GRAIL Certificates of Incorporation

obtained by Lead Plaintiffs. The GRAIL capitalization tables reflect (1) GRAIL's undiluted equity, including equity interests that were not disclosed by GRAIL or Illumina in their SEC filings ("undisclosed equity interests"), and (2) GRAIL's fully diluted equity, including undisclosed equity interests.

GRAIL's fully diluted equity is the total common shares of the company counting not only shares that are currently issued and outstanding but also shares that could be claimed through the conversion of convertible preferred stock or through the exercise of outstanding options and warrants. The calculation of "fully diluted" shares for a company is generally made so that an individual stock owner can determine their "fully diluted" ownership percentage, which is the number of common shares owned by that owner divided by the total fully diluted shares. The fully diluted calculation is necessary here to account for Illumina's May 9, 2016 10-Q (for the quarterly period ended April 3, 2016) disclosure that it had a "52% equity ownership interest in GRAIL . . . [o]n a fully diluted basis" and also allows the calculation of GRAIL's total diluted equity.

#### F. GRAIL Equity as of April 3, 2016 – Presented on an Undiluted Basis

The following is the GRAIL capitalization table as of April 3, 2016 derived from Illumina and GRAIL's public disclosures concerning GRAIL's equity as reported in their respective SEC filings and as informed by Lead Plaintiffs' review of GRAIL Certificates of Incorporation.

	Grail	Equity as of April 3, 20	16 - U	Indiluted			
Shareholder	Class A & B Common	Series A Preferred		Undisclosed		Total	Common Stock Percentage
Common Stock:							
Illumina	122,500,000 (a)	-		-		122,500,000	90.0%
Series A Investors	-	-		-		-	0.0%
Undisclosed	13,611,111 (b)				_	13,611,111	10.0%
Total	136,111,111				_	136,111,111	100.0%
Preferred Stock:							
Illumina	-	40,000,000	(c)	-		40,000,000	-
Series A Investors		80,000,000	(c)	-		80,000,000	
		120,000,000			_	120,000,000	
Undisclosed:							
Undisclosed				56,388,889	(d)	56,388,889	
				56,388,889		56,388,889	

The attached exhibits contain the source SEC filings and GRAIL Certificates of Incorporation. The following provides additional details about how those disclosures were used to derive the GRAIL capitalization table.

- The GRAIL S-1/A of September 17, 2020 disclosed that Illumina a. received 1,000 shares of GRAIL's Class B common shares in connection with GRAIL's founding on September 11, 2015. The GRAIL Amended and Restated Certificate of Incorporation of GRAIL, Inc., as of January 8, 2016, disclosed that GRAIL had undertaken a share split whereby each holder of Class B common shares would receive 122,500 shares of Class B common stock for each share of such stock held on or before January 8, 2016. The GRAIL S-1/A of September 17, 2020 disclosed that GRAIL issued 10,000,000 shares Class A common stock on January 11, 2016 to Illumina upon the conversion of 10,000,000 shares of Illumina's Class B common stock. There were no other equity transactions reported by Illumina or GRAIL through April 3, 2016, the end of the first quarter. Therefore, as of April 3, 2016, Illumina held 10,000,000 shares of GRAIL Class A common stock and 112,500,000 shares of GRAIL Class B common stock, for a total of 122,500,000 shares of common stock.
- b. Illumina disclosed in its April 3, 2016 10-Q that it owned 90% of GRAIL's common stock. The total shares of GRAIL common stock

- can be determined by dividing the 122,500,000 shares owned by Illumina by the 90% of GRAIL's total common shares. That calculation (122,500,000 ÷ 90%) confirms GRAIL's total undiluted common shares (Illumina + undisclosed common stock investors) equals 136,111,111. Therefore, the common shares held by unidentified investors equals 13,611,111.
- c. Illumina disclosed in its April 3, 2016 10-Q that GRAIL had issued a Series A convertible preferred stock offering that raised \$120 million. Illumina funded \$40 million and Series A investors funded the remaining \$80 million. There were no disclosures of the total number of shares issued. GRAIL's S-1/A of September 17, 2020 discloses that its \$120 million Series A convertible preferred offering issued 120,000,000 shares at the price of \$1.00 per share. Therefore, Illumina had 40,000,000 shares of Series A convertible preferred stock and the Series A investors had the remaining 80,000,000 shares.
- d. The estimated remaining 56,388,889 of undisclosed GRAIL shares (70,000,000 estimated total undisclosed GRAIL shares 13,611,111 undisclosed GRAIL common shares) is addressed below in GRAIL's fully diluted equity calculations.

#### G. GRAIL Equity as of April 3, 2016 – Presented on a Fully Diluted Basis

The following is the GRAIL fully diluted capitalization table as of April 3, 2016 derived from Illumina and GRAIL's public disclosures concerning GRAIL's equity as reported in their respective SEC filings and as informed by Lead Plaintiffs' review of GRAIL's January 8, 2016 Amended and Restated Certificate of Incorporation.

	Grail Eq	uity as of April 3, 2016	- Fully	Undiluted			
Shareholder	Class A & B Common	Series A Preferred	_	Undisclosed		Total	Common Stock Percentage
Common Stock:							
Illumina	122,500,000	40,000,000	(e)	-		162,500,000	52.0%
Series A Investors	-	80,000,000	(e)	-		80,000,000	25.6%
Undisclosed	13,611,111		_	56,388,889	(f)	70,000,000	22.4%
Total	136,111,111	120,000,000	_	56,388,889	_	312,500,000	100.0%
Preferred Stock:							
Illumina	-	-		-		-	-
Series A Investors	<u> </u>		_				
			_		_		
Undisclosed:							
Series A Investors	<u></u>		_				
			_				

The attached exhibits contain the source SEC filings and GRAIL Certificates of Incorporation. The following provides additional details about how those disclosures were used to derive the GRAIL fully diluted capitalization table. Note that the fully-diluted calculation converts all the GRAIL equity interests, including those of undisclosed origin, into GRAIL common shares.

The fully diluted calculation presented below demonstrates the existence of 70,000,000 shares of GRAIL equity comprised of Class A or B common stock (13,611,111) and equity interests of unknown origin (56,388,889).

e. Illumina's disclosures in its April 3, 2016 10-Q did not identify the conversion rate for the GRAIL Series A convertible preferred shares into GRAIL Class A common shares that would occur upon a change of control. However, GRAIL's S-1/A of September 17, 2020 (page F-27) disclosed the conversion rate is 1:1. Thus, for the calculation of GRAIL's fully diluted equity, the \$120 million Series A convertible preferred shares would convert into 120 million of GRAIL's Class A common shares. Illumina's fully diluted shares in GRAIL's equity include the 122,500,000 of GRAIL common shares owned by Illumina and the 40,000,000 shares of Series A convertible preferred stock that

would convert into 40,000,000 shares of common stock, which equals total fully diluted shares of 162,500,000. Illumina's April 3, 2016 10-Q disclosed that it owned 52% of GRAIL's fully diluted shares as of that date. That means the total fully diluted shares of GRAIL common stock can be derived by dividing the 162,500,000 of shares by Illumina's 52% ownership. That calculation (162,500,000 ÷ 52%) confirms GRAIL's fully diluted common shares total 312,500,000.

f. While GRAIL's fully diluted shares totaled 312,500,000, the number of undisclosed shares must still be calculated by subtracting Illumina's 162,500,000 fully diluted shares and the 80,000,000 Series A shares. That calculation (312,500,000 – 162,500,000 – 80,000,000) confirms that GRAIL's undisclosed fully diluted common shares total 70,000,000, which represents approximately 22.4% of GRAIL's fully diluted common shares. The above analysis of GRAIL's common stock estimated that 13,611,111 of GRAIL's common stock was undisclosed—i.e., these shares existed but were not publicly reported or accounted for in Illumina or GRAIL's public SEC filings. Those 13,611,111 common shares must be subtracted from GRAIL's 70,000,000 estimated total undisclosed shares to calculate GRAIL's remaining 56,388,889 (70,000,000 – 13,611,111) shares of undisclosed equity interests.

#### H. Analysis of Undisclosed GRAIL Equity

Lead Plaintiffs conducted an extensive review of publicly available information and could find only one disclosure that identified the existence or ownership of any of the estimated 70,000,000 equity interests that existed as of April 3, 2016.

Specifically, Lead Plaintiffs investigated whether the GRAIL 2016 Equity Incentive Plan ("the Plan"), in its original form, could account for any, some, or all of the undisclosed 70,000,000 equity interests. Lead Plaintiffs could not identify any publicly available version of the Plan. The Plan was amended on February 6,

2017, February 27, 2017, September 18, 2019, and May 7, 2020. The earliest version of the Plan that is publicly available is May 7, 2020 and it provides no information on the quantitative terms and conditions of the original plan as of January 2016.

Lead Plaintiffs identified only one employee incentive plan award granted under the 2016 Equity Incentive Plan—the Initial Time Base Equity Award of 5,714,286 Class B Common Stock shares to Jeffery T. Huber. The accelerated vesting of this award is documented in the October 12, 2017 Transition Agreement between Mr. Huber and GRAIL. This grant is included in Note 10 Stock Incentive Awards to GRAIL's December 31, 2019 and 2018 Audited Financial Statements contained in GRAIL's Form S-1/A Registration of Securities amendment filed on September 17, 2020. However, there were no financial terms disclosed to allow for dilution to be calculated.

Lead Plaintiffs identified no other publicly available information for the original Plan that was in effect as of April 3, 2016 or any disclosures of shares available under the various types of equity incentives under the original Plan that account for the undisclosed equity identified above.

#### I. Value of Undisclosed GRAIL Equity Interests

Lead Plaintiffs calculated the value of the undisclosed equity interests as \$837,550,000 as of the date the GRAIL acquisition was announced on September 21, 2020, based upon Illumina's 2021 10-K as follows.

			Rounded to 3 Decimal Places
$\mathbf{A}$	Cash Consideration		\$2,862,000,000
$\mathbf{B}$	Stock Consideration		\$4,975,000,000
C	Contingent Consideration		\$757,000,000
$\mathbf{D}$	Total Relevant Consideration		\$8,594,000,000
E F G	Fully diluted number of shares of GRAIL Stock Less owned by Illumina (E*12%) Owned by other shareholders (E-F)	12%	816,218,586 (97,946,230) 718,272,356
$\mathbf{H}$	The per share Consideration of Grail Stock (A/C)		\$11.97
I	Missing Grail Shares		70,000,000
$\mathbf{J}$	Total Value of Missing Shares (H*I)		\$837,550,000

The portion the value of the undisclosed equity attributable to the Grail common shares with undisclosed ownership is \$83,755,000 and the value attributable to the undisclosed equity interests is \$753,795,000.

### Exhibit 1

**GRAIL Common Shares** 

References (a) and (b)

Source: GRAIL, Amendment No. to Form S-1 (Sept. 17, 2020) at II-2.

Reference (a) that Illumina received 1,000 founding shares of Grail Class B common shares and converted 10,000,000 of its Class B common shares into Class A common shares.

Since September 11, 2015, the registrant has sold the following securities without registration under the Securities Act of 1933:

(a) certain shares of our capital stock to Illumina, Inc. in the following transactions: on September 11, 2015, we issued 1,000 shares of Class B common stock at par value, in connection with our formation; on January 11, 2016, we issued 10,000,000 shares of Class A common stock upon the conversion of 10,000,000 shares of Class B common stock; on June 23, 2016 we issued 97,500,000 shares of Series A-1 redeemable convertible preferred stock upon the conversion of 97,500,000 shares of Class B common stock; and on February 27, 2017 we issued 78,105,879 shares of Class A common stock upon conversion of 78,105,879 shares of Class B common stock;

Source: Amended and Restated Certificate of Incorporation of GRAIL, Inc. (Jan. 8, 2020) at 1-2.

Reference (a) that Illumina received 122,500,000 GRAIL shares from a stock split.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is 594,000,000 shares, of which the Corporation shall have authority to issue (i) 297,000,000 shares of Class A Common Stock, each having a par value of \$0.001 ("Class A Common Stock"), (ii) 172,000,000 shares of Class B Common Stock, each having a par value of \$0.001 ("Class B Common Stock," and together with the Class A Common Stock, "Common Stock"), and (ii) 125,000,000 shares of Preferred Stock, each having a par value of \$0.001 ("Preferred Stock"). At the effective time of the filing of this Amended and Restated Certificate of Incorporation, and without further action on the part of the corporation or the holders of its stock, each share of Class B Common Stock of the corporation outstanding immediately prior thereto shall be split into One Hundred Twenty Two Thousand Five Hundred (122,500) fully paid and nonassessable shares of Class B Common Stock of the corporation, and at such time each holder of record of Class B Common Stock shall, without further action, be and become the holder of One Hundred Twenty Two Thousand Five Hundred (122,500) shares of Class B Common Stock for each share of Class B Common Stock held of record immediately prior thereto.

Source: Illumina, Form 10-Q for the period ended April 3, 2016 (May 9, 2016), at 12.

Reference (b) that Illumina owns 90% of GRAIL common stock.

#### Investments in Consolidated Variable Interest Entities

GRAIL Inc.

In January 2016, the Company obtained a majority equity ownership interest in GRAIL, Inc. (GRAIL), a company formed with unrelated third party investors to pursue the development and commercialization of a blood test for asymptomatic cancer screening. The Company determined that GRAIL is a variable interest entity as the entity lacks sufficient equity to finance its activities without additional support. Additionally, the Company determined that it has (a) control of the entity's Board of Directors, which has unilateral power over the activities that most significantly impact the economic performance of GRAIL and (b) the obligation to absorb losses of and the right to receive benefits from GRAIL that are potentially significant to GRAIL. As a result, the Company is deemed to be the primary beneficiary of GRAIL and is required to consolidate GRAIL. On a fully diluted basis, the Company holds a 32% equity ownership interest in GRAIL as of April 3, 2016.

During the three months ended April 3, 2016, GRAIL completed its Series A convertible preferred stock financing, raising \$120.0 million, of which the Company invested \$40.0 million. Additionally, the Company and GRAIL executed a long-term supply agreement in which the Company contributed certain perpetual licenses, employees, and discounted supply terms in exchange for 112.5 million shares of GRAIL's Class B Common Stock. Such contributions are recorded at their historical basis as they remain within the control of the Company. The \$80.0 million received by GRAIL from unrelated third party investors upon issuance of its Series A convertible preferred stock is classified as a noncontrolling interest in stockholders' equity on the Company's consolidated balance sheet.

For the three months ended April 3, 2016, the Company absorbed \$90% of GRAIL's losses based upon its proportional ownership of GRAIL's common stock.

In accordance with GRAIL's Equity Incentive Plan, the Company may be required to redeem certain vested stock awards in cash at the then approximate fair market value. The fair value of the redeemable noncontrolling interests is considered a

### Exhibit 2

GRAIL Series A Convertible Preferred Stock

Reference (c) and (e)

Source: Illumina, Form 10-Q for the period ended April 3, 2016 (May 9, 2016), at 12

Reference (c) that GRAIL issued \$120 million Series A convertible preferred stock, with Illumina funding \$40 million and unrelated third party investors (Series A investors) funding \$80 million.

#### Investments in Consolidated Variable Interest Entities

GRAIL, Inc.

In January 2016, the Company obtained a majority equity ownership interest in GRAIL, Inc. (GRAIL), a company formed with unrelated third party investors to pursue the development and commercialization of a blood test for asymptomatic cancer screening. The Company determined that GRAIL is a variable interest entity as the entity lacks sufficient equity to finance its activities without additional support. Additionally, the Company determined that it has (a) control of the entity's Board of Directors, which has unilateral power over the activities that most significantly impact the economic performance of GRAIL and (b) the obligation to absorb losses of and the right to receive benefits from GRAIL that are potentially significant to GRAIL. As a result, the Company is deemed to be the primary beneficiary of GRAIL and is required to consolidate GRAIL. On a fully diluted basis, the Company holds a 52% equity ownership interest in GRAIL as of April 3, 2016.

During the three months ended April 3, 2016, GRAIL completed its Series A convertible preferred stock financing, taising \$120.0 million, of which the Company invested \$40.0 million. Additionally, the Company and GRAIL executed a long-term supply agreement in which the Company contributed certain perpetual licenses, employees, and discounted supply terms in exchange for 112.5 million shares of GRAIL's Class B Common Stock. Such contributions are recorded at their historical basis as they remain within the control of the Company. The \$80.0 million received by GRAIL from unrelated third party investors upon issuance of its Series A convertible preferred stock is classified as a noncontrolling interest in stockholders' equity on the Company's consolidated balance sheet. For the three months ended April 3, 2016, the Company absorbed \$0% of GRAIL's losses based upon its proportional ownership of GRAIL's common stock.

In accordance with GRAIL's Equity Incentive Plan, the Company may be required to redeem certain vested stock awards in cash at the then approximate fair market value. The fair value of the redeemable noncontrolling interests is considered a

Source: GRAIL, Amendment No. to Form S-1 (Sept. 17, 2020) at II-2.

Reference (c) that GRAIL's Series A convertible preferred stock has 120,000,000 shares.

(b) between January 8, 2016 and February 10, 2016, we sold 120,000,000 shares of Series A redeemable convertible preferred stock to 13 accredited investors at a price of \$1.00 per share, for aggregate proceeds of approximately \$120,000,000; between February 28, 2017 and December 27, 2017, we sold 271,836,114 shares of Series B redeemable convertible preferred stock to 55 accredited investors at a price of \$4.0085 per share, for aggregate proceeds of approximately \$1,089,655,000; and on May 16, 2018 we sold 63,144,600 shares of Series C redeemable convertible preferred stock to 10 accredited investors at a price of \$4.751 per share, for aggregate proceeds of approximately \$300,000,000; and between November 27, 2019 and May 15, 2020, we sold 76,743,836 shares of Series D redeemable convertible preferred stock to 14 accredited investors at a price of \$5.1080 per share, for aggregate proceeds of \$392,007,514;

Source: GRAIL, Amendment No. to Form S-1 (Sept. 17, 2020) at F-27.

Reference (e) that each share of GRAIL Series A convertible preferred stock converts into a share of GRAIL Class A common stock

Conversion

Each share of preferred stock is convertible, at the option of the holder, according to a conversion ratio, which is subject to adjustment for dilutive share issuances as described in the next paragraph. The total number of shares of common stock into which the preferred stock may be converted is determined by dividing the then-applicable conversion price by the initial conversion price. The preferred stock automatically converts into shares of Class A common stock at the then-applicable conversion price in the event of an underwritten public offering of shares of common stock with aggregate gross proceeds of no less than \$150 million (Qualifying IPO), provided that, prior to November 27, 2021 (24 months after the initial closing date of November 27, 2019), such automatic conversion shall also require either (i) the per share price of the Qualifying IPO to be at least \$5,1080 per share (i.e., the Series D preferred stock original issue price) or (ii) the vote of the holders of a majority of the combined Series C and D preferred stock. The preferred stock also automatically converts into shares of Class A common stock at the then-applicable conversion price upon the vote of a majority of the holders of preferred stock and, if prior to November 27, 2021, the vote of the holders of two-thirds of the combined Series C and D preferred stock shall also be required. As of December 31, 2019, each share of Series A, B, C, and D preferred stock was convertible into one share of Class A common stock.

Subject to certain exceptions, including issuances of shares to employees or consultants pursuant to a stock option plan approved by the board of directors and issuances of shares to lenders or strategic partners or in connection with the acquisition of a company or technology, in each case approved by the board of directors, the conversion price of each applicable series of preferred stock is subject to adjustment to prevent dilution in the event that the Company issues additional shares at a purchase price less than the then-applicable conversion price.

### Exhibit 3

GRAIL Undisclosed Equity

Reference (e) and (f)

# Illumina, Form 10-Q for the period ended April 3, 2016 (May 9, 2016), at 12. Reference (e) that Illumina owned 52% of GRAIL's fully diluted equity

#### Investments in Consolidated Variable Interest Entities

GRAIL, Inc.

In January 2016, the Company obtained a majority equity ownership interest in GRAIL, Inc. (GRAIL), a company formed with unrelated third party investors to pursue the development and commercialization of a blood test for asymptomatic cancer screening. The Company determined that GRAIL is a variable interest entity as the entity lacks sufficient equity to finance its activities without additional support. Additionally, the Company determined that it has (a) control of the entity's Board of Directors, which has unilateral power over the activities that most significantly impact the economic performance of GRAIL and (b) the primary beneficiary of GRAIL and is required to consolidate GRAIL. On a fully diluted basis, the Company holds a 52% equity ownership interest in GRAIL as of April 3, 2016.

During the three months ended April 3, 2016, GRAIL completed its Series A convertible preferred stock financing, raising \$120.0 million, of which the Company invested \$40.0 million. Additionally, the Company and GRAIL executed a long-term supply agreement in which the Company contributed certain perpetual licenses, employees, and discounted supply terms in exchange for 112.5 million shares of GRAIL's Class B Common Stock. Such contributions are recorded at their historical basis as they remain within the control of the Company. The \$80.0 million received by GRAIL from unrelated third party investors upon issuance of its Series A convertible preferred stock is classified as a noncontrolling interest in stockholders' equity on the Company's consolidated balance sheet. For the three months ended April 3, 2016, the Company absorbed 90% of GRAIL's losses based upon its proportional ownership of GRAIL's common stock.

In accordance with GRAIL's Equity Incentive Plan, the Company may be required to redeem certain vested stock awards in cash at the then approximate fair market value. The fair value of the redeemable noncontrolling interests is considered a