

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK**

IN RE ICON PLC  
SECURITIES LITIGATION

Case No. 2:25-cv-00763-HG

CLASS ACTION

**AMENDED COMPLAINT FOR  
VIOLATIONS OF THE FEDERAL  
SECURITIES LAWS**

**JURY TRIAL DEMANDED**

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Court-appointed Lead Plaintiffs Police and Fire Retirement System of the City of Detroit (“PFRSD”) and The Trustees of the Local 464A United Food & Commercial Workers Union Welfare Service Benefit Fund and the Trustees of the Welfare and Pension Funds of Local 464A (“Local 464A”) (collectively, “Plaintiffs”) by and through their counsel, bring this action individually and on behalf of all others similarly situated who purchased or otherwise acquired ICON plc (“ICON” or the “Company”) ordinary shares between July 27, 2023 and January 13, 2025, both dates inclusive (the “Class Period”), and were injured thereby (the “Class”). This action is brought against defendants ICON and its former and current executive officers, CEO Stephen Cutler (“Cutler”), former CFO Brendan Brennan (“Brennan”), and the former President of ICON Pharma Development Solutions and current COO Barry Balfe (“Balfe”; together with Cutler and Brennan, the “Individual Defendants” and with ICON, “Defendants”).

Plaintiffs allege the following upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters. Plaintiffs’ information and belief is based upon, among other things, the ongoing investigation conducted by and through their attorneys. This investigation includes, but is not limited to, reviewing and analyzing: (i) documents that ICON filed with the United States Securities and Exchange Commission (“SEC”); (ii) securities analyst reports about ICON; (iii) transcripts of ICON investor conference calls and conference appearances; (iv) ICON press releases and publicly available slide presentations; (v) press and media reports, including online news sources; and (vi) interviews of former ICON employees (“Former Employees” or “FEs”). Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## **I. INTRODUCTION**

1. This securities class action arises from Defendants’ false and misleading statements about ICON’s key business metrics and financial performance in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”), and Rule 10b-5 promulgated thereunder. Defendants’ misstatements propped up ICON’s share price, allowing Defendants Cutler (ICON’s former CEO) and Brennan (ICON’s former CFO) to enrich themselves with nearly \$30 million from insider sales before Defendants’ fraud collapsed.

2. ICON is a Clinical Research Organization (“CRO”) that handles clinical trials for large pharmaceutical and biotech companies. Because clinical trials have finite durations, ICON’s financial performance depends on securing a stream of new business and maintaining and growing its relationships with existing customers.

3. Before the Class Period, ICON benefited from a temporary boost in COVID-19-related work, and in 2021, acquired one of its main competitors, PRA Health Sciences, Inc. (“PRA”), for a premium price. PRA had focused on biotech customers, and the PRA acquisition sought to increase ICON’s exposure to the biotech sector. But the costly PRA acquisition was a failure: Customers began to leave due to ICON’s low-quality work, poor culture, heavy offshoring to low-cost countries, and the risk of overconcentrating their CRO work at the combined entity.

4. Nonetheless, the PRA acquisition left ICON saddled with billions of dollars in debt and large interest payments. Further, the temporary boost from COVID-19 work began to fade. On top of that, the high-interest-rate environment in 2022 and early 2023 deprived CROs’ biotech customers of funding, triggering an industry-wide downturn in the CRO industry.

5. By mid-2023, ICON’s share price was well below its prior December 2021 peak, and ICON’s credit rating sank to “junk.”

6. With the pandemic boom fading, and the PRA acquisition failing to deliver, ICON and the Individual Defendants—CEO Cutler, CFO Brennan and COO Balfe—resorted to fraud. Notably, Cutler had an internal goal of boosting ICON’s stock price to \$500 per share by 2025, a strategy called “**\$500 by 2025**” that set the stage for Cutler’s and Brennan’s lucrative insider sales.

7. During the Class Period (July 27, 2023 through January 13, 2025), Defendants repeatedly lied about ICON’s key business metrics and inflated ICON’s financial performance in violation of GAAP. Specifically:

8. **Misstatements about ICON’s RFP Growth and Win Rate:** The first step for ICON to secure new business is receiving RFPs, or Requests for Proposals, from customers. Because ICON depends on RFPs to obtain new business, ICON’s RFP volume is highly material to investors and serves as a leading indicator of ICON’s business strength. Specifically, increasing RFPs to ICON conveyed the level of demand for ICON’s services and the strength of its business.

9. During the Class Period, Defendants repeatedly touted an increase in ICON’s RFP volume—including in biotech, which was the focus of the PRA acquisition and comprised about a third of ICON’s revenue post-acquisition. Because biotech customers represented an increasing proportion of clinical development spending, biotech was critical to ICON’s growth.

10. Defendants claimed that ICON saw “a *notable pickup in RFP activity within the biotech segment*” (July 27, 2023); a “*significant kind of uptick*” in RFPs “from our biotech customers” (Nov. 14, 2023); and that RFP growth was “continuing or even accelerating early in 2024,” with a “*mid-single digits*” increase “in the biotech space” (Feb. 22, 2024).

11. These statements were false. In truth, ICON’s RFPs from biotech customers were consistently *decreasing* throughout 2023 and 2024. FE-1, a former ICON director of business



development who tracked RFPs in ICON's Salesforce system, confirmed the decline and explained that there was *no quarter* during this period when biotech RFPs increased.

12. The Individual Defendants knew biotech customers' RFPs were decreasing because they attended quarterly meetings where the decreasing biotech RFPs were presented and discussed. (FE-1.) During these quarterly meetings, Defendants Brennan and Balfe also presented a Salesforce dashboard that showed increasing biotech cancellations from mid-2023. (FE-1.)

13. Further, beyond biotech, ICON's customer RFPs were declining across the board in 2023. As a former ICON Senior Proposal Manager (FE-7) explained, toward the end of each quarter in 2023, *internal emails—which consistently copied Cutler—called out a decline in ICON's RFPs and awards across the board.*

14. Even as Cutler knew the truth, he told investors the opposite. For example, Cutler claimed on July 27, 2023 that “[o]verall *RFP activity continued the sequential improvement* we experienced in quarter 1” and “we have seen *RFP activity continue its positive trajectory in July,*” and claimed on October 26, 2023 that ICON had RFP “*growth in the high single digits.*” Indeed, at the time of receiving the emails in 2023, FE-7 questioned why Cutler publicly stated that ICON's RFPs were increasing when they were actually decreasing.

15. Defendants' statements touting ICON's purported RFP growth were also materially misleading because they concealed the fact that up to 40% of customer RFPs never resulted in awards: as Defendant Cutler eventually admitted, many sponsors issued RFPs merely for price discovery—not to award actual business to ICON. These RFPs had zero prospect of being converted into new business. Moreover, many of the RFPs that ICON received were duplicative because they involved multiple proposed studies that were all competing for limited funding from

the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (“BARDA”), but BARDA would ultimately fund only one study.

16. Nonetheless, analysts credited Defendants’ lies about RFP growth. For example, when Cutler falsely touted “a *notable pickup in RFP activity within the biotech segment*” on July 27, 2023, Barclays raised its price target by 12% and praised ICON’s “*notable pickup in RFP activity within biotech*,” repeating Cutler’s misstatement nearly verbatim.

17. Cutler also lied about ICON’s biotech “win rate,” meaning the percentage of ICON’s bids that resulted in actual awards for ICON. On April 25, 2024, Cutler claimed that “[o]ur win rate in that biotech space has gone up over the last quarter or so” and touted a “*nice uptick*” on ICON’s biotech “win rate.”

18. At the time, however, Cutler knew ICON’s biotech win rate had *decreased*. At a Company-wide town hall in February 2024, Cutler personally complained about ICON’s *lower* biotech win rate and stated that the biotech RFPs that ICON received were not converting to wins at the same rate as in the past. (FE-3.)

19. Underscoring the dramatic decline in ICON’s biotech business, by the fourth quarter of 2023, ICON’s senior management *secretly transferred \$350 million in revenue to biotech* from another business unit within ICON to prop biotech up and make it appear to be doing better than it actually was (FE-9). Further, ICON initiated quarterly “*revenue sweeps*” to close “gaps” between ICON’s actual biotech performance and its targets, culminating with a “gap” of \$100 million in the third quarter of 2024 (FE-3). The “revenue sweeps” were initiated by ICON Biotech President Chris Smyth, who reported directly to CEO Cutler. (FE-3.)

20. **Misstatements about ICON's Large Pharma Business:** Defendants also lied about ICON's deteriorating business relationship with its large pharmaceutical customers—including Pfizer, ICON's largest customer and a material driver of its financial performance.

21. Pfizer single-handedly accounted for nearly 9% of ICON's revenue at the start of the Class Period. Confirming the materiality of Pfizer's business to ICON, the Company even set up a Pfizer Strategic Business Unit (the "PSBU") with thousands of ICON employees dedicated to Pfizer.

22. Unknown to investors, however, ICON's business with Pfizer was collapsing.

23. In 2023, Pfizer completed a "strategic refresh" and stopped awarding ICON any lucrative full-service work (which had generated ICON's highest margins, approaching 50%). As a former ICON Director of Clinical Operations (FE-2) explained, in fall 2023, Pfizer directed ICON to participate in a "mock bid defense" to decide how much business to allocate to ICON going forward. While CEO Cutler personally approved ICON's "pitch" to Pfizer to keep the business, the pitch failed: Before Christmas 2023, Pfizer communicated to ICON that it would award 85% of its Phase 2 and 3 studies—which are the largest and most financially significant studies—to another CRO. (FE-2.) Cutler knew about Pfizer's decision at the time: when ICON executives Sarah Gore (Executive Director of Project Management for the Pfizer oncology business) and Heather West (Vice President, Strategic Alliance Management) conveyed the decision to FE-2, their messaging indicated that Cutler and other senior executives had already been informed.

24. Thus, ICON entered a dry spell where Pfizer was awarding ICON virtually no new business, with a win rate near zero. (FE-1.) By the beginning of 2024, the absence of new Pfizer business was so extreme that ICON secretly started to wind down its dedicated PSBU and lay off

its employees—whose employment was project-specific—because there was no more work from Pfizer, as a former Clinical Trial Manager in the PSBU explained. (FE-8.)

25. To make matters worse, in January 2024, CEO Cutler—desperate to hang on to the remaining Pfizer business—agreed to cut \$50 million from the budget for ICON’s portfolio of Pfizer studies, and approved similar requests from other top 10 customers with increasing frequency in early 2024 (FE-2). FE-2 saw Cutler’s emails personally approving these budget cuts.

26. In parallel, Pfizer switched from ICON’s full-service offering (FSO) to outsourced staffing (FSP). Again, Cutler was fully aware of Pfizer’s switch to FSP: He reviewed and approved ICON’s internal announcement of the change, headed a special Pfizer “liaison team” at ICON, and met with Pfizer regularly to work out the details of the transition, which was to be completed by April 2024. (FE-2.) Two other large ICON customers, including Bristol Myers Squibb (“BMS”), also switched to FSP during the same period in late 2023 and early 2024.

27. For ICON, the financial implications of three large customers’ shift to FSP were enormous. ICON’s profit margins on FSP were only around 15%, compared to 40–50% for FSO. (FE-2, FE-9.) As FE-2 emphasized, the combination of losing Pfizer’s Phase 2 and 3 studies and simultaneously losing “a huge chunk of margin” because of Pfizer’s switch to FSP was a “huge blow to ICON.” Across the three customers that switched to FSP by early 2024, the 25–35% decrease in margin slashed up to \$500 million (or 21%) from ICON’s profits.

28. However, revealing the truth that Pfizer had largely stopped awarding ICON new business—and that ICON’s profit margin from Pfizer and two other large customers was eroding by over one-third—would have immediately tanked ICON’s share price.

29. Thus, when analysts probed whether ICON’s relationships with Pfizer and other large customers were experiencing any issues, Defendants consistently deflected and denied. For

example, in February 2024, Cutler insisted that ICON was “*not hearing . . . any further concerns* on funding or on their R&D spend” and claimed that ICON’s large pharma customers “do appear to [be] becoming more open to outsourcing and *outsourcing even more than they’re doing at the moment.*” Brennan declared in March 2024 that “[t]hey are all saying that they’re going to *increase spending.*” And to the extent Defendants acknowledged any customer shift to FSP at all, they falsely assured investors that it would have a minimal impact on ICON’s margins, would be small and “very gradual,” and had already been incorporated into ICON’s guidance.

30. Defendants knew none of that was true. By January 2024, Cutler knew ICON had lost 85% of Pfizer’s Phase 2 and 3 studies and all of Pfizer’s full-service business, knew Pfizer’s shift to nearly 100% FSP would be completed by April 2024, and had personally authorized a \$50 million budget cut for the Pfizer portfolio.

31. Leaving no doubt as to Cutler’s scienter, in February 2024, Cutler admitted at an internal, Company-wide town hall that *ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer* (FE-3)—even as he continued to tell investors that “[n]othing has *changed*” and touted “very stable and very strong demand in the large pharma.”

32. As FE-2 emphasized, “[t]here is no way that Cutler or any member of leadership could say they didn’t know what was happening or they didn’t have access to it.” Indeed, Cutler was intimately involved with every aspect of ICON’s large customer relationships, personally reviewing “pitch” presentations and approving final budgets and cuts. Cutler was formally assigned as Pfizer’s executive sponsor at ICON. Cutler also initiated “Partner of Choice” meetings where he personally met with senior executives from Pfizer and other large customers to address challenges with the business, and Cutler publicly touted his personal involvement in “strategic

meetings” with ICON’s large pharmaceutical customers. This extensive personal interaction gave Cutler unique visibility into ICON’s declining business from its largest customers.

33. ICON suffered another large setback in mid-2024, when one of its largest remaining projects for Pfizer—a large Phase 3 COVID-flu vaccine study—failed its trial. This was disastrous for ICON because the trial was huge, involving nearly 9,000 participants, and stood to generate at least \$60 million in revenue for ICON. Defendants knew about the failure by early August 2024 at the latest.

34. Nonetheless, on September 10, 2024, Cutler affirmed ICON’s financial guidance and falsely stated that there had been “*no material changes*” in the business. In truth, ICON had already lost material work from Pfizer—including all full-service work, at least 85% of Phase 2 and 3 studies, and the large Phase 3 COVID-flu vaccine trial. And ICON’s margins from Pfizer and two other large customers had materially eroded.

35. **ICON’s Inflated Business Wins and Book-to-Bill Ratio:** Defendants also materially overstated ICON’s “business wins” and “book-to-bill ratio”—key metrics that indicated whether ICON’s business was shrinking or growing.

36. For context, ICON regularly reported the amount of new business it had purportedly secured each quarter, called “business wins,” and its book-to-bill ratio, defined as net business wins divided by revenue. These metrics were critical to investors and analysts because they indicated whether ICON’s business was shrinking or growing. For example, a book-to-bill ratio of 1.2 meant growth: ICON had secured 20% more new business than the work it had performed.

37. During most of the Class Period, Defendants reported book-to-bill ratios well above 1.0, peaking at 1.27 in the first quarter of 2024. However, unknown to investors, ICON’s book-to-bill ratio and business wins were inflated by the inclusion of numerous “awards” without signed

contracts. Many of these purportedly “awarded” studies were later canceled. As a result, ICON reported inflated book-to-bill ratios for at least three years based on sales representatives entering “wins” into Salesforce that they knew were highly unlikely to materialize. (FE-9.) ICON’s actual book-to-bill ratios for 2023 and 2024 were **0.9 or lower** (FE-9)—evidence of a declining business, and far lower than Defendants publicly reported.

38. ICON’s book-to-bill ratio and business wins were also inflated because CEO Cutler personally directed ICON to book awards at larger dollar amounts than sponsors had approved to boost ICON’s claimed award numbers at least \$20 to \$30 million per quarter. As FE-7 explained, when sponsors gave ICON awards with caveats about reducing the size or scope of a study before a contract was signed, Cutler directed ICON to book the larger amount anyway. FE-7 was copied on emails from Cutler—and sometimes was standing in Cutler’s office—when Cutler gave these directions. ICON used this practice regularly, including in the second and third quarters of 2023.

39. **ICON’s False Financial Statements and GAAP Violations:** Finally, to obscure ICON’s declining business performance, Defendants engaged in improper revenue recognition and accounting practices in violation of Generally Accepted Accounting Principles (“GAAP”).

40. These practices inflated ICON’s reported revenue, profit, income, margins, and cash—even as Defendants falsely claimed that ICON complied with GAAP, had “effective” internal controls, and that its financial statements “fairly present[ed] in all material respects [ICON’s] financial condition, results of operations and cash flows.” Specifically:

41. Extending Reporting Periods to Inflate Financial Metrics: In a basic violation of GAAP, ICON held reporting periods open beyond their stated close—typically by 10 to 14 days—to increase ICON’s purported billing and cash numbers, as a former Senior Finance Manager (FE-4) confirmed. For example, ICON’s purported billing and cash as of “December 31, 2023”

included amounts from January 2024. In doing so, ICON recorded assets and transactions that it was not entitled to collect from its customers at the end of the relevant period. (ASC 606-10-45-4.) This practice also allowed ICON to recognize additional revenue and profit for work performed while the periods were held open.

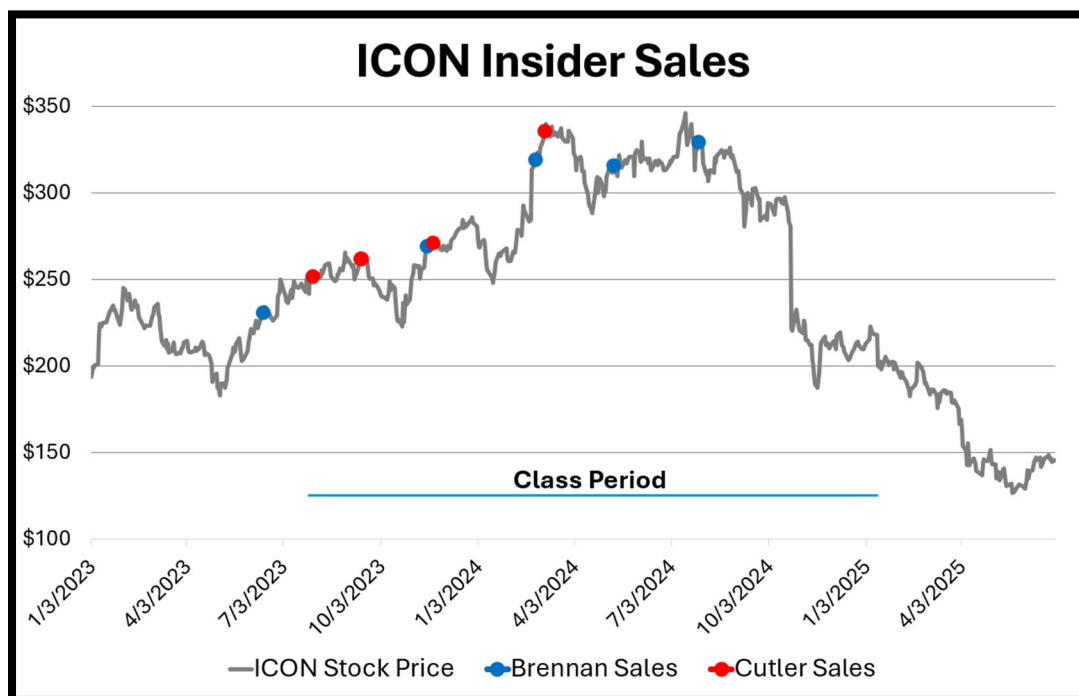
42. Issuing “Fake” Invoices to Prematurely Recognize Additional Revenue: ICON created *fake invoices* for future work that ICON had not yet performed—*marked with an asterisk* because they were “*known to be fake*.” (FE-4.) These fake invoices served to get “invoices on the books” and allowed ICON to prematurely recognize revenue it had not earned. The issue came to a head in Christmas 2023, when ICON fell significantly short of its cash and billing targets, prompting a “*mad scramble*” as employees worked 14- to 16-hour days to try to find cash. With no legitimate basis for the fake invoicing, which was widely discussed within ICON’s Finance Department, employees suspected that Brennan and Cutler wanted to “jack up” ICON’s share price before leaving ICON. Indeed, CFO Brennan resigned shortly before the scheme began to collapse.

43. Omitting Project Costs to “Hold the Margins” and Generate More Revenue: When actual project costs exceeded ICON’s budget—a common situation called “overburn” that reduced ICON’s profitability on studies—Defendants simply omitted the additional costs to “*hold the margins*.” (FE-5, FE-6.) To be clear, these were actual costs that ICON incurred and was required to include in its revenue recognition. Instead of including the costs, ICON used a dedicated Excel workbook to calculate the amount of costs to omit. This practice substantially inflated ICON’s margin and resulted in ICON prematurely recognizing additional revenue in violation of GAAP.

44. Other Improper Practices: In further violation of GAAP, ICON prematurely recognized revenue from draft, unsigned change orders; prematurely recognized revenue before meeting contractual milestones; and forecast “efficiencies” to boost margins. (FE-3.)



45. Defendants' misstatements and false financials set the stage for CEO Cutler and CFO Brennan to capitalize on their fraud with lucrative insider sales. Between July 2023 and July 2024, Cutler and Brennan unloaded *over 126,000 shares* of stock near ICON's all-time high share price. Cutler's and Brennan's insider sales are shown below:



46. These large, unusual insider sales strongly support scienter. Cutler and Brennan reaped *over \$37 million in proceeds and \$29.6 million in net profits*. They respectively sold 23.2% and 98.6% of their shares and vested options. Their sales occurred at suspicious times, including shortly after several of their misstatements to investors. And since the Class Period, neither executive has sold a *single share* (excluding sales to satisfy tax withholding).

47. After Cutler and Brennan cashed out, the truth emerged through a series of partially corrective events.

48. First, on July 25, 2024—the first earnings announcement for a period after Brennan's resignation announcement—ICON reported weak results for the second quarter of 2024 as Defendants' scheme began to collapse, driving a share price decline of \$18.67, or 5.6%.

49. Second, on October 23, 2024, ICON announced disastrous results for the third quarter of 2024, including a surprise “revenue shortfall” of \$100 million for the quarter, and reduced ICON’s full-year 2024 revenue guidance by \$220 million at the midpoint—despite having reiterated guidance just six weeks earlier. Defendants blamed the revenue shortfall and reduced guidance on “material headwinds from two large customers undergoing budget cuts and changes in their development model” as well as “ongoing cautiousness from biotech customers resulting in award and study delays.”

50. In reality, Defendants had long known about substantial business reductions from ICON’s large customers—including Pfizer’s decisions in 2023 to stop awarding ICON *any* new full-service business and to exclude ICON from at least 85% of Pfizer’s large, lucrative Phase 2 and 3 studies—and the looming slowdown in ICON’s biotech business, as evidenced by the continuous decline in biotech customer RFPs over the prior two years and a decreasing win rate.

51. On this news, ICON’s share price plunged by \$59.03 per share, or 21%.

52. Finally, on January 14, 2025, ICON issued financial guidance for 2025 well below analysts’ expectations due to “trial activity [that] has been impacted by cautious spending from biopharma customers” and “a headwind from our top two customers.” Again, Defendants had long known of these issues. Defendants also revealed that 2025 would be a “transition period” for ICON, indicating that the Company would not return to normal growth for some time. ICON’s share price declined another \$17.75, or 8.1%.

53. In the aftermath of Defendants’ fraud, ICON’s long-time auditor KPMG resigned, and on September 4, 2025, ICON announced Defendant Cutler’s abrupt departure as CEO. Defendants’ fraud has left investors with billions of dollars in losses.

## **II. JURISDICTION AND VENUE**

54. The claims alleged herein arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (“Exchange Act”), 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

55. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa), and 28 U.S.C. §§ 1331 and 1337, because this is a civil action arising under the laws of the United States.

56. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, as many of the acts and transactions alleged herein occurred in substantial part in this District. Additionally, Defendant ICON carried out substantial economic activity in this District, including through ICON subsidiary ICON Central Laboratories, which has its headquarters in Farmingdale, New York.

57. 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 exchange.

## **III. PARTIES**

### **A. Plaintiffs**

58. Plaintiff PFRSD provides retirement, disability, and death benefits to uniformed employees of the city of Detroit, Michigan, including police officers and firefighters, through a combination of defined benefit and defined contribution plans administered by a Board of Trustees. As indicated on the certification submitted herewith, PFRSD purchased ICON ordinary shares at artificially inflated prices during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

59. Plaintiff Local 464A represents and advocates for workers primarily employed in the food industry. As indicated on the certification submitted herewith, Local 464A purchased ICON ordinary shares at artificially inflated prices during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

**B. Defendants**

60. Defendant ICON is a CRO incorporated in Ireland, with its headquarters in Dublin, Ireland. ICON's ordinary shares trade on the NASDAQ Global Select Market under the ticker symbol "ICLR."

61. Defendant Cutler has served as ICON's Chief Executive Officer ("CEO") since March 2017 and on ICON's Board of Directors (the "Board") since November 2015. On September 4, 2025, ICON announced that Cutler has purportedly "retire[d]" as CEO, to be replaced by Defendant Balfe effective October 1, 2025. Prior to serving as CEO, Defendant Cutler served as ICON's Chief Operating Officer ("COO"). As CEO, Cutler has actively participated in ICON's process for preparing and making public disclosures regarding the Company's financial performance and related matters, including demand for ICON's services and various metrics such as RFP levels. Since 2017 and throughout the Class Period, Cutler was a core participant in preparing, reviewing, and approving: (i) ICON's quarterly earnings calls and Q&A scripts (in which Cutler was regularly a main speaker); (ii) the press releases that ICON published and filed with the SEC on Forms 6-K along with each quarterly earnings release (in which Cutler was often quoted); and (iii) the SEC Forms 20-F and 6-K that ICON filed and published for each fiscal period. Throughout the Class Period, Cutler approved ICON's periodic filings with the SEC, certifying based on his knowledge that the information in each filing "fairly present[ed], in all material respects, the financial condition and results of operations of the Company." Cutler also regularly spoke to investors and securities analysts about ICON's operations and financial

performance in conference calls, and at meetings and conferences, after personally participating in the preparation and finalization of his public statements on behalf of ICON.

62. Defendant Brennan served as ICON's Chief Financial Officer ("CFO") from February 2012 until his departure in October 2024. During his twelve-year tenure as CFO, Brennan actively participated in ICON's process for preparing and making public disclosures regarding the Company's financial performance and related matters, including demand for ICON's services and various metrics such as RFP levels. During this time, Brennan was a core participant in preparing, reviewing, and approving: (i) ICON's quarterly earnings calls and Q&A scripts (in which Brennan was regularly a main speaker); (ii) the press releases that ICON published and filed with the SEC on Forms 6-K along with each quarterly earnings release (in which Brennan was often quoted); and (iii) the SEC Forms 20-F and 6-K that ICON filed and published for each fiscal period. Throughout the Class Period, Brennan approved ICON's periodic filings with the SEC, certifying based on his knowledge that the information in each filing "fairly present[ed], in all material respects, the financial condition and results of operations of the Company." Brennan also regularly spoke to investors and securities analysts about ICON's operations and financial performance in conference calls, and at meetings and conferences, after personally participating in the preparation and finalization of his public statements on behalf of ICON.

63. Defendant Balfe has served as ICON's COO since January 2025. From July 2021 through December 2024, Balfe served as ICON's President of Pharma Development Solutions and focused on maintaining partnerships with large pharmaceutical customers. During his more than twenty years at ICON, Defendant Balfe also held roles in global business development, the FSP leadership team, and the business development team. Balfe reviewed and supplied information to Cutler, Brennan, and other executives in connection with ICON's statements to investors. Balfe

also spoke to investors and securities analysts about ICON's operations and financial performance at meetings and conferences after personally participating in the preparation and finalization of his public statements on behalf of ICON.

64. Based on their positions with ICON, the Individual Defendants possessed the power and authority to control the contents of the Company's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors.

65. Each of the Individual Defendants was directly involved in the management and day-to-day operations of the Company at its highest levels and was privy to confidential proprietary information concerning the Company and its business, operations, services, customers, and business prospects, as alleged herein.

66. Defendants Cutler and Brennan were provided with copies of the Company's presentations and SEC filings alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were materially false and/or misleading when made.

#### **IV. FACTUAL BACKGROUND**

##### **A. ICON's Business Model**

67. ICON is a CRO that claims to provide a range of services to assist pharmaceutical companies, biotechnology companies, government bodies, and public health organizations in bringing new drugs and medical devices to the market. ICON's service offerings include clinical development, functional outsourcing, and laboratory services.

68. During the Class Period, ICON offered its services through two main operating models: (1) Full-Service Outsourcing (“FSO” or “Full Service”); and (2) Functional Service Provision (“FSP”).

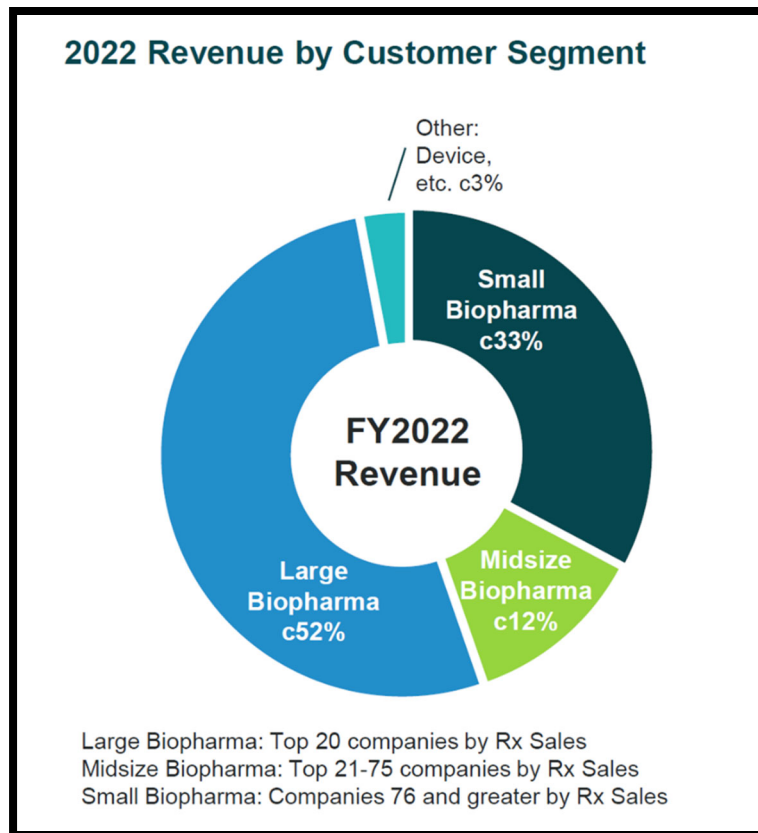
69. Through the FSO model, ICON was responsible for conducting an entire clinical study on behalf of a client. Accordingly, FSO work provided ICON’s highest profit margins.

70. Through FSP arrangements, in contrast, customers only outsourced discrete functions or portions of the clinical trial to ICON, while performing other functions internally. For example, ICON may have provided individuals or teams that are specialized in certain areas to supplement the sponsor’s existing workforce. An FSP model thus allowed customers to retain more control and offered customers lower costs. For ICON, however, FSP has substantially lower profit margins compared to FSO work.

71. Because clinical trials have limited duration, ICON’s business model, including both its FSO and FSP offerings, relies on a constant stream of new contracts, which are typically secured through requests for proposals that ICON receives from customers.

#### **B. ICON’s Large Pharma and Biotech Customer Segments**

72. During the Class Period, ICON had two major customer segments: (1) large pharmaceutical (“large pharma”) companies with significant research and development (“R&D”) expenditures; and (2) small and mid-size biotechnology (“biotech”) companies with lower R&D expenditures (which ICON defines as companies outside the top 50 by R&D spending). ICON depicted its revenues from these customer segments as follows:



73. ICON’s financial performance depended heavily on a handful of its largest customers. ICON’s SEC filings admitted that it “depend[ed] on a limited number of customers.” For example, in the first half of 2023, ICON derived nearly 9% of its revenue from its largest customer. For the full year of 2023, ICON’s top five customers represented 26.8% of its revenues, its top ten customers represented 41.4% of its revenues, and its top twenty-five customers represented 62.9% of its revenues. According to FE-14, a Director of Business Development for ICON’s clinical trial services, ICON’s relationships with large pharmaceutical companies, such as Pfizer, were the “bread and butter” that kept ICON’s revenue rolling.<sup>1</sup>

<sup>1</sup> Regardless of gender, all FEs are described in the masculine to protect their identities. Each FE’s title, tenure, and role are provided in Section VII.B.



**1. ICON's Critical Relationship with Its Largest Customer, Pfizer**

74. Historically, ICON's largest customer was Pfizer. Based on regularly working with Pfizer for over a decade, FE-1 explained that Pfizer was ICON's "number one since day one" and was a "centerpiece" of ICON's business. Pfizer alone represented 8.8% of ICON's revenues, or \$683 million, in 2022.

75. CEO Cutler was central to ICON's relationship with Pfizer. FE-1 noted that Cutler was Pfizer's "executive sponsor" at ICON, and FE-11, a former Vice President and General Partner in ICON's FSP division, confirmed that Cutler has always managed the Pfizer account given its prominence and size.

76. ICON's own press releases confirmed Cutler's knowledge of and involvement in the key Pfizer relationship. For example, when ICON publicly announced in April 2020 that Pfizer had signed a new service agreement, Cutler praised the "further progression of ICON's long-standing relationship with Pfizer." In a January 2021 ICON press release touting ICON's work with Pfizer in a global Phase 3 trial of a COVID-19 vaccine, Cutler highlighted ICON's "close collaboration with Pfizer."

77. Cutler repeatedly interacted personally with Pfizer executives. FE-11 explained that Cutler personally led Partner of Choice ("POC") meetings where ICON invited senior executives from Pfizer, Novartis, and other large accounts to the Company's U.S. headquarters in Blue Bell, Pennsylvania. FE-11 attended these POC meetings together with Cutler, Samir Shah (former President of ICON Strategic Solutions ("ISS")), and others. The goal of the POC meetings was to convene a think tank or whiteboard session to discuss challenges in the industry and issues related to ICON's business—including Pfizer's move from FSO to FSP, which threatened ICON's margins because the FSP work was less profitable for ICON.

78. According to FE-11, Balfe, Debbie Gilmore, and other senior ICON executives were also intimately involved with the Pfizer relationship. FE-11 described Pfizer as their “baby.”

79. Similarly, FE-14 reported that senior ICON executives, such as Cutler and Chief Commercial Officer (“CCO”) George McMillan, had direct involvement in ICON’s business dealings with Pfizer and other large customers. ICON senior leadership reviewed any revenue opportunity worth approximately \$30 million or more; for example, Cutler viewed target deals with Eli Lilly. (FE-14; FE-7.) McMillan was involved at the “pitch” phase of ICON’s target deals with Eli Lilly and flew to meet customers for dinner and in-person meetings to win the deals. (FE-14.)

## **2. ICON’s Other Largest Customers**

80. Beyond Pfizer, ICON’s other largest customers included Novartis, Janssen/Johnson & Johnson, Sanofi, BMS, Merck, GSK, and Eli Lilly, as FE-2, FE-11, FE-14, and FE-12, a former ICON Resource Manager, confirmed.

81. For example, FE-11 stated that Novartis was one of ICON’s five largest accounts, with over 2,000 ICON employees embedded. The last award FE-11 obtained from Novartis was for three years and \$780 million. FE-11 noted that the Janssen/Johnson & Johnson relationship involved 3,000 ICON employees. FE-12 confirmed that the Sanofi relationship involved over \$900 million in contracts with an average duration of about three years, translating into hundreds of millions of dollars each year.

## **C. Before the Class Period, ICON Temporarily Benefits from COVID-19 Work and Incurs Significant Debt in the Costly PRA Merger**

### **1. ICON’s Revenues Surge Due to COVID**

82. During the COVID-19 pandemic, many large pharmaceutical companies increased their R&D spending as they worked to develop COVID vaccines and treatments.

83. This led to a temporary boom in business for ICON as it secured large COVID-era contracts. In January 2021, ICON itself publicly touted its role in Pfizer’s large global trial of the first successful COVID-19 vaccine.<sup>2</sup>

## **2. The PRA Merger**

84. ICON leveraged the temporary boom in COVID-19 work to acquire PRA, one of its main CRO competitors. At the time, PRA was the fifth-largest CRO by revenue, while ICON was sixth-largest.

85. Unlike ICON, PRA focused on the biotech space. As FE-14 explained, ICON acquired PRA because it was a leader in biotech—meaning that everything at PRA was built for biotech—and ICON saw the acquisition as a way to build out its biotech arm.

86. On July 1, 2021, ICON completed its acquisition of PRA (the “PRA Merger”). ICON touted the PRA Merger as bringing together “38,000 employees across 47 countries, creating the world’s most advanced healthcare intelligence and clinical research organization.” CEO Cutler asserted that “[b]oth ICON and PRA have track records of robust growth and performance and we are ready to build on this unrivalled position of strength.”

87. The PRA Merger saddled ICON with a heavy debt burden: a high-interest term loan of \$5.515 billion, requiring ICON to make substantial interest payments, including over \$80 million in the second half of 2021 alone. Given ICON’s heavy debt load, credit rating agencies downgraded ICON to “junk.” Specifically, in mid-2021, Moody’s and S&P downgraded ICON’s credit rating to BB+ and Ba1—below investment-grade. Moody’s highlighted that “the announced [PRA] acquisition will materially change ICON’s capital structure,” while S&P flagged that “the debt-funded acquisition will put pressure on ICON’s credit metrics.”

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<sup>2</sup> <https://www.iconplc.com/news-events/press-releases/icon-pfizer-biontech>

**D. The PRA Merger Proves to Be a Disaster**

88. Unknown to investors, the PRA Merger proved to be a disaster. ICON's failure to integrate PRA, coupled with ICON's failure to provide the same level of service to legacy PRA biotech sponsors, and sponsors' concerns regarding overconcentration at the combined entity, resulted in a significant loss of customers and new business in the wake of the PRA Merger.

**1. ICON Failed to Retain PRA's Biotech Customers**

89. FE-14 described the PRA Merger as a "terrible merger" and a "failure." According to FE-14, following the Merger, ICON continued to promise strong biotech partnerships, but in reality, ICON was losing ground with its biotech customers.

90. FE-14 reported that although ICON tried to "spruce it up," customers eventually began to "see through the façade" and realize that ICON did not have biotech solutions. For example, ICON's Standard Operating Procedures were not always built for biotech, and ICON team members were not well-versed in biotech.

91. Similarly, FE-15, a former ICON Regional Lead, Business Development, explained that through the PRA Merger, ICON was simply buying a book of business and did not know how to properly execute with the new customers. According to FE-15, after the Merger, smaller biotech companies that had previously worked with PRA were not getting the attention and resources they needed.

92. As FE-14 explained, this led to legacy PRA customers leaving ICON "in droves" and not providing ICON with additional work. FE-14 estimated that at least 30% of his biotech customers did not want to conduct business with ICON at all after the PRA Merger.

## **2. The PRA Merger Led to Overconcentration Among Large Customers**

93. Further, several of ICON’s large customers had business with both ICON and PRA before the PRA Merger. After the Merger, these customers were unhappy with the resulting overconcentration of their CRO business with ICON.

94. FE-11 confirmed that Janssen—a relationship that generated about \$500 million per year—was unhappy with the overconcentration with ICON and ultimately used it as leverage to demand lower pricing, reducing ICON’s margins. Similarly, FE-15 reported that some of ICON’s large pharma customers had business with both PRA and ICON before the Merger and they “didn’t want to put all of their eggs in one basket.”

95. The overconcentration issue was exacerbated because the legacy PRA business (relabelled as ICON Strategic Solutions Group, or ISS) competed with ICON’s FSP business for similar business from the same sponsors, including Sanofi. FE-12 noted that ICON ISS and FSP “were constantly bidding against” each other on roughly half of Sanofi’s RFPs, or approximately 20 RFPs per quarter.

### **E. As COVID-Related Revenues Decline, Defendants Resort to Fraud**

96. As the COVID-19 pandemic subsided, there was a significant reduction in pandemic-related funding and associated spending by study sponsors, and the temporary surge in trials came to an end.

97. For example, in early 2023, BARDA significantly reduced its funding for COVID-related vaccine research, and Sanofi lost approximately \$150–\$200 million in BARDA funding across two major COVID vaccine studies, which involved thousands of patients in 15–25 countries. (FE-12.) As FE-12 said, ICON “was not going to get \$300 to \$400 million per year” in vaccine revenue after the COVID vaccine funding cuts began.

98. Further, as interest rates rose dramatically during 2022, biotech companies saw significant decreases in funding—a slowdown that affected CRO companies, including ICON. At the J.P. Morgan Healthcare Conference on January 11, 2023, Cutler admitted that ICON had “seen some attenuation of biotech funding on the RFP side of things.”

99. Meanwhile, ICON still had to service the debt it had incurred to acquire PRA.

100. These pressures impacted ICON’s share price: after peaking at \$309.70 in December 2021, ICON’s share price suffered throughout 2022, ending the year at \$194.25.

101. By mid-2023, ICON had reached a crucial juncture: Defendants were highly motivated to create the impression that ICON had overcome the recent industry headwinds and now had a healthy and growing business. That would help restore ICON’s credit rating, clearing the path for ICON to offer new securities to pay down its \$4.35 billion in remaining debt from the PRA Merger.

102. Significantly, persuading investors of ICON’s growth would also allow Defendants Cutler and Brennan to sell stock for personal profit. In this regard, FE-3—an Executive Director of Project Delivery at ICON from early 2023 until November 2024—highlighted that Cutler had an internal goal of boosting ICON’s stock price to \$500 per share by 2025, a strategy called “***\$500 by 2025.***”

103. However, Defendants knew key aspects of ICON’s business were declining, particularly its biotech RFP volume and business from large customers, including Pfizer, as detailed below. But revealing the truth would immediately depress ICON’s share price, further imperil its credit rating, and sharply reduce Defendants’ ability to profit from lucrative insider sales.

104. Thus, as detailed herein, Defendants turned to a fraudulent scheme to conceal ICON's weakening business and cash out by selling stock at inflated prices.

**F. The Class Period Begins: Defendants Tout ICON's Purportedly Increasing RFPs and Strong Demand Across All Customer Segments**

105. The Class Period begins on July 27, 2023, when ICON held a conference call to discuss its financial results for the second quarter of 2023.<sup>3</sup>

106. ICON's 2Q23 earnings call was an inflection point. ICON reported its highest-ever quarterly revenue of \$2.02 billion—the first time its quarterly revenues had exceeded \$2 billion—and touted broad growth across all areas of ICON's business.

107. During Defendant Cutler's introductory remarks, he declared that “[t]he industry demand environment has been solid with *positive trends across all customer segments*.”

108. The volume of potential customers' RFPs to ICON is a key leading indicator of demand for ICON's services and its growth. As ICON's 2023 annual report explained: “We are generally awarded projects based upon our responses to requests for proposals received from companies in the pharmaceutical, biotechnology and medical device industries[.]”

109. During the 2Q23 earnings call, Cutler touted increased RFP opportunities as evidence of more demand for ICON's services, stating that “*the demand increase, the RFP opportunities are really across the segments of the business*. I mean our large pharma group, in our biotech group[.]” Cutler added that “an *increase in RFP[s]* on a sequential basis” had “continued in the second quarter,” and that ICON had “seen RFP activity continue its positive trajectory in July.”

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<sup>3</sup> Throughout this Complaint, ICON's quarterly results are referenced by quarter and the last two digits of the year. For example, the second quarter of 2023 is “2Q23.”

110. Defendants also specifically stated that RFPs were increasing in the biotech segment. Cutler stated that ICON saw “a *notable pickup in RFP activity within the biotech segment* toward the end of quarter 2.”

111. Biotech RFPs were particularly important to investors because biotech customers comprised an increasing proportion of clinical development spending, and thus were critical to driving ICON’s growth. For example, on July 25, 2024, Cutler highlighted that about half of ICON’s 25 largest opportunities are with biotech customers. On April 25, 2024, Cutler indicated that biotech customers comprised about one-third of ICON’s revenues, stating: “we think of biotech overall . . . sort of low 30% of our revenues.”

112. Further, Defendants deflected any concerns about ICON’s large customers. Cutler stated that “we continue to work well with” ICON’s largest customer. And when an analyst asked about the potential for growth among large pharma customers, Cutler claimed that ICON potentially had “more of an opportunity” when R&D budgets were constrained, stating that “*even when [R&D budgets are] going down or staying flat, we have an opportunity*,” and asserting that “sometimes it’s more of an opportunity for organizations like ours when budgets are flat because the pharma companies look at how they’re spending and try to optimize their spend.”

113. Defendants also touted ICON’s business wins and book-to-bill ratio, reporting net business wins of \$2.419 billion and a book-to-bill ratio of 1.20 in the second quarter of 2023.

114. Analysts credited Defendants’ misstatements. For example, on July 27, 2023, Barclays raised its price target on ICON from \$250 to \$280 (a 12% increase), adding that ICON’s “recent success is due to the company broadening its services to new *and existing clients*” (emphasis in original). Tracking Cutler’s statements, Barclays flagged ICON’s “*notable pickup*



*in RFP activity within biotech* towards the end of 2Q” and that “RFP volume has continued its positive trajectory in July as well.”

**G. In Reality, ICON’s Business Was Slowing Significantly**

115. Contrary to Defendants’ public statements, key aspects of ICON’s business were slowing and declining throughout the Class Period.

**1. Biotech Customer RFPs Continuously Declined**

116. Defendants knew biotech customer RFPs were continuously *decreasing*—not increasing—before and during the Class Period.

117. Specifically, after peaking by 2021 or 2022, ICON received fewer biotech RFPs every quarter during 2023 and through fall 2024, with a total decline of approximately 40% over this period. (FE-1.) The overall 40% decline in seven quarters indicates that ICON’s volume of RFPs from biotech customers consistently declined by approximately 6% per quarter. FE-1 further confirmed that ICON’s biotech customer RFPs did not increase at any point through his departure in September 2024.

118. Similarly, FE-13—ICON’s Vice President, Scientific Affairs from spring 2019 to September 2023—noted that RFPs from biotech and large pharma customers on the laboratory services side were noticeably down, by at least 20%, starting from January 2023.

119. ICON’s flow of customer RFPs was carefully tracked internally. FE-1 explained that ICON’s full-service RFPs with an Interactive Response Technology (“IRT”) component—which were largely biotech and covered more than half of ICON’s full-service biotech work—peaked by 2021 or 2022 at close to 50 RFPs per month, but dropped to the low 30s each month by 2024. There was always a direct relationship between trends in these RFPs and the broader set of ICON’s biotech customer RFPs based on FE-1 seeing reports for both categories.

120. FE-1 knew about the trends in ICON’s biotech area from participating in weekly meetings that included reports on open and closed RFPs, and from accessing the Salesforce system. In particular, FE-1 attended weekly meetings to review Salesforce reports with Amanda Cohen (Executive Director Sales Strategy, Biometrics & Pharmacovigilance) and other colleagues. These reports could be viewed by logging in to Salesforce and were also circulated as screenshots for the meetings. The reports contained standard metrics, including how many open RFPs were in the pipeline, the percentage chance of winning the RFPs (as low as 30 percent), total awards, cancellations, and actual year-to-date numbers.

121. Similarly, FE-15 stated that he and all managers had access to ICON’s Salesforce system, which contained managers’ dashboards with RFP wins and losses, the win/loss reasons, and a year-over-year report. FE-15 further explained that Salesforce tracked both “outstanding” and “anticipated” RFPs.

122. ICON’s declining biotech RFPs were regularly presented to the Individual Defendants. Specifically, FE-1 reported that ICON’s decreasing biotech RFPs through 2023 and 2024 were presented in quarterly business development meetings with Defendants Brennan and Balfe, as well as CCO McMillan (who reported to CEO Cutler). These quarterly meetings were held by video and typically lasted an hour; Defendant Cutler sometimes attended. Balfe and Cutler also attended structured, two-and-a-half-day Quarterly Business Review (“QBR”) meetings where RFP information was presented, as discussed further below. (*Infra* Section VII.B.11.)

## **2. Overall RFPs Significantly Declined**

123. ICON’s customer RFPs were declining across the board in 2023. As FE-7 explained, toward the end of each quarter in 2023, internal emails—copying CEO Cutler—called out a decline in ICON’s customer RFPs.

124. The emails stated that ICON's RFPs and awards were declining across the board. (FE-7.) FE-7 described the emails as "calls to action" that urged employees' full attention to each RFP given the diminishing number. FE-7 further stated that the emails described the gap between ICON's current numbers and target, indicating that ICON needed to "book X amount more."

125. The emails usually came from the head of sales, consistently copied Cutler and McMillan, and sometimes came from Cutler or McMillan themselves. (FE-7.) Thus, Cutler knew throughout 2023 that ICON's overall RFPs were declining.

### **3. ICON's Claimed RFP Flow Was Significantly Inflated**

126. Further undermining Defendants' public statements about RFPs, many of the RFPs that ICON received were duplicative or intended only for price discovery, meaning they had no prospect of translating into new business for ICON.

127. First, up to 40% of RFPs were issued merely for price discovery—not to award actual business to ICON. These RFPs had zero prospect of converting into new business. On November 21, 2024—near the end of the Class Period—Defendant Cutler admitted that "we've seen a number of projects or bids that we've made that really never have come to a decision. It tends to be around 20% to 30% of the RFP dollars that we put out don't come to a decision. We call it close cancel. In other words, they're canceled before they even get to a contracting point."

128. In fact, Cutler understated the magnitude of the problem. FE-7 stated that up to 40% of the large pharma RFPs ICON received in 2023 were just "testing the waters"—*i.e.*, intended merely for price discovery. FE-7 stated that in about one-third of these cases, sponsors actually told ICON that the RFPs were just for price discovery purposes. In other cases, the sponsors sent three RFPs, reflecting three scenarios for the same study, which indicated to FE-7 and ICON that the sponsors were just "fishing" to discover ICON's pricing. FE-7 confirmed that the price discovery RFPs happened throughout 2022 and 2023 and increased towards the end of

his tenure. FE-7 believed that Cutler and McMillan were both aware of the price discovery RFPs given their prevalence and because Cutler and McMillan were both “very hands on.”

129. Likewise, FE-2 confirmed that customers sent RFPs to ICON merely to get a sense of ICON’s pricing; once ICON responded, the customers indicated that they did not wish to move forward with the study. Similarly, FE-15 reported that in 2024, companies were sending out more RFPs than before: while sponsors had generally gone to three to four CROs for RFPs before, in 2024, they started going to as many as six to eight. Indeed, during the first quarter of 2024, Smyth (President of ICON Biotech) indicated that sponsors were going to more vendors than in the past and price shopping across six or more CROs (compared to three in the past). (FE-3.)

130. Second, many of the RFPs were duplicative because multiple customers submitted RFPs to conduct the same study using limited funding from BARDA. FE-1 reported that in 2023 and 2024, ICON bid on several relatively large studies, in the \$30 to \$50 million range, to be funded by BARDA. However, in each case, multiple companies were competing for the same BARDA funding for the same study, so even where ICON responded to three or four RFPs for a given study, there would ultimately only be one study and one award. Thus, for example, what appeared to be “\$1 million” in RFPs could all relate to a single \$250,000 study. (FE-1.) As a result of this duplication, ICON’s volume of RFPs from BARDA-funded studies was several times higher than the maximum possible award.

#### **4. ICON’s Biotech Cancellations Consistently Increased**

131. Further demonstrating the slowdown in ICON’s biotech business, biotech study cancellations had consistently increased since late 2022. As FE-1 explained, it was clear by June 2023 that the elevated cancellations were a trend, and the trend never improved. Instead, ICON’s biotech cancellations progressively worsened into 2024. The biotech cancellations were

financially significant and amounted to hundreds of millions of dollars, as most biotech studies ranged from \$8 million to \$30 million—and some were much larger.

132. ICON’s senior leadership—including Defendants Cutler, Brennan, and Balfe—knew biotech cancellations were increasing throughout 2023 and 2024. As FE-1 explained, cancellation data was aggregated and rolled up to McMillan and SVP of Business Development Mark Cooper, who then submitted it to Cutler and Brennan; FE-1 learned from executives Cohen, Eloise Harris (Vice President of Business Development), and Yves Grenon (Senior Vice President) that “we need” the cancellation “numbers because it is going all the way up to the top and they are reviewing it.”

133. FE-1 also attended multiple quarterly business development meetings in 2023 and 2024 where Defendants Brennan and Balfe personally used a company-wide Salesforce dashboard to present ICON’s increasing biotech cancellations, which were “very high,” and complained that high cancellations were really hurting ICON’s numbers. And in April 2024, Cutler attended an ICON sales meeting in Tampa, Florida, where ICON’s increasing biotech cancellations were discussed. (FE-1.)

## **5. ICON’s Business from Pfizer and Other Large Customers Was Collapsing**

134. Before and during the Class Period, ICON also experienced a trend of its largest customers, including Pfizer, significantly reducing their business with ICON.

135. According to FE-1, Pfizer was not awarding a lot of new business to ICON throughout 2023 and 2024. For context, ICON had enjoyed a 50% win rate for Pfizer’s studies through approximately 2021, but saw a trend of a declining Pfizer win rate over the next several years.

136. Corroborating FE-1, FE-2—ICON’s Director of Clinical Operations, Oncology/Director of Clinical Research from summer 2022 to February 2024—explained that throughout his tenure, ICON’s oncology business with Pfizer decreased, and Pfizer had largely stopped giving ICON new late-phase awards (which involved the largest and most financially significant studies). In late 2023, Pfizer dropped various oncology studies with ICON, and ICON’s margins on the remaining studies eroded; ICON was “overburning on the budgets and eating the costs” because its staff was incurring extensive overtime that was not being billed to Pfizer. FE-2’s supervisor, Vice President, Global Project Management Martin Lachs—who reported to Cutler—described the situation as “like a dying dinosaur.”

137. Further, in mid- to late 2023, Pfizer stopped awarding new full-service business to ICON as part of a “strategic refresh.”

138. FE-1 explained that in the “strategic refresh,” Pfizer asked ICON to bid on mock studies under several models, ranging from FSP to full-service to a combination of both. FE-1 worked on preparing the bids submitted to Pfizer, together with Michael Ohrwashel (Senior Director, Business Development), Karen Tormey (Executive Director, Business Development), and other ICON executives, including CCO McMillan. ICON provided the bids in 2023. In response, Pfizer responded that ICON was not getting any full-service work. This was a negative development for ICON given the higher margins for full-service work and the lower margins on FSP work, coupled with the fact that Pfizer’s full-service work had previously involved large, global Phase 3 studies of \$20 to \$30 million each.

139. Corroborating FE-1, FE-2 explained that in fall 2023, Pfizer had directed ICON and its other CRO providers (PPD, Parexel, and Syneos) to participate in a “mock bid defense” so Pfizer could decide how to allocate its CRO business. Cutler was intimately involved: he

approved ICON's final budget forecasting and "pitch" presentation to Pfizer; FE-2 knows this from seeing the email where Cutler signed off.

140. Nonetheless, ICON's "pitch" to Pfizer was unsuccessful. Shortly before Christmas 2023, Pfizer communicated to ICON that it would award all of its Phase 1 business—and 85% of its Phase 2 and 3 business—to other CROs. (FE-2.) FE-2 explained that these results effectively capped ICON's opportunities with Pfizer, as ICON was shut out of the vast majority of Pfizer's Phase 2 and 3 studies, which are the largest and most financially significant.<sup>4</sup>

141. Cutler knew about Pfizer's decision at the time: when FE-2 learned about it from Gore and West, their messaging indicated that Cutler and other senior executives had already been informed.

142. Once Pfizer's "strategic refresh" was completed, ICON's win rate with Pfizer dropped near zero, as FE-1 confirmed. FE-1 was aware of the declining Pfizer business from participating in monthly business development calls dedicated to Pfizer, which included representatives from each of ICON's functional groups on the sales side, including Ohrwashel (for the full-service business), Tormey, and sometimes Mark Cooper (then head of ICON FSP). During these monthly calls, the participants reviewed detailed Salesforce reports (maintained by Ohrwashel) that included, among other things, Pfizer's backlog, awards, pipeline, all open RFPs, and ICON's chance of winning those RFPs. FE-1 explained that during these monthly meetings, no one offered positive projections for the Pfizer relationship. Instead, the most positive development concerning Pfizer was an IRT award of about \$2.5 million that FE-1 achieved shortly

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<sup>4</sup> For example, an article highlighted that "[c]linical studies are responsible for the major costs of vaccine development" and estimated development costs as \$17-28 million for Phase 2 and about \$200 million for Phase 3. Thomas J. Brouwers and Bernard AM Van der Zeijst, *Vaccine Production, Safety, and Efficacy*, *ENCYCLOPEDIA OF VIROLOGY*, published Mar. 1, 2021, available at <https://pmc.ncbi.nlm.nih.gov/articles/PMC7917445/> (Figure 2).

before he left ICON in September 2024. While this award was “small dollars,” FE-1 explained that it stood out given the lack of other new awards from Pfizer.

143. As another indication of ICON’s declining business from Pfizer, FE-8—a Clinical Trial Manager in ICON’s Pfizer Strategic Business Unit from March 2022 until September 2024— noted that ICON’s dedicated PSBU was initially handling several large Phase 3 trials for Pfizer, with at least four or five Pfizer trials active. During FE-8’s tenure (starting in March 2022), however, the PSBU continuously decreased in size. FE-8 applied for a new job outside ICON in June 2024 and began interviewing in early August 2024.

144. ICON’s issues with large customers were not confined to Pfizer. By October 2023, several large pharma companies, including GSK and Sanofi, were shutting down their studies in the oncology area. (FE-2.) In fall 2023, Janssen stopped awarding any new studies to ICON due to performance issues—a situation that continued through at least February 2024. (FE-2.) FE-9 learned from his supervising SVP that large customers like Pfizer, Janssen, Eli Lilly, and Roche were reducing their business with ICON, including in the full-service area, from late 2023 and onward. And FE-15 reported that in 2023 and 2024, both internal and external sales representatives indicated that sponsors were shopping around their business and not reupping with ICON as much as in previous years.

145. Overall, FE-4—a Senior Finance Manager employed at ICON from 2019 to November 2024 who worked on large pharma customers and saw billing and revenue information for ICON’s top 5 to 10 customers—confirmed that ICON experienced a decrease in business from Pfizer and all other large clients—with only two exceptions—in early 2023 through 2024.

146. Further, Cutler approved requests from top 10 customers to reduce ICON’s project budgets. FE-2 knows this from seeing emails where Cutler approved budget cuts, which also



included Lachs, Gore, West, and Ohrwashel. For example, if an ICON budget included 40% of the budget for project management, Cutler would state something along the lines of “this is too much. They are not going to approve it. Take another \$1 million out.” The frequency of these emails increased towards the end of FE-2’s tenure in February 2024. And in 2Q24, ICON’s slowing business with large pharma drove Cutler to personally meet with the CEO of ICON’s tenth-largest customer and accept unfavorable terms in an effort to “boost” ICON’s book through new business at an even lower margin. (FE-4.)

147. FE-2 said Cutler was “aware in near real time” what the status of business was with Pfizer. As FE-2 put it, Cutler was “aware of everything as soon as we were.” Thus, as FE-2 summarized, “[t]here is no way that Cutler or any member of leadership could say they didn’t know what was happening or they didn’t have access to it.”

#### **6. ICON’s Business Wins and Book-to-Bill Ratio Were Materially Inflated**

148. Defendants materially overstated ICON’s gross and net business wins and book-to-bill ratio.

149. Crucially, these metrics indicate whether ICON’s business is shrinking or growing: since clinical trials have limited duration, ICON must replace trials that end with a stream of new business. Thus, ICON’s business wins and book-to-bill ratio measure whether ICON was securing more or less new business than the work it had performed.

150. During the Class Period, ICON reported gross business wins and net business wins (after cancellations) for each quarter. ICON calculated its book-to-bill ratio as net business wins divided by revenue in the quarter using the formula below:

$$\text{Book – to – Bill Ratio} = \frac{\text{Net Business Wins}}{\text{Revenue}}$$

151. A book-to-bill ratio above 1.0 means that ICON's new business exceeded revenue, indicating growth. For example, a book-to-bill ratio of 1.2 means that ICON had secured 20% more new business than its revenue during the period.

152. By contrast, any book-to-bill ratio below 1.0 indicates a decline, since ICON had failed to secure enough new business to replace the work it had performed during the period. For example, a book-to-bill ratio of 0.8 means that ICON had secured 20% less new business than its revenue during the period.

153. During most of the Class Period, Defendants reported book-to-bill ratios well above 1.0, starting at 1.20 for the second quarter of 2023 and peaking at 1.27 in the first quarter of 2024. Analysts highlighted this metric. For example, on October 26, 2023, UBS stated that "ICON beat our bookings expectations for Q3 . . . with a quarterly net book-to-bill of 1.26x (vs. 1.22x UBSe)."

154. In reality, however, ICON's business wins and book-to-bill ratio were significantly inflated by numerous "wins" entered into Salesforce that were highly unlikely to materialize, including "wins" without signed contracts.

155. FE-1 confirmed, from personally accessing the Salesforce system, that there were numerous studies marked as "awarded" in Salesforce even though the contract was not signed. For example, FE-1 noticed that Salesforce was showing a larger amount of "awards" than FE-1 tracked in his own Excel file of awards. Further, FE-1's manager Cohen had concerns that some of the full-service sales representatives were marking contracts in Salesforce as "awarded" to improve their numbers—even before receiving the necessary assurances and/or documentation that the studies would materialize.

156. The “awards” without signed contracts were included in Salesforce dashboards, and FE-1 believed they were also included in ICON’s public forecasts, revenues and earnings guidance, despite the absence of signed contracts.

157. Many of the “awarded” studies without signed contracts were later canceled. FE-1 knows this because he was the client account manager for the IRT component of ICON’s full-service studies (covering more than half of ICON’s full-service work for biotech customers), and thus had access to those full-service awards in the Salesforce system and tracked whether they materialized into work and revenue or whether they were canceled. FE-1 also received automatic email notifications from Salesforce when cancellations or other changes were made to these studies.

158. Corroborating FE-1, FE-9—the department head of one of ICON’s clinical research divisions until late 2024—noted that ICON’s Salesforce system shows whether a given “win” has a signed contract and recalled seeing many “wins” recorded in Salesforce, without signed contracts, during FE-9’s tenure at ICON.

159. FE-9 explained that ICON’s sales representatives are paid a percentage of the contract value for their “wins” as a commission. They are also given sales targets: (1) the dollar value of new contracts, and (2) the dollar value of change orders (called “upselling” at ICON). As a result of this compensation structure, the sales representatives are incentivized to record “wins,” even without a signed contract. (FE-9.)

160. FE-9 learned from an ICON employee that ICON has publicly reported inflated book-to-bill ratios for at least three years based on ICON sales representatives entering “wins” into Salesforce that they knew were highly unlikely to materialize, and were later canceled. Without these “wins,” ICON’s actual book-to-bill ratios for 2023 and 2024 were 0.9 or lower. (FE-9.)

161. The gap between ICON's actual book-to-bill ratios of 0.9 or lower—and its reported ratios well above 1.0—is highly material. It translates into hundreds of millions of dollars and the difference between a declining business and growth. For example, for the second quarter of 2023, ICON reported net business wins of \$2.419 billion and \$2.020 billion in revenue, yielding a reported book-to-bill ratio of 1.20. At an actual book-to-bill ratio of 0.9, however, ICON's actual net business wins were only \$1.818 billion. FE-9 noted that any book-to-bill ratio below 1 is a serious problem and means ICON's pipeline is below the level necessary to sustain the business in the medium term. (FE-9.)

162. ICON's gross and net business wins and book-to-bill ratio were further inflated because CEO Cutler personally directed ICON to book awards at larger dollar amounts than sponsors had approved. FE-7 knows this because he was copied on emails from Cutler, and sometimes was standing in Cutler's office, when Cutler gave these directions.

163. As FE-7 explained, sponsors often gave ICON awards with caveats about reducing the size or scope of a study before a contract was signed. For example, if ICON bid for a \$100 million study with 500 patients, the sponsor might award the study with the caveat that the sponsor was only approving a \$60 million study with 300 patients. At Cutler's direction, ICON would book the \$100 million award reflected in its bid. (FE-7.) However, when booking the larger award amounts, ICON knew the award amounts would decrease because ICON had agreed to the reductions during the bid defense phase, or because the award itself referenced a reduction in costs. (FE-7.)

164. FE-7 explained that ICON engaged in this practice regularly, especially near the end of the quarter, when ICON would “creatively get there” to hit the numbers. FE-7 confirmed that ICON used this practice in the second and third quarters of 2023.

165. Within the subset of ICON’s awards that FE-7 personally observed, this practice raised ICON’s claimed award numbers by \$20 to \$30 million for the quarter. (FE-7.) Further, Cutler and McMillan were aware of the practice because of the large dollar amounts involved: Cutler’s sign-off was required for opportunities of \$30 million and above, while McMillan’s sign-off was required for opportunities of \$15-\$20 million and above. (FE-7.)

#### **H. With ICON’s Share Price Artificially Inflated, Cutler and Brennan Begin Their Insider Sales**

166. Just two business days after the start of the Class Period, CEO Cutler began to unload his stock with a series of lucrative insider sales. First, Cutler sold 5,202 shares on July 31, 2023, followed by 16,000 shares on September 14, 2023, and 2,500 more shares on September 15, 2023. These sales of over 21,000 shares reaped over \$4.2 million in net profits in just seven weeks.

167. ICON’s purported success also lifted its credit rating. On October 12, 2023, ICON issued a press release touting that S&P had upgraded ICON to investment-grade (BBB-), stating that S&P highlighted ICON’s “solid operating performance and voluntary debt prepayments,” the “expansion of scope with existing clients, and profitability” after the PRA Merger.

#### **I. When Pfizer Spending Cuts Threaten ICON’s Purported Turnaround, Defendants Double Down, While Continuing to Tout Increased RFPs**

168. On October 13, 2023, Pfizer announced an “enterprise-wide cost realignment program,” including spending cuts of at least \$3.5 billion. During Pfizer’s October 16, 2023 conference call, Pfizer CFO David Denton explained that Pfizer’s cost-cutting program was “comprehensive” and would “touch all parts of the business in all regions,” “across both R&D and [Selling, Informational, and Administrative]” expenses.

169. Given Pfizer’s centrality to ICON’s business, Defendants knew Pfizer’s spending cuts posed an existential threat. Indeed, Pfizer had already significantly cut its business with

ICON, and ICON's PSBU was decreasing in size. But disclosing that reality would immediately sink ICON's share price and end Cutler's and Brennan's ability to profit from insider sales.

170. Thus, when analysts probed whether ICON's relationship with Pfizer was experiencing any issues, Defendants consistently deflected and denied.

171. On October 26, 2023, ICON held its earnings call for the third quarter of 2023. During the call, an analyst pointedly asked about "Pfizer's recently announced cost cuts" and questioned whether this was "baked into [ICON's] outlook? Or were they unexpected?"

172. In response, Cutler assured investors that the cuts were "*relatively expected*," claiming that "[w]e're in close contact with our partner customers on a regular basis, and . . . [w]e're working closely with them in terms of what they're looking to do." Cutler further declared that "*nothing has been decided at this point*."

173. Cutler was quick to spin the Pfizer initiative as a positive for ICON, stating that "*[there is] some opportunity for us and that they were happy to further consolidate their spending*," and that "these things aren't always a negative for us, but we work closely with our partners to look at it, and *we have that in the forecast*."

174. These statements were false and misleading. As detailed above, the amount of new business Pfizer was awarding ICON had dropped significantly, and ICON's dedicated PSBU had been shrinking for over a year. (FE-1; FE-8.)

175. During ICON's 3Q23 earnings call, Cutler also touted ICON's purportedly increasing RFP numbers, stating that "[o]verall, RFP activity continued to improve in quarter [three] with *growth in the high single digits* on a trailing 12-month basis." Cutler added that ICON's claimed RFP growth covered "*all the segments across biotech, large pharma . . . .* So I

talked about *high single digits as being sort of across the landscape*, and it's fairly consistently across those segments."

176. Again, these statements were false and misleading. ICON's RFPs from biotech customers had consistently declined in every quarter during 2023, and Cutler himself received quarterly emails stating that RFPs were declining across the board. Further, ICON's claimed RFP flow was significantly inflated, with up to 40% of RFPs merely for price discovery.

177. Cutler further downplayed "challenges out there in the macroeconomic environment," asserting that "*there's nothing that we've seen, certainly from an RFP point of view or from an awards point of view that would change*" the current "constructive solid positive environment." In reality, ICON had experienced a trend of losing awards from its largest customer, Pfizer, and ICON's RFP flow had been declining for at least three consecutive quarters.

178. Further, Defendants touted ICON's purported business wins and book-to-bill ratio—both of which were significantly inflated, as detailed above. Cutler cited a "good book-to-bill of 1.26x revenue in the quarter," and Brennan stated: "In quarter 3, ICON achieved gross business wins of \$3.06 billion and recorded \$474 million worth of cancellations. This resulted in an impressive level of net awards in the quarter of \$2.58 billion, and net book-to-bill of 1.26x."

179. Analysts credited Defendants' misstatements. Barclays wrote on October 26, 2023 that "RFP activity continued to grow in HSD [high single digits] in 3Q following HSD growth in 2Q. *RFP growth was broad based across biotech and pharma customers.*" Similarly, on October 26, 2023, Evercore ISI wrote that Defendants' commentary "should be helpful in quelling some worries about the overall demand environment" and accepted their assurances as to "Pharma R&D cuts," specifically citing Defendants' representations that they "*[h]ave Pfizer in the #s.*"

180. On November 14, 2023, Brennan participated in the Jefferies London Healthcare Conference. In response to an analyst question about “the RFP flow acceleration that both you and Steve Cutler have talked about kind of seemingly starting in 2Q and extending to now,” Brennan stated: *“We’ve seen definitely an uptick. . . . what we saw really in around -- it was probably around June, July time, was a significant kind of uptick from our biotech customers.* And that certainly has persisted into the good volumes that we saw and we talked about in the Q3 call and persists as we go into Q4 as well.”

181. Brennan’s claim of an “uptick” in biotech RFPs was false and directly contrary to the facts known to him at the time. ICON’s biotech RFP volume had consistently declined in every quarter during 2023. Brennan knew the truth because he personally attended quarterly meetings in 2023 where ICON’s decreasing biotech RFPs were presented. (FE-1.)

182. The Individual Defendants quickly seized the opportunity to profit from their fraud. On November 16, 2023, just two days after lying about ICON’s biotech customer RFPs at the Jefferies conference, Brennan made his first—and largest—insider sale during the Class Period, selling 30,206 shares for net profits of \$5.2 million. On November 21, 2023, Cutler followed suit, selling 18,517 shares for net profits of \$5 million.

**J. Multiple Negative Developments Further Threaten ICON’s Business**

183. Several key negative developments occurred in late 2023 and early 2024.

184. First, before Christmas 2023, Pfizer completed the “refresh” described above and shut ICON out of at least 85% of its most lucrative Phase 2 and 3 studies, as well as all full-service work. These actions slowed the pipeline of new Pfizer work to a trickle (at most).

185. Second, in late 2023 and early 2024, Pfizer, BMS, and a third large customer all switched their ICON work from FSO to FSP for both new studies and existing awards. (FE-2.)



BMS shifted to FSP in part due to a “crisis” in fall 2023 when an ICON CRA fraudulently claimed to have performed monitoring that she did not perform. (FE-2.) Corroborating FE-2, FE-3 confirmed the issue with ICON’s fraudulent monitoring for BMS and noted that BMS had not awarded ICON any new business during FE-3’s entire tenure at ICON (January 2023 through November 2024).

186. By January 2024, Pfizer advised ICON that it was moving to FSP to reduce costs. Cutler was aware of Pfizer’s switch to FSP because he reviewed and approved ICON’s internal email announcing the change. (FE-2.) Indeed, Cutler headed a special Pfizer “liaison team” at ICON, which also included senior executives Gore and West. FE-2 explained that Gore and West managed ICON’s transition from FSO to FSP and prepared multiple presentations describing the organization, treatment of benefits, and other issues.

187. Based on email updates and regular meetings with Gore, FE-2 learned that Cutler was meeting with Pfizer regularly to work out the details of the transition to FSP. FE-2 explained that Cutler and his management team had to “work out what the finances were going to be” and “approve what the structure was going to look like.” Pfizer’s transition to FSP was scheduled to occur in three “waves,” each affecting a group of studies, from February to March 2024 (with the third “wave” later extended to April 2024). (FE-2.) By February 2024, in advance of Wave 1, Gore conducted internal training sessions with slide decks to explain the FSP rollout. (FE-2.)

188. For ICON, the financial implications of three large customers’ simultaneous shift to FSP were extreme and amounted to losing hundreds of millions of dollars each year. FE-2 explained that Pfizer, BMS, and the third customer switched from nearly 100% FSO to nearly 100% FSP. This was a huge loss for ICON, since FSP was significantly cheaper for customers

and its profit margins were only around 15%, compared to 40–50% margins for FSO. (FE-2, FE-9.) Assuming that the three customers accounted for 18% of ICON’s revenues,<sup>5</sup> the 25–35% lower margin on FSP work *slashed up to \$500 million (or 21%) from ICON’s profits*—even before considering these customers’ overall reduction in revenue.

189. Corroborating FE-2, in late 2023, FE-9’s supervising SVP explained that “FSP was keeping us afloat.” To FE-9, that was a major concern, since ICON’s margins on the FSP business were significantly lower than those of the full-service segment. And as FE-2 emphasized, the combination of losing Pfizer’s Phase 2 and 3 studies and simultaneously losing “a huge chunk of margin” because of Pfizer’s switch to the FSP model was a “huge blow to ICON.”

190. Third, in January 2024, CEO Cutler—desperate to keep Pfizer’s remaining business—personally approved a \$50 million budget cut that Pfizer had demanded in September 2023. FE-2 saw emails where Cutler approved the cuts, as well as an electronic notification from ICON’s computer system that Cutler had given final approval to the cuts. FE-2 emphasized that Cutler was extensively involved in approving final budgets related to Pfizer and was “always undercutting margin” in an effort to obtain more business from Pfizer.

191. Fourth, ICON’s biotech business continued to dramatically underperform. In the fourth quarter of 2023, ICON’s senior management internally transferred \$350 million in revenue to biotech from another business unit within ICON to prop biotech up and make it appear to be doing better than it actually was. (FE-9.) FE-9’s supervising SVP explained that ICON’s biotech business was “doing miserably” and “dying.”

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<sup>5</sup> ICON claimed that in 2023, its largest customer comprised about 8.9% of revenue, while the next four largest customers (2-5) each averaged 4.5% of revenue.

192. Indeed, the \$350 million transferred to biotech is **over 13%** of ICON’s purported biotech revenues—and over 4.3% of ICON’s purported overall revenue—for 2023. The fact that \$350 million was falsely allocated to biotech also confirms ICON’s deficient internal controls.

193. Finally, with ICON’s large pharma and biotech businesses both failing, ICON’s finance operations in Ireland went into overdrive, initiating a “mad scramble” around Christmas 2023 as employees tried to find cash before year-end. As part of this scheme, ICON created fake invoices for future work that ICON had not performed to get “invoices on the books.” While this practice violated GAAP, as detailed further below (at Section IV.T), these desperate measures temporarily succeeded in concealing ICON’s actual decline from investors.

**K. In February 2024, ICON Reports Strong Earnings and Affirms Guidance**

194. As 2024 began, Defendants’ public mantra remained unchanged—demand was strong, ICON was receiving more RFPs, and ICON had already accounted for any potential impact from Pfizer’s cost-cutting initiative.

195. On January 9, 2024, ICON issued a press release announcing positive earnings guidance for 2024, stating that ICON expected revenue “in the range of \$8,400 - \$8,800 million, representing growth of 3.2% – 8.1%, and adjusted earnings per share is expected to be in the range of \$14.50 - \$15.30, representing growth of 13.5% – 19.8%, over Full Year 2023 revenue and adjusted earnings per share guidance midpoints, respectively.”

196. On February 21, 2024, ICON announced the Company’s FY2023 and 4Q23 results and re-affirmed its 2024 guidance. Cutler praised these “strong financial results despite challenging macroeconomic conditions” and cited “the positive demand environment as we enter this year.”

197. On February 22, 2024, ICON held an earnings call to discuss the FY2023 and 4Q23 results. During the call, Cutler continued to tout increasing RFPs: “In totality, across all segments, *our overall trailing 12-month RFP activity increased in the high single digits in quarter 4*, consistent with quarter 3[,] and this appears to be *continuing or even accelerating* early in 2024.” Cutler further claimed that ICON had seen an “*early ‘24 mid-teens increase in RFP[s] on a trailing 12-month basis.*” In other words, Cutler claimed that the growth in RFPs was accelerating from “high single digits” to “mid-teens.”

198. In response to an analyst question about whether ICON’s recent trends could create “upside to your expectations for the year,” Cutler reiterated that “we’re seeing sort of *mid-teens growth on the RFP opportunity.*” In the same response, Cutler claimed that ICON was “seeing a *modest uptick around mid-single digits in the biotech space* as well,” noting that “biotech stabilizing and improving . . . seems to be playing out in the first . . . very early part of this year.”

199. Contrary to these statements, ICON’s biotech customer RFPs *decreased*—never increased—during the Class Period, ICON’s overall RFPs decreased throughout 2023, and ICON’s claimed RFP flow was significantly inflated.

200. During the call, an analyst asked about the pricing and demand environment for customers in ICON’s large pharmaceutical segment and whether ICON was “seeing fewer projects across large pharma.”

201. By this point, Pfizer and other large ICON customers had already made significant cuts—including Pfizer’s decisions during 2023 to stop awarding ICON full-service business and to exclude ICON from at least 85% of its Phase 2 and 3 studies. (FE-1; FE-2.) Further, Cutler had personally approved a \$50 million budget cut for ICON’s portfolio of Pfizer studies, and was approving similar requests from other large customers with increasing frequency. (FE-2.) To

make matters worse, three large customers' shift to nearly 100% FSP had depressed ICON's margins and slashed its profit by hundreds of millions of dollars.

202. Instead of disclosing these material, negative facts, Cutler assured that ICON was *“[c]ertainly seeing more opportunities in large pharma. No question about that.”*

203. Further, when an Evercore analyst probed the “trajectory” of ICON’s “strategic partnerships with large pharma,” Cutler asserted: *“I’m not hearing again at this stage any further concerns on funding or on their R&D spend.”* The truth was the opposite. Pfizer and other large customers had already sharply reduced their business with ICON, and Cutler had personally approved large budget cuts—including \$50 million for Pfizer alone.

204. During the call, Cutler even claimed that ICON’s large customers were “becoming more open” to “outsourcing even more”: “If anything, based on the RFP[s] of opportunities we’ve got over the last couple of months and even last quarter, . . . we’re seeing more opportunities. So I guess I keep saying it, but as their budgets become perhaps a little bit more constrained or they watch where they’re spending their dollars, they do appear to [be] becoming *more open to outsourcing and outsourcing even more than they’re doing at the moment.*” Again, Pfizer and other large customers were doing the opposite.

205. To the extent Defendants acknowledged any customer shift to FSP, they consistently—and falsely—downplayed its significance. For example, during the February 22, 2024 call, Cutler falsely claimed that any shift would be “very gradual”—and, crucially, Brennan assured that *“certainly”* the “midpoint” of ICON’s guidance *already reflected “the mix shift, if you like, to the extent we see that* during the course of the current year.” Brennan further tried to deflect by claiming that *“I’m not even sure we’ll see a material shift in terms of the percentage year-over-year from ‘23 to ‘24 in terms of the FSP, non-FSP business.”*

206. At the time of these statements, Defendants knew that Pfizer, BMS, and a third large customer—which comprised about 18% of ICON’s overall business—were shifting to nearly 100% FSP within weeks.

207. Defendants also continued to tout ICON’s purported business wins and book-to-bill ratio. During the call, Defendant Brennan stated: “In quarter 4, ICON achieved gross business wins of \$2.99 billion and recorded \$461 million worth of cancellations. This resulted in a solid level of net awards in the quarter of \$2.53 billion, and net book-to-bill of 1.22x.”

208. On February 26, 2024, just days after the earnings call, Defendant Brennan sold 7,021 shares at \$316.33 per share, reaping \$2.2 million in net profits.

**L. In February 2024, Cutler Internally Admits That ICON Is No Longer a Pfizer Preferred Partner**

209. Despite Defendants’ highly positive public statements in early 2024, within ICON, Cutler admitted that the Pfizer relationship was collapsing.

210. Specifically, during a Company-wide quarterly town hall in February 2024, Cutler announced (in a pre-recorded video) that ICON had lost its contract with Pfizer as a result of softening in the COVID vaccine space. As FE-3 recalled, Cutler indicated ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer.

211. Notably, when ICON became a Pfizer preferred partner in 2011, ICON publicly touted that its “strategic partnership with Pfizer” would “see [ICON] serve as one of two preferred providers of clinical trial implementation services.”<sup>6</sup>

212. When ICON lost the Pfizer preferred partnership, however, Defendants issued no press release. Instead, they concealed the truth and repeatedly misled investors.

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<sup>6</sup> <https://investor.iconplc.com/news-releases/news-release-details/icon-selected-pfizer-global-strategic-partner-clinical-research>

213. During the same February 2024 town hall, Cutler also stated that ICON had missed its revenue and new business award targets and presented a slide deck that showed ICON had missed its targets. (FE-3.)

214. Cutler's internal disclosure of this negative news prompted FE-3 to discuss the impact of losing the Pfizer preferred partnership in meetings with his supervisor, Vice President Mary Frances Sassaman, and Sassaman's boss, Brandon Early (VP of Project Delivery until December 2023, then SVP, Global Project Delivery—ICON Biotech through November 2024), as well as instant messages with colleagues.

**M. In March and April 2024, Defendants Continue to Misrepresent ICON's Business Growth**

215. On March 5, 2024, Brennan spoke at an industry conference hosted by TD Cowen. The TD Cowen analyst asked Brennan about the funding environment in biotech and how ICON's relationships with large pharma clients had evolved following the PRA Merger.

216. In response, Brennan lauded the PRA Merger, claiming that ICON had "good customer retention" and that ICON's large pharma business was increasing: "in the large and midsized pharmas, it's worked well over the last couple of years. We've seen good traction. We've seen the evolution of existing relationships and development of new relationships in that space."

217. Further, when the analyst cited potential issues with "cost-cutting and concerns with the large customers," Brennan misleadingly deflected any issues, claiming that "*the thinking around what the model should look like has been done*." Even some of the new selections of partners has been done. And I think what I'd like to see now is more of a traction. *They are all saying that they're going to increase spending*, even some of the -- I think, some of the companies that have been more troubled over the last period have even said in their own press releases over

the last while that Q4 was probably at a later point and they want to continue to increase R&D spend as they go forward.”

218. What Brennan did *not* say was that ICON’s key relationship with Pfizer—its largest customer—had continued to decline. Indeed, Pfizer’s “thinking around what the model should look like” meant drastically reduced business for ICON, as detailed above, and two other large customers had also shifted nearly 100% of their business to FSP, slashing ICON’s profit margins. And a month earlier, Cutler had internally admitted that ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer.

219. Further, ICON had started “dissolving” the dedicated PSBU because Pfizer was moving the work in-house. (FE-8.) That led FE-8’s supervisor to encourage FE-8 to apply to Pfizer in-house positions in February or March 2024. And by March 2024, ICON had made significant layoffs, including from the PSBU. FE-8 indicated that Cutler and Brennan were aware that ICON was dissolving the PSBU, since they participated in periodic Zoom town halls where they answered questions from ICON employees submitted by Zoom chat. (FE-8.) FE-8 explained that by early 2024, these questions expressed concern about bonuses and why ICON was laying off employees. FE-8 confirmed that there wasn’t much work within the PSBU in the first half of 2024 and emphasized, “everyone was applying for jobs outside of the PSBU.”

220. On March 6, 2024, the day after the TD Cowen conference, Cutler executed a large insider sale, unloading 15,442 shares at \$335.98 per share—ICON’s highest share price to date—to reap \$5.2 million in net profits. This was Cutler’s final insider sale during the Class Period. In total, Cutler sold 23.2% of his shares and vested options during the Class Period and secured \$15.8 million in proceeds and \$14.5 million in net profits.



221. On March 12, 2024, Defendant Cutler participated in the Barclays Global Healthcare Conference, where he asserted that “the demand environment for us is strong.” Cutler further asserted that ICON was “seeing overall a very constructive environment, fueled for us mainly by large pharma.” Cutler claimed that “[w]e’ve *certainly seen some significant upticks in opportunity in large pharma over the last 3 to 6 months*”—while knowing that ICON’s business from three large customers, including Pfizer, had sharply declined, and after admitting that ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer.

222. In addition, Cutler asserted that “[t]he biotech front has also been positive. We see RFPs in the mid-single digits, up a trailing 12-month basis.” In truth, ICON’s biotech customer RFPs had continued to decline.

223. On April 3, 2024, ICON issued a press release announcing that Brennan would be stepping down as the Company’s CFO for “a new opportunity outside of the CRO industry.” Behind the scenes, as detailed further below, ICON’s fraudulent revenue recognition and other GAAP violations had begun to collapse in light of Brennan’s imminent departure.

224. Publicly, however, ICON allayed any concerns about a CFO transition by reaffirming its previously announced full-year 2024 guidance in the same press release. Analysts accepted ICON’s assurances. On April 3, 2024, an Evercore ISI report expressed “surprise timingwise” at the announcement, but noted that Brennan’s departure was occurring “at as calm a time as any for a transition.” On April 4, 2024, a Truist report noted Brennan’s departure but highlighted ICON’s statement that “this transition will not impact its approach to guidance in any manner, especially as . . . the first 2 quarters are important in terms of impact to full year revenue.” Truist added that “Brennan reiterated the company’s tone and comments from earlier in the year around the stronger start to the year and biotech being in a more favorable position.”

225. On April 25, 2024, ICON held a conference call to discuss its financial results for the first quarter of 2024. In his prepared remarks, Defendant Cutler claimed that “underlying demand drivers are incrementally more positive . . . . Proposal volumes are at healthy levels with ***overall RFP volume increasing low-double digits on a trailing 12-month basis.***” In response to analyst questions, Cutler stated that ICON saw an increase in biotech RFPs that was “probably ***more in the mid-singles.***”

226. However, Cutler made no mention of the fact that ICON’s biotech customer RFPs had continued to decrease, not increase.

227. Cutler and Brennan also fielded a specific analyst question about how much large pharma R&D “is already locked in,” especially in light of recent news about Bristol Myers Squibb’s layoffs of 2,200 employees, and “upside/downside risk for the rest of the year.”

228. In response, Cutler declared that ICON had seen “***very stable and very strong demand*** in the large pharma” over the last 12 to 18 months and that “[n]othing has changed”: “we’ve seen pretty strong demand in the large pharma space. And it’s not just this quarter. ***It’s been really over the last 12, 18 months. Nothing has changed in that for now.*** . . . Overall we see a very stable and very strong demand in the large pharma.”

229. That was simply false. Cutler had internally admitted that ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer. And Cutler had known for months that (i) Pfizer and other large customers had made significant cuts and shifted nearly 100% to FSP, slashing ICON’s profit by hundreds of millions of dollars; (ii) Pfizer had stopped awarding ICON any new full-service business and at least 85% of its Phase 2 and 3 studies; (iii) Cutler had given Pfizer a \$50 million budget cut on the remaining work; and (iv) ICON was “dissolving” the dedicated PSBU and laying off employees. And notably, while ICON had previously reported the

percentage of revenue from its largest customer on a quarterly basis, ICON *stopped disclosing* that figure in 1Q24—as ICON was shutting down the PSBU and laying off employees.

230. During ICON’s April 25, 2024 earnings call, Cutler further claimed that ICON’s “*win rate in that biotech space has gone up over the last quarter or so.*” This statement was highly significant to investors because it indicated that ICON was securing a higher percentage of “wins” in a key growth area. A UBS analyst followed up, asking Cutler: “Steven, I was hoping maybe you could elaborate a bit further on your improved win rate in biotech.” Cutler responded, “Dan, I could give you a million reasons why we’ve improved that. It’s a multifactorial thing,” and reiterated that ICON had “a *nice uptick on the win rate.*”

231. These statements were outright false. In reality, Cutler knew ICON’s biotech win rate had *decreased* because he had personally complained about it at a Company-wide town hall in February 2024. Specifically, during the Company-wide town hall in February 2024, Cutler spoke about ICON’s lower biotech win rate, indicating that the biotech RFPs that ICON received were not converting to wins at the same rate as in the past. (FE-3.)

232. In addition, FE-3 attended a separate town hall for ICON’s biotech division in the first quarter of 2024 where Smyth similarly announced that the biotech RFPs that ICON received were not converting to wins at the same rate as in the past. As FE-3 stated, it was clear that ICON’s win rate had declined and not improved: Smyth explained that the fourth quarter of 2023 had been “difficult” and that instead of winning 1 of 3 RFPs, ICON was now only winning 1 of 5 or 6 RFPs. During the town hall, Smyth attributed the lower conversion rate to sponsors going to more vendors than in the past and price shopping across six or more CROs (compared to three in the past).

233. Nonetheless, analysts accepted Cutler's lies: on April 25, 2024, UBS wrote that "*ICON flagged an increasing win rate in biotech* driven by commercial/marketing rebranding efforts in its biotech segment" and raised its price target on ICON to \$380 (from \$368).

**N. Defendants Exploit ICON's Inflated Share Price to Offer New Securities and Refinance Its Costly Debt from the PRA Merger**

234. With ICON's share price north of \$300, Defendants capitalized on ICON's apparent success to offer \$2 billion in bonds to repay a portion of its \$3 billion term loan from the PRA Merger. ICON's bond offering closed on May 8, 2024.

235. Two days later, on May 10, 2024, CFO Brennan sold 7,930 shares of stock at \$316.43 per share, pocketing \$2.5 million in net profits.

**O. Defendants Make Further Misstatements at ICON's May 2024 Investor Day**

236. Next, ICON held an Investor Day on May 30, 2024. In prepared remarks, Defendant Balfe stressed ICON's growth in the "large pharma space." Balfe declared that "[t]he rate at which we've managed to add new alliances in the space and to expand the alliances we already have into new business areas has increased," claiming that "[o]ne of the founding pillars of the deal rationale for the merger between ICON and PRA was that we would advance our position in this sector, and I'm pleased to say that is borne out by the data."

237. Balfe further asserted: "We have seen in the last 18 months, in my 25 years, the most sustained and intense period of realignment or *refreshing of large pharma preferred partnerships*. And it's particularly encouraging that *ICON has come out of that period with all of the alliances we had before, many of them expanded.*"

238. Balfe concealed the truth that the "refreshing of large pharma preferred partnerships" was highly negative for ICON. ICON's largest customer, Pfizer, had sharply reduced its business starting in 2023, leading ICON to shut down the PSBU and lay off employees

(whose employment was project-specific), and forcing Cutler to admit internally that ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer. Further, Pfizer and other large customers’ shift to nearly 100% low-margin FSP work stripped ICON of hundreds of millions of dollars in profits.

239. Balfe knew the truth. His role focused specifically on ICON’s large pharma customers. He was intimately involved with the Pfizer relationship and attended two-and-a-half-day QBR meetings where he saw PowerPoint presentations with detailed operational metrics for ICON’s key accounts, including Pfizer (FE-11), as detailed below. (*Infra* Section VII.B.11.)

240. At the May 30, 2024 Investor Day, Defendants also continued to claim that ICON’s RFP flow was increasing, including in biotech. CEO Cutler stated that “we’ve been in a pretty good place on RFPs, both in the large pharma and the biotech space over the last several quarters.” Again, that was false: ICON’s biotech customer RFPs had consistently declined, ICON’s overall RFPs had declined throughout 2023, and ICON’s overall RFP volume was significantly inflated.

241. As ICON’s business continued to slow, the Company executed two more rounds of layoffs—with no public announcement—in May and June 2024.

**P. In July 2024, ICON Reports Soft Earnings, But Defendants’ Misstatements Continue**

242. On July 24, 2024, ICON reported relatively weak financial results for the second quarter of 2024 in a press release filed on Form 6-K with the SEC. As detailed further below, ICON’s weak results reflected the initial, partial collapse of Defendants’ fraudulent scheme, although Defendants continued to make misstatements that concealed the full truth.

243. On July 25, 2024, ICON held a conference call with analysts to discuss the 2Q24 results. In prepared remarks, Cutler stated: “We remain encouraged by the *leading indicators in*

*our market that support a solid demand environment*, including *continued growth in RFP flow* and the overall consistent level of opportunities we are seeing across our customer segments.” Cutler added that the biotech market was “continuing to stabilize,” with “a *modest uptick in RFPs on a trailing 12-month and sequential basis* within this segment.” Again, that was not true; ICON’s biotech customer RFPs had declined for over a year and continued to do so.

244. Despite Defendants’ efforts to put a positive spin on ICON’s relatively weak results, ICON’s share price declined by over \$18 after the 2Q24 earnings call.

245. With Defendants’ scheme beginning to unravel, CFO Brennan rushed to execute his final insider sale. On July 29, 2024—just two business days after the 2Q24 earnings call—Brennan unloaded 26,064 shares at \$325.99 per share to generate net profits of \$5.2 million. In total, Brennan sold 98.6% of his shares and vested options during the Class Period and raked in \$21.3 million in proceeds and \$15.1 million in net profits.

**Q. By Mid-2024, a Large Pfizer Vaccine Trial Fails, Further Crippling ICON’s Pfizer Business**

246. On top of Pfizer’s sharp reduction in new business awarded to ICON, by mid-2024, one of ICON’s largest remaining projects for Pfizer—a large Phase 3 COVID-flu vaccine study—failed its trial. This failure was disastrous because the trial, if completed, stood to generate significant money for ICON—at least \$60 million.

247. FE-8, who joined ICON as a Clinical Trial Manager in the PSBU in March 2022, was hired into the PSBU to work on COVID trials and specifically worked on Pfizer’s RSV and COVID/flu “combo” vaccine studies.

248. FE-8 explained that the COVID/flu “combo” vaccine study was a large Phase 3 trial that involved about 8,800 participants. Corroborating FE-8, the U.S. government’s database

of clinical studies, [clinicaltrials.gov](https://clinicaltrials.gov), identifies Pfizer's Phase 3 trial of a COVID-flu vaccine candidate called PF-07926307 involving 8,798 people.<sup>7</sup>

249. According to FE-8, over 50 ICON personnel within the PSBU worked on the Pfizer COVID-flu vaccine trial, which had an estimated contract value of at least \$60 million. He supervised 15 trial sites that collectively enrolled about 1,000 patients.

250. However, the Pfizer trial quickly failed to meet one of its primary objectives: showing that PF-07926307 was at least as effective against influenza B as existing influenza vaccines. In vaccine development, the failure to meet a primary objective is a highly material negative development that calls the potential vaccine's viability into question. Indeed, since Pfizer's proposed COVID-flu vaccine was *less effective* against flu than a flu-only vaccine, it had no regulatory or commercial viability.

251. FE-8 reported that by early August 2024, he and ICON learned that the Pfizer COVID-flu vaccine had failed its Phase 3 trial. FE-8 recalls learning of the trial failure by early August 2024 because he had begun interviewing for a new job at the time.

252. Defendants knew about the Pfizer trial failure by early August 2024 at the latest. Indeed, on August 16, 2024, Pfizer itself publicly disclosed that "[t]he trial did not meet one of its primary immunogenicity objectives of non-inferiority against the influenza B strain"<sup>8</sup>—although ICON's involvement in the failed trial was not publicly disclosed.

253. The Pfizer COVID-flu vaccine trial's failure was a large financial setback for ICON. FE-8 noted that under its contract with Pfizer, ICON would lose a significant amount of money from the COVID-flu vaccine trial's failure. Further, once a trial fails, enrollment stops

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<sup>7</sup> <https://clinicaltrials.gov/study/NCT06178991?a=1&b=5>

<sup>8</sup> <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-mrna-based-combination>

immediately and Pfizer's staffing needs decrease. FE-8 explained that there was "nowhere for me to go" in terms of another study with Pfizer. He saw that there were no Pfizer jobs posted on ICON's job board and no more active studies with Pfizer, confirming the dry spell with Pfizer in the first half of 2024.

**R. In Late August 2024, ICON's Deteriorating Biotech Performance Triggers a \$100 Million "Revenue Sweep"**

254. FE-3 explained that Smyth demanded quarterly "revenue sweeps" when ICON's actual performance in the biotech segment was not meeting its targets. Such sweeps had occurred twice in 2023 and initially involved shortfalls of about \$10 million.

255. However, in the first three quarters of 2024, the sweeps continued every quarter, with increasingly large shortfalls—culminating with a "gap" of \$100 million in the third quarter of 2024. (FE-3.) Specifically, the \$100 million "revenue sweep" was initiated in late August 2024 on a Thursday night and demanded responses by Monday morning Irish time.

256. FE-3 noted that the request was "ridiculous" given the short time remaining in the third quarter and the large dollar amount. The "gap" of \$100 million compared to total quarterly revenues of approximately \$750 million for ICON's biotech segment. (FE-3.)

257. The "revenue sweep" began with an email announcing the "sweep," which was sent by Smyth or one of his SVPs and signed by Smyth (who was always copied), to all of ICON's Project Delivery personnel, from SVPs down to junior levels. (FE-3.) The emails linked to or attached a spreadsheet identifying the studies where additional revenue could be recognized (*e.g.*, by pulling billable work forward or adding work from ICON's out-of-scope logs). (FE-3.)

258. Next, the recipients (including FE-3) responded with their updates to the spreadsheet identifying additional revenue. FE-3 noted that the spreadsheet covered ICON's biotech segment, and FE-3 saw the updates that others were sending.



259. Although the revenue sweep instructions formally came from Smyth, ICON employees widely understood that the sweeps were directed by CEO Cutler given his extensive involvement in the details of ICON's operations; Smyth reported directly to Cutler. (FE-3.)

**S. In September 2024, Defendants Affirm Guidance and Falsely Claim There Had Been “No Material Change” in ICON’s Business**

260. With the Pfizer relationship collapsing, the large COVID-flu vaccine trial's failure, and ICON's ongoing slowdown in biotech, by September 2024, Defendants' time was running out.

261. Nonetheless, Defendants seized another opportunity to mislead investors. On September 10, 2024, Cutler participated in the Baird Healthcare Conference. In prepared remarks, Cutler assured investors that ICON was “reiterating guidance” for 2024. Cutler further claimed that in the “biotech space,” *“the percentage of RFPs that are coming through, the dollar amounts that are coming through remain strong, remain good.”* Again, this was false: ICON's biotech customer RFPs had continuously declined since 2022.

262. Cutler further asserted that there were *“[n]o material changes” “to the environment or to our business* apart from, as I said, some of the biotech slowdown and some of the biotech decision making, which is having potentially some impact in the very short term.”

263. In response to an analyst, Cutler confirmed that any potential headwinds were already incorporated into ICON's guidance, assuring that *“there’s nothing that’s fundamentally changed that we hadn’t already thought about or included in our guidance.* We are seeing a little bit of what we thought we were thinking, and those predictions if you like or that planning, is coming to fruition, if that makes sense. So we’re seeing what we thought we’d see.”

264. When the analyst asked if “there’s really no notable change in, frankly, much of anything since you talked last quarter,” Cutler reiterated the point: “No, that’s exactly right. *No material -- no really material changes.*”

265. These assurances were false: ICON's business had materially worsened, as Pfizer and other large customers had made significant cuts and shifted nearly 100% to FSP, and ICON was no longer a preferred partner of Pfizer; the Pfizer vaccine trial's failure by early August 2024 was another material setback. Further, biotech RFPs continued to decline, and ICON's biotech segment was subject to a "revenue sweep" to attempt to close a \$100 million "gap" in the third quarter of 2024 (FE-3). None of these existing, material negative facts—known to Defendants at the time—were reflected in ICON's guidance.

**T. Defendants Violate GAAP Through Fraudulent Accounting Practices to Overstate ICON's Revenues, Profits, and Cash**

266. To boost ICON's claimed financial performance and obscure its declining business performance, during the Class Period, Defendants engaged in multiple fraudulent revenue recognition and other accounting practices that violated GAAP.

267. Specifically, Defendants (1) extended ICON's reporting periods to inflate billing, cash received, revenues, and profit; (2) deliberately created fake invoices to inflate ICON's purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON's revenue, profit, income, and margins by not "loading" project costs that had "overburned" ICON's budget; and (4) prematurely recognized revenue from unsigned change orders and before contractual milestones, while forecasting "efficiencies" to boost margins. Each violation is detailed below.

268. As a result of these GAAP violations, ICON's publicly reported revenue, income, profit margins, billing, and cash were materially overstated, and its financial statements did not accurately reflect its actual billing, cash, and revenue at the end of the stated periods.

# **1. Percentage-of-Completion Revenue Recognition**

269. Defendants represented that ICON complied with GAAP. ICON purported to recognize revenue under Accounting Standards Codification 606 (“ASC 606”), which constitutes GAAP’s governing revenue recognition standard for sales contracts.

270. Under ASC 606, ICON claimed to apply the following five steps to recognize revenue during each reporting period:

1. Identify the contract(s) with a customer;
2. Identify the performance obligation in the contract;
3. Determine the transaction price;
4. Allocate the transaction price to the performance obligations in the contract;
5. Recognize revenue when (or as) the entity satisfies the performance obligation(s).

271. Under ASC 606, ICON is only permitted to recognize revenue as it *performs* work under a given contract based on its percentage of completion. ICON explained that “[r]evenue is recognized over time as the single performance obligation is satisfied. The progress towards completion for clinical service contracts is measured based on an input measure being total project costs incurred (inclusive of pass-through/ reimbursable expenses) at each reporting period as a percentage of forecasted total project costs.”

272. Thus, ICON purported to calculate the percentage of completion as (1) costs incurred to date, divided by (2) the total estimated costs of the project. For example, when ICON had performed 25% of its contractual obligation, ICON could recognize 25% of the revenue. At 100% completion, ICON could recognize 100% of the revenue. The difference between the revenue recognized and ICON’s costs incurred is ICON’s profit.

## 2. **ICON Extended Reporting Periods to Inflate Billing, Cash Received, Revenue, and Profit**

273. One basic GAAP violation involved holding reporting periods open beyond their stated close, which rendered ICON's Class Period financial statements false and allowed ICON to inflate its reported revenue and profit.

274. FE-4 stated that ICON regularly held its books open for 10 to 14 days after month- or quarter-end to increase its billing and cash numbers. FE-4 explained that when ICON's monthly and quarterly targets for billing and cash were not met by the end of the month or quarter, the reporting period was simply held open—typically by 10 to 14 days—until the targets were reached. Holding the periods open led to a cycle where the next period was effectively shortened by 10 to 14 days, preventing ICON from hitting the targets for that period, which was then held open in turn.

275. Senior Vice President of Finance Alan Sheehan communicated the “directive” to hold periods open to FE-4 and “took a hard line” on the issue in meetings. However, as FE-4 explained, “there’s no way” Sheehan would have done that if CFO Brennan was unaware. Notably, Sheehan reported directly to Brennan.

276. As the CFO and CEO of a public company, Brennan and Cutler knew—and were required to know—when ICON's reporting periods actually closed. Indeed, Brennan and Cutler personally affirmed that “*material information*” and “*information required to be disclosed*” was “*accumulated and communicated to*” them. Specifically, under the Sarbanes-Oxley Act of 2002 (“SOX”), Brennan and Cutler each certified that they had designed ICON's disclosure controls and procedures to “ensure that material information relating to” ICON “is made known to us by others within [ICON], particularly during the period in which this report is being prepared.” They further affirmed that ICON's disclosure controls and procedures “ensure that information required

to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the Company's management, including its principal executive and principal financial officers [Cutler and Brennan]."

277. FE-4 further noted a "mad scramble" at ICON to find "anything" that could be counted towards the cash and billing targets. Sheehan, Vice President of Finance Pat O'Grady and Senior Director of Finance Ronan Flood relayed to FE-4 that it was Brennan's "priority one, two and three to get cash in the door," and that Brennan was aware of the "anemic" cash ICON was actually receiving at times.

278. Holding reporting periods open beyond their stated close is a classic violation of GAAP. ASC 606-10-25-23 only allows revenue to be recognized "when (or as)" ICON "satisfies a performance obligation." By holding periods open, ICON inflated projects' percentage of completion with additional work performed while the periods were held open and recognized additional revenue and profit. Further, ICON recorded assets and transactions that it was not entitled to collect from its customers at the end of the relevant period. (ASC 606-10-45-4.)

279. In addition, the Public Company Accounting Oversight Board's Accounting Standard 1105: Audit Evidence, AS 1105.11, "Financial Statement Assertions," states that in "representing that the financial statements are presented fairly in conformity with the applicable financial reporting framework, management" makes the following "assertions" (among others):

- "*Existence or occurrence*—Assets or liabilities of the company exist at a given date, and recorded transactions have occurred during a given period."
- "*Completeness*—All transactions and accounts that should be presented in the financial statements are so included."

280. ICON violated both assertions by holding periods open past their reported closing date. First, ICON's financial statements included assets and transactions that occurred *after* the close of the "given period," and thus did not "exist at a given date" or "occur during a given

period.” For example, ICON’s purported cash received as of “December 31, 2023” in reality included cash received in January 2024. Second, by recording assets and transactions in periods in which they did not exist or occur, ICON’s financial statements did not include “all transactions and accounts that should be presented in the financial statements.” Accordingly, ICON’s fraudulent practice of holding its reporting periods open violated GAAP.

281. Holding ICON’s reporting periods open had a significant impact on its financial statements. FE-4 stated that ICON’s practice of holding reporting periods open by 10 to 14 days added approximately \$100 to \$200 million to ICON’s billing and cash each quarter.

282. Notably, these amounts are 5–10% of ICON’s purported quarterly revenue reported in its public filings, and even larger percentages of its purported cash from operating activities. For example, ICON claimed \$440.1 million in cash generated from operating activities for 4Q23—a figure that was *inflated by up to 45%* as a result of holding the period open. This practice also significantly inflated ICON’s profit and margins.

283. Further, ICON recorded clients’ mere *promises* to pay as cash that ICON had *received*; ICON included those promised amounts in the cash it had purportedly received when it closed a period. (FE-4.) This is another violation of GAAP. (ASC 606-10-45-4.)

### **3. ICON Used “Fake” Invoices to Improperly Recognize Additional Revenue**

284. ICON also issued fake invoices to prematurely recognize additional revenue and pull it forward from future periods.

285. FE-4 stated that under Sheehan’s direction, ICON “deliberately” created “fake” invoices for future work that ICON had not performed. For example, ICON issued invoices during a given period where the contractual billing milestone was in the first 10 days of the next period. These fake invoices served to get “invoices on the books.”

286. There is no legitimate reason for creating fake invoices for work that ICON had not yet performed. Indeed, the fake invoices were *marked with an asterisk* because they were “*known to be fake*” and were not intended to be sent to ICON clients.

287. Nonetheless, FE-4 was given a “firm directive that this had to happen.” The fake invoices were widely discussed within ICON’s Finance Department; the only reason FE-4 and his colleagues could identify for this practice is that CFO Brennan and CEO Cutler were probably about to leave ICON and wanted to “jack up” its share price.

288. Indeed, ICON used these fake invoices to artificially inflate its percentage of completion and prematurely recognize revenue pulled forward from future periods. Under ASC 606, ICON can only recognize revenue once it has actually *performed* its contractual obligations. Crucially, ICON’s fake invoices—for work it had *not* yet performed—provided a pretext for ICON’s management to claim that it had performed services and thereby recognize revenue that ICON had not actually earned. ICON thus manipulated its financial results by prematurely recognizing revenue in violation of GAAP.

289. As FE-4 explained, ICON’s creation of fake invoices created a “hole” in the next month, which continued over time. The issue came to a head in Christmas 2023, when ICON fell significantly short of its targets. FE-4 described a “mad scramble” as employees worked 14- to 16-hour days to try to find cash. “The billing practices got pretty ropery” as ICON issued fake invoices to clients, such as Celgene. (FE-4.)

#### **4. ICON Omitted Project Costs to “Hold the Margins” and Recognize Additional Revenue**

290. As detailed below, ICON manipulated and inflated its revenues, profit, and margins, and obscured negative margins on projects, by not “loading” certain project costs.

291. ICON Bears Responsibility for Cost Overruns: ICON worked primarily with fixed-price contracts, where any cost overruns are ICON's responsibility. Thus, ICON customers are not required to pay for hours or fees beyond the original accepted bid. As ICON's 2022 annual report explained, "Many of our contracts are long-term fixed price or fixed unit price contracts for services." For example, a 2020 agreement between ICON and the U.S. government specified: "Under no circumstances shall the Government's financial obligation exceed the amount obligated in this Agreement or by amendment to the Agreement."<sup>9</sup>

292. Because ICON Underbid Studies, ICON Regularly Experienced "Overburn": In an effort to win business, ICON regularly issued low-ball bids for studies. For example, FE-10 reported that at the direction of senior management, ICON regularly made "lean" bids for projects that were "not enough to get the work done." Similarly, FE-14 explained that it was common for ICON senior leadership to green-light discounts on \$30 million-plus deals to get the work. FE-14 recalled that a member of ICON's senior leadership said ICON would never lose a deal due to pricing. FE-6, a Finance Manager at ICON from 2021 to November 2023, corroborated that ICON consistently bid studies too low.

293. Internally, ICON called the difference between its budgeted and actual project costs "overburn." ICON rigorously tracked overburn given its significance for ICON's profits and margins. For example, ICON used the Tableau tool within Salesforce to track the actual hours for each project, as well as "units" based on the number of hours for a given task, and compared these figures to ICON's budget to assess overburn. (FE-10.) The Tableau tool provided dashboard reports, including a "finance" report and a report that flagged each study as being in "red," "amber"

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<sup>9</sup> <https://www.hhs.gov/sites/default/files/covid-related-mcm-clinical-trial-agreement-with-icon.pdf>



or “green” status, with red and amber indicating that the project was underperforming. (FE-10.) FE-8 explained that ICON’s studies for Pfizer experienced overburn on the CRA monitoring component; ICON closely tracked this cost and Pfizer was not happy with the overburn, requiring ICON to reduce monitoring visits. Similarly, FE-2 stated that ICON was overburning on four multiple myeloma studies for Pfizer and incurring extensive overtime that was not being billed to Pfizer.

294. ICON’s regular underbidding of projects—and the resulting “overburn”—directly eroded its profit margins because under ICON’s fixed-price contracts, customers were under no obligation to pay any additional amounts to ICON for work beyond the project budget. For example, if a project budget reflected \$20 million in revenue and \$10 million in costs (yielding \$10 million profit at a 50% margin), but actual costs reached \$16 million, ICON would be left with only \$4 million in profit (at a 20% margin).

295. GAAP Required ICON to Continuously Update Estimated Costs: If ICON incurs additional costs—even if they make a project less profitable—they must be included in ICON’s revenue and margin calculations. ASC 606-10-25-35 requires that “[a]s circumstances change over time, an entity shall update its measure of progress to reflect any changes in the outcome of the performance obligation.” And ICON’s SEC filings represented that its cost calculations were up-to-date and accurate, stating that ICON performed (1) “an evaluation of labor and related time cost incurred at the reporting date” and (2) “an up to date evaluation of the forecast costs to complete” projects.

296. In violation of GAAP, however, ICON artificially inflated its gross margins and revenue by omitting significant portions of project costs that ICON had actually incurred.

297. ICON Omitted Project Costs to Inflate Margins: ICON's finance personnel were instructed to inflate ICON's margins using a process called "cost not loaded," or "CNL." FE-5, a Project Financial Analyst from spring 2022 until August 2024, was instructed by his managers Justin Mason (Director, Finance Business Partnering) and Matt Doran (Supervisor, Financial Planning) not to "load" certain project costs to prevent margins from declining.

298. Specifically, FE-5 explained that Mason and Doran indicated that they wanted no change in margins. Thus, whenever additional project costs caused margins to decline, even by 0.2%, Mason and Doran instructed FE-5 to apply a "CNL" entry in ICON's software used for financial reporting (called "Revenue") to prevent the increased costs from impacting margins. These instructions were typically given to FE-5 via Teams chat. Mason also held Teams meetings and explained that the "CNL" practice came from Mason's supervisor or ICON's CFO, explaining that the "instructions from above" were that "we need to hold margin for the studies."

299. FE-5 explained that the CNL process had three steps:

- (1) First, FE-5 used an Excel workbook with a "CNL" tab that calculated the dollar amount of costs necessary to keep margins the same.
- (2) Second, ICON's Revenue software had a button to add costs to a study, with a drop-down menu that allowed the user to select "Costs Not Loaded." FE-5 selected the "Costs Not Loaded" option and entered the dollar amount from the Excel workbook. The software also required a mandatory text comment, which FE-5 entered as "CNL to hold the margins."
- (3) Finally, FE-5 submitted the Revenue entry for approval. FE-5 explained that if the entry showed a drop in margin, Mason rejected it and instructed FE-5 to add a CNL entry.

300. FE-5 noted that the CNL practice was standardized and applied across studies. FE-5's own portfolio was about \$30 million and included over 20 studies, mostly biotech with some large pharma. FE-5's friends at ICON worked on large pharma studies, including for Janssen and Pfizer, and reported that the CNL practice was also applied on their studies.

301. FE-5 confirmed that the CNL practice substantially impacted ICON's current margin on studies. For example, FE-5 stated that the use of CNL greatly impacted at least half of his studies, resulting in up to a 10% to 20% difference in margin. FE-5 further stated that for one study, without CNL, the margin was negative—meaning ICON's project costs exceeded its revenue.

302. FE-5 noted that margins declined over time for most projects; as a result, the amount of CNL grew to keep the margins the same. Several of FE-5's studies had margins that worsened by a few percent each month, so applying CNL to hold the margins had a large impact over a year.

303. FE-5 was uncomfortable with ICON's use of CNL. The explanation provided by FE-5's supervisors was that they would "fix it next month," which never happened. Instead, FE-5 was provided with the same CNL and "hold the margins" instruction the next month. The CNL practice continued until FE-5 left ICON in August 2024.

304. FE-6 corroborated FE-5's account of how ICON used CNL to "hold the margins." FE-6 was instructed to hold the margins by using the CNL procedure. The instruction was communicated by Senior Finance Director Bridget Hennessy (via email or phone), although FE-6 believed that Hennessy was new to the role and inexperienced, so the actual instruction came from the person above her, Senior Director of Finance Ronan Flood.

305. FE-6 also corroborated FE-5's description of the mechanics of the CNL process. FE-6 explained that ICON used a "reserve workbook" to calculate the amount of costs that were necessary to remove to keep the margin the same. The calculation was based on hours and an average rate. For example, the spreadsheet included an average hourly rate for North America-based workers to facilitate calculation of how many hours needed to be removed to preserve the

study's margin. FE-6 noted that the workbook was saved in ICON's Revenue system as audit support. Finally, FE-6 entered the CNL amount into the Revenue system and inserted comments that "per Bridget [Hennessy]," he was adding a reserve to hold the margins.

306. FE-6 explained that the number of CNL instructions increased towards the end of his tenure in October and November 2023, and he became uncomfortable that ICON was "pushing the line." As a result, FE-6 decided to add comments indicating the source of the CNL instruction so more junior team members would not get into trouble.

307. FE-6 managed a team of 9 to 12 analysts and worked on ICON's Janssen partnership. As such, FE-6 explained that the "CNL" treatment applied to most or all Janssen studies and noted that ICON had at least five to six large Janssen studies, which totaled about \$150 to \$300 million and averaged about \$1.5 to \$2 million in revenue per month. The reserves on these studies fluctuated in size, but could be as large as \$1 million for a given study.

308. FE-6 confirmed that the CNL procedure impacted ICON's financial reporting: FE-6 stated that ICON's revenue team used the results of the "CNL" for ICON's financial reporting and also had access to the reserves and comments indicating to hold the margin, including the workbook showing the calculation of the "CNL" amount.

309. Finally, FE-6 indicated that in addition to the "CNL" process, ICON consistently included a "management reserve" to account for an assumption of 2% overburn at the beginning of each study. Specifically, because ICON consistently bid studies too low, ICON included a reserve to accommodate 2% overburn through the end of the study startup phase (when the last site was activated). This reserve prevented overburn from reducing margin in the early stages of the study. FE-6 explained that this 2% management reserve was "company standard" and affected each study FE-6 worked on.

310. The Omitted Costs Inflated ICON's Reported Revenue: ICON's "CNL" and "management reserve" practices also resulted in recognizing additional revenue by overstating ICON's percentage of completion.

311. Specifically, under ASC 606, omitting existing project costs shrank the denominator of the ASC 606 formula (total estimated costs) and thus overstated ICON's percentage of completion.

312. For example, on a \$20 million project where ICON's budget assumed total costs of \$10 million, but actual costs had reached \$8 million halfway through the project, ASC 606 requires updating the total project costs to \$16 million to include the "overburn" to date and the expected overburn through project completion. *See, e.g.*, ASC 606-10-25-35. Thus, the proper ASC 606 calculation would recognize \$10 million in revenue, or 50% of total project revenue, based on incurring \$8 million of \$16 million, or 50%, of total project costs. Given ICON's \$8 million in costs incurred, the \$10 million in revenue would yield \$2 million in profit at a 20% margin.

313. However, ICON's "CNL" and "management reserve" practices resulted in omitting the "overburn" from total project costs. That error significantly overstated ICON's percentage of completion and inflated its profit and margin. In the example above, the error kept total project costs at \$10 million instead of \$16 million. Halfway through the project, that error inflated revenue to \$16 million, or 80% of total project revenue, based on incurring \$8 million of \$10 million, or 80%, of total project costs. In turn, the inflated revenue boosted ICON's profit to \$8 million (at an inflated 50% margin).

314. The examples above are illustrated below.

	<b>Correct ASC 606 Calculation</b>	<b>Erroneous Calculation in Violation of GAAP</b>
<b>Total Project Value</b>	\$20 million	\$20 million
<b>Costs Incurred to Date</b>	\$8 million	\$8 million
<b>Total Project Costs</b>	\$16 million	<b>\$10 million</b>
<b>Percentage of Completion</b>	50%	<b>80%</b>
<b>Revenue Recognized</b>	\$10 million	<b>\$16 million</b>
<b>Profit</b>	\$2 million	<b>\$8 million</b>
<b>Profit Margin</b>	20%	<b>50%</b>

315. Ultimately, ICON's premature revenue recognition in violation of ASC 606 led to reaching "100%" completion on projects before they were complete. Confirming the point, FE-5 noted that five or six of his studies were still ongoing but reported 100% completion in ICON's Revenue software (which calculated percentage of completion from a forecast in Salesforce). FE-5 explained that the studies were ongoing and still incurring costs, but ICON was not forecasting them out. The Revenue software's "100%" completion was significantly different than the studies' actual status at the time. For example, one study marked as 100% complete was only 75% complete, while another marked as 100% complete was subject to repeated change orders and months of additional work.

##### **5. ICON Prematurely Recognized Revenue from Draft, Unsigned Change Orders and Before Contractual Milestones, and Used "Efficiencies" to Inflate Margins**

316. Finally, in violation of GAAP, ICON prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast "efficiencies" to boost margins. FE-3 indicated that these practices added \$5 to \$10 million per year to FE-3's portfolio, which generated \$350 million in annual revenue and accounted for about 10% of ICON's biotech division.

317. Premature Revenue Recognition from Unsigned Change Orders: FE-3 stated that ICON used draft, unsigned change orders to recognize revenue as “standard operating procedure” during 2023 and 2024, and that this practice increased ICON’s revenue and margins.

318. Recognizing revenue from draft, unsigned change orders affected both the timing and amount of revenue. As to timing, FE-3 explained that obtaining a final, signed change order could take six months.

319. As to the amount of revenue, FE-3 explained that the first draft of a change order typically provides for a much larger amount of revenue than the client ultimately approves. Specifically, FE-3 estimated that the final change orders were typically 20–30% smaller than the first draft that ICON used to recognize revenue, and this disparity between the draft and final change orders increased over time.

320. ICON violated GAAP by prematurely recognizing revenue from draft, unsigned change orders. For change orders, ASC 606-10-25-10 requires that “the parties to a contract *approve* a modification that either creates new or changes existing *enforceable rights and obligations* of the parties to the contract.” However, ICON’s draft, unsigned change orders were not legally enforceable and were not “approved” in any meaningful sense. Demonstrating the point, ICON regularly failed to recover the full amount stated in the draft, unsigned change orders. For example, FE-3 noted that for one large customer, Gilead, ICON regularly wrote off 50% of the amounts it initially sought via change orders.

321. The revenue that ICON prematurely recognized from draft, unsigned change orders was significant. For example, FE-3’s studies—which accounted for about 10% of ICON’s biotech division—involved large change orders of \$5–6 million, with some exceeding \$10 million, and generally had one to two change orders of \$5 million or more per quarter.

322. ICON’s practice of recognizing revenue from draft, unsigned change orders was directed by senior management. FE-3 stated that the instructions as to change orders were communicated by Aine McGill, VP Client Contract Services. McGill convened weekly meetings about change orders with FE-3, other project leaders with change orders and VPs of Project Delivery, and Sassaman. FE-3 explained that McGill (who was located in Ireland) reported to CFO Brennan or CEO Cutler and always framed her instructions as “the directive is.” During each weekly meeting, the attendees provided updates about what they were able to achieve in accordance with the directive; McGill then consulted with either Cutler or Brennan and returned the next week with new marching orders.

323. Premature Revenue Recognition Before Contractual Milestones: When ICON needed to “find revenue” for the quarter, it recognized revenue in advance of contractual milestones. For example, FE-3 explained, if the contract only allowed ICON to claim revenue upon site activation, and ICON planned to activate the site in September but encountered challenges that delayed activation to October, ICON still recognized the revenue in September.

324. Forecasting “Efficiencies” to Boost Margins: When studies experienced cost overruns, ICON forecasted offsetting “efficiencies” near the end of the studies. As FE-3 explained, this led to an overly positive margin because it assumed that the future “efficiencies” would offset the near-term cost overruns. The effect of this practice is to understate total project costs and inflate ICON’s margins, as described above with respect to ICON’s CNL practice.

## **V. DEFENDANTS’ FRAUD UNRAVELS**

325. The truth about ICON came to light through a series of partially corrective events driven by the facts that Defendants misstated and concealed—including ICON’s collapsing business from Pfizer and other large customers, declining biotech RFPs, inflated book-to-bill ratio



and business wins, and fraudulent accounting practices in violation of GAAP. Each event was followed by a significant decline in ICON's share price.

326. First, on July 24, 2024—ICON's first earnings announcement for a period after Defendant Brennan's resignation was announced—ICON reported 2Q24 financial results in a press release filed on Form 6-K with the SEC after market close. In the press release, ICON reported relatively weak financial results, including 2Q24 revenue of \$2.12 billion—below analysts' expectations. On ICON's July 25, 2024 earnings call, held before market open, Cutler also alluded to challenges and pricing pressure in the large pharma space (while denying that they had affected ICON). These negative disclosures reflected the initial, partial unraveling of Defendants' fraud, including their accounting scheme and GAAP violations.

327. On this news, the price of ICON ordinary shares declined \$18.67 per share, or 5.6%, from \$331.77 per share on July 24, 2024 to \$313.10 per share on July 25, 2024.

328. Next, on October 23, 2024, ICON reported 3Q24 financial results in a press release filed on Form 6-K with the SEC after market close. In the press release, ICON revealed a surprise "revenue shortfall" of \$100 million for 3Q24 and reduced 2024 guidance—which Defendants had reiterated just six weeks earlier—from a range of \$8.45 billion to \$8.55 billion to a range of \$8.26 billion to \$8.3 billion. This guidance cut was a \$220 million cut at the midpoint.

329. The press release also revealed that leading indicators of underlying demand had significantly deteriorated. For instance, ICON's quarterly gross business wins were \$2.83 billion and cancellations were \$504 million, resulting in net new business wins of \$2.33 billion during the quarter, down from \$2.58 billion the previous quarter, and the Company's book-to-bill ratio declined to 1.15 from 1.22 the previous quarter.

330. During ICON's earnings conference call the following day, October 24, 2024, held before market open, Cutler purported to explain the drivers of the poor financial results and reduced guidance.

331. First, Cutler revealed that ICON experienced "lower than anticipated revenue contribution from two of our largest customers." Cutler claimed that the customers had "delay[ed] the expected ramp-up of new work that was forecast to begin in the new models." As a result, "studies clos[ed] out . . . without the counterbalancing revenue from new studies as expected."

332. These explanations were misleading (at best). As detailed above, Cutler had long known about the prolonged slowdown in business from Pfizer and other large customers, including Pfizer's decisions in 2023 to stop awarding ICON any lucrative full-service work and to exclude ICON from 85% of Pfizer's largest studies.

333. By early 2024, Pfizer, BMS and a third large customer had shifted to nearly 100% FSP, decimating ICON's margins from 40–50% to 15%. That slashed hundreds of millions of dollars from ICON's profits, leaving a hole ICON could not fill.

334. Further, in January 2024, Cutler personally approved Pfizer's request to cut \$50 million from the budget for ICON's remaining studies. These developments drove ICON's efforts to dissolve the dedicated PSBU since early 2024 and significant layoffs in March 2024. Pfizer's large COVID-flu vaccine trial had also failed by early August 2024.

335. FE-11 described the notion that CEO Cutler only learned about Pfizer's cuts in September 2024 as "**bullshit**." FE-11 explained that a business reduction of that magnitude was known to Cutler and ICON's other executives 12 to 18 months ahead of time, and they simply decided to delay public disclosure in an effort to generate other business to make up for the known

loss. FE-11 cited Novartis' 10% headcount reduction, which was extensively discussed internally starting seven months before it happened.

336. Moreover, with ICON's years-long trend of declining business from Pfizer and other large customers—including budget cuts that Cutler had personally approved—Defendants had no factual basis to “expect[]” “counterbalancing revenue from new studies.” Indeed, the three large customers' shift to FSP carried a 25–35% lower margin and slashed up to \$500 million from ICON's profits. Filling that substantial hole in profits would require ICON to immediately *triple* its revenue from these customers. But these customers never offered to triple their business with ICON. Instead, they canceled studies and aggressively pushed ICON for budget cuts, which Cutler approved.

337. Defendants' purported expectation of “counterbalancing revenue from new studies” also had no factual basis because ICON's study revenue is tied to enrollment of patients—a lengthy process that can take over a year. ICON itself has stated that it “typically takes 6-12 months to start up a global phase III drug trial and another 12 months to enroll the required number of patients.”<sup>10</sup> Given this lengthy start-up period, Cutler and other ICON executives necessarily knew long before October 2024 that there would be no “counterbalancing revenue” in 2024. Indeed, Defendant Brennan admitted on November 29, 2023 that “80% of our business for next year or there or thereabouts is already decided by the time we get to the end of Q3.” Thus, the vast majority of ICON's 2024 business was already decided by 3Q23.

338. Second, Cutler revealed “slower than expected activity in our biotech segment” that “impacted our total level of new awards” and led to “delays in study startup.”

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<sup>10</sup> <https://www.iconplc.com/news-events/press-releases/revolutionising-clinical-trials>

339. Again, this biotech slowdown had long been known to Defendants: ICON had seen a continuous reduction in biotech RFPs since late 2022, and a trend of increasing biotech cancellations by mid-2023, even as Defendants told investors the opposite. These internally known metrics made clear to Defendants that ICON's biotech business was dying.

340. Third, Cutler asserted that "an outsized level of vaccine related cancellations" was "contributing to the lower than expected revenue in the second half of this year." However, Defendants had known for months that the Pfizer COVID-flu vaccine trial had failed; Pfizer itself had admitted the failure on August 16, 2024 (though ICON's role was not revealed at the time).

341. Tellingly, in response to analyst questions, Cutler admitted that ICON had not accurately gauged the "risks and opportunities" in 3Q24, explaining that "going forward [we] will reformulate and relook at what those risks and opportunities are and *be able to be a little bit more accurate*, if that's the right word in terms of in terms of how we I [sic] think the world is going to go and how it's going to come in." Cutler added that "we need to just look at ourselves a little bit more closely and *make sure that we are projecting and forecasting in a way that is reflective of those risks*," tacitly admitting that Defendants had not done so before.

342. In response to an analyst question, Cutler also admitted that customers' overconcentration with ICON after the PRA Merger played a part in the disappointing results: "it's fair to say that one or two [customers] have looked at if PRA and ICON were significant providers in the previous mix and now [that] we've come together" customers have "looked at that" concentration of work and "in one or two cases [they] brought on [a] competitor" to take work ICON previously handled. Cutler then revealed, "that's what we expected."

343. ICON's poor 3Q24 results and guidance cut also reflected the further collapse of Defendants' accounting scheme and GAAP violations.

344. While ICON's October 23 and 24, 2024 disclosures were highly negative, Defendants continued to conceal the full truth. For instance, Cutler indicated in ICON's October 23 press release that the headwinds would be short-lived, while insisting the "fundamentals of our business remain strong," and during ICON's October 24 earnings call, Cutler falsely claimed that "the RFP flow continues to be solid across both segments of our market, both large pharma and biotech."

345. On the news from October 23, 2024 to October 24, 2024, the price of ICON ordinary shares declined \$59.03 per share, or 21%, from \$280.76 per share on October 23, 2024, to \$221.73 per share on October 24, 2024.

346. Analysts were shocked by ICON's sudden disclosure of materially weaker financial results, especially given Defendants' repeated prior assurances about the strength of ICON's business and affirming ICON's guidance on September 10, 2024. For example, J.P. Morgan's October 24, 2024 report stated that "*the magnitude of the miss was surprising*" and the "*incrementally new dynamic flagged in the quarter was the drop-off in spending from the two large pharma customers.*" UBS's October 24, 2024 report added that ICON management admitted "that the [two large customers'] relative customer concentration and heightened magnitude of their decline had a *material, outsized impact* on ICON's performance."

347. Finally, on January 14, 2025, before market open, ICON issued financial guidance for 2025 in a press release filed on Form 6-K with the SEC. ICON announced revenue guidance for 2025 in the range of \$8.05 billion to \$8.65 billion, a wider-than-typical range for the Company that was below analysts' expectations. In the press release, ICON quoted Defendant Cutler as stating, "ICON continues to navigate dynamic clinical development market conditions, as trial activity has been impacted by cautious spending from biopharma customers, in both the biotech

and large pharma businesses. Our outlook for this year reflects an expected transition period which includes a headwind from our top two customers on a combined basis, coupled with an inconsistent recovery in biotech.”

348. Also on January 14, 2025, ICON participated in an industry conference call hosted by J.P. Morgan. During the call, Cutler revealed, “we believe ‘25 will be a transition period, really due to a combination of market and customer-specific factors for ICON,” before “normal growth will be resumed” in 2026 and 2027.

349. In response to an analyst question about the disappointing guidance, Cutler explained: “What we see is, particularly on the biotech side, a little bit of softening and softening of the backlog. Cancellations ticked up modestly in Q4.” As detailed above, however, ICON’s biotech cancellations had steadily increased for over two years, since late 2022.

350. When pressed on ICON’s assumptions on growth for its “two largest customers and the rest of the portfolio,” Cutler further revealed that ICON only expected “lower single digits [growth] outside of [its] top 2” customers, while newly-appointed COO Balfe added that ICON did not have “a huge update” on its two largest customers from the 3Q24 earnings call.

351. On the January 14, 2025 news, the price of ICON ordinary shares declined \$17.75 per share, or 8.1%, from \$217.99 per share on January 13, 2025, to \$200.24 per share on January 14, 2025.

352. Again, analysts were disappointed. J.P. Morgan flagged ICON’s lower-than-expected revenue and Adjusted EPS guidance, while TD Cowen wrote that ICON’s 2025 outlook was “worse than expected.”

## VI. DEFENDANTS' FALSE AND MISLEADING STATEMENTS

353. Defendants made false and misleading statements throughout the Class Period concerning the following topics: (1) ICON's RFPs, large pharma and biotech businesses; (2) ICON's book-to-bill ratio and gross and net business wins; (3) ICON's purported GAAP compliance, revenue recognition, and accounting methodology; (4) ICON's internal controls over financial reporting and disclosure controls; and (5) ICON's financial performance. Each misstatement that Plaintiffs allege to be actionable is identified in this section.

### A. Misstatements about ICON's RFPs, Large Pharma and Biotech Businesses

#### 1. 2Q23 Earnings Call

354. On July 27, 2023, ICON hosted a conference call with analysts to discuss the Company's 2Q23 financial results. In his prepared remarks, Defendant Cutler stated:

*Overall RFP activity continued the sequential improvement we experienced in quarter 1, and we saw a notable pickup in RFP activity within the biotech segment toward the end of quarter 2.*

This statement was materially false because ICON's overall RFPs and biotech customer RFPs declined throughout 2023. This statement was also materially misleading because it cited purported improvements in ICON's "RFP activity" while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; and (3) ICON's biotech business was experiencing declining RFPs and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

355. Defendant Cutler then continued with his prepared remarks, stating:

Within the mid and large biopharma segments, we continue to see a resilient environment with another quarter of strength in functional service and hybrid opportunities. We are cautiously optimistic that we will see an improving trend in bookings through the second half of this year. ***And while it's early in the third quarter, we have seen RFP activity continue its positive trajectory in July.***

This statement was materially false because ICON's overall RFPs declined throughout 2023. This statement was also materially misleading because it cited purported improvements in ICON's "RFP activity" while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; and (3) ICON's biotech business was experiencing declining RFPs and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

356. Later in the call, analyst Alexander Yearley Draper from Guggenheim Securities, LLC, asked for "any more color on how you see [bookings improvement] and is that primarily driven by the biotech area?" Defendant Cutler replied:

The opportunities that we're seeing in the business and not just in the biotech, they're really fairly broad-based across the business. So really, we -- I think ***we reported last quarter an increase in RFP[s] on a sequential basis. That's continued in the second quarter.*** I mean, as I said early in July, we're seeing further opportunities. So we're certainly cautiously optimistic of a strong business development performance in the back end of the year right across the various segments.

This statement was materially false because ICON's overall RFPs declined throughout 2023. This statement was also materially misleading because it cited "an increase in RFP[s] on a sequential basis" while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA



funding, such that only one study would materialize; and (3) ICON's biotech business was experiencing declining RFPs and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

## 2. 3Q23 Earnings Call

357. On October 26, 2023, ICON hosted a conference call with analysts to discuss the Company's 3Q23 financial results. In his prepared remarks, Defendant Cutler stated:

***Overall, RFP activity continued to improve in quarter 3 with growth in the high single digits on a trailing 12-month basis.***

This statement was materially false because ICON's overall RFPs declined throughout 2023. This statement was also materially misleading because it cited the purported fact that "RFP activity continued to improve in quarter 3" while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; and (3) ICON's biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

358. During the call, analyst Christine Rains of William Blair asked about the "impact [that] Pfizer's recently announced cost cuts [would have]? And was this baked into your outlook? Or were they unexpected?" Defendant Cutler replied:

***No, these are relatively expected. We're in close contact with our partner customers on a regular basis, and we recognize the challenges that, that particular customer has. We're working closely with them in terms of what they're looking to do. No. [N]othing has been decided at this point. There is sometimes, with these sort of***

*things, some opportunity for us and that they were happy to further consolidate their spending, even though they're looking to take that overall spend down over the relatively short term. So these things aren't always negative for us, but we work closely with our partners to look at it, and we have that in the forecast.*

This statement was materially false because Pfizer had already “decided” to implement significant spending cuts, as detailed herein, that were “negative for” ICON and did not present “some opportunity for us.” This statement was also materially misleading because it omitted the existing, material, negative facts, as detailed herein, that (1) Pfizer had materially decreased the amount and dollar value of its awards to ICON; (2) Pfizer had demanded significant budget cuts for ICON’s existing studies; (3) ICON’s PSBU continuously decreased in size from 2022; (4) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (5) Pfizer and other large customers were switching to nearly 100% FSP, slashing ICON’s profit margins; and (6) the PRA Merger had led to large customers’ overconcentration that caused them to reduce their business with ICON. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

359. Later in the call, analyst Justin D. Bowers of Deutsche Bank asked, “can you sort of take the landscape for large pharma customers and biotech customers and maybe sort of like contrast that to this time last year or maybe even earlier this year?” Defendant Cutler responded:

*Yes. Justin, I mean, we've seen pretty constructive positive RFP numbers for -- certainly for the last 2 quarters over all the segments across biotech, large pharma, in more sort of ancillary services, labs, early phases, et cetera, et cetera, and obviously, FSP as well. So I talked about high single digits as being sort of across the landscape, and it's fairly consistently across those segments. So overall, we see a very constructive, a very positive sort of business environment.*

This statement was materially false because ICON’s overall RFPs and biotech customer RFPs declined throughout 2023. This statement was also materially misleading because it cited the purported fact that “we’ve seen pretty constructive RFP numbers . . . for the last 2 quarters over

all the segments across biotech, large pharma” while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; and (3) ICON’s biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

360. Later in the call, analyst Patrick Bernard Donnelly of Citigroup Inc. asked, “given what you’re seeing on RFPs, it would be helpful maybe to frame up that 4Q book-to-bill expectations given what you’ve seen over the last couple of months.” Defendant Cutler responded:

Well, I think, Patrick, we’ve said pretty clearly that *RFPs have been up in the last couple of quarters*. So we’re seeing plenty of opportunities. *We’ve got the [1.26] this quarter*. My expectations would be at a similar number for Q4.

This statement was materially false because ICON’s overall RFPs and biotech customer RFPs declined throughout 2023. This statement was also materially misleading because it cited the purported fact that “RFPs have been up in the last couple of quarters” while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; and (3) ICON’s biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

### 3. November 2023 Jefferies Conference

361. On November 14, 2023, Defendant Brennan attended Jefferies' London Healthcare Conference. At the conference, analyst David Howard Windley asked Brennan "to start at the demand environment again this afternoon and talk about the RFP flow acceleration that both you and Steve Cutler have talked about kind of seemingly starting in 2Q and extending to now." Defendant Brennan replied:

*Yes, it's been a solid environment over the last couple of quarters. We've seen definitely an uptick. We were talking a lot about the fact that in the period up to -- really from beginning of '22 up to kind of mid-'23 was a more subdued environment. And we obviously talked about the fact a lot of that was around biotech and biotech funding. I think what we saw really in around -- it was probably around June, July time, was a significant kind of uptick from our biotech customers. And that certainly has persisted into the good volumes that we saw and we talked about in the Q3 call and persists as we go into Q4 as well. So that's been a -- it's been a positive move in the right direction.*

This statement was materially false because ICON had not seen "an uptick" or "a significant kind of uptick from our biotech customers" that "persisted into the good volumes that we saw and we talked about in the Q3 call and persists as we go into Q4." Instead, ICON's overall RFPs and biotech customer RFPs declined throughout 2023. This statement was also materially misleading because it cited an "uptick," "a significant kind of uptick from our biotech customers," and "the good volumes that we saw and we talked about in the Q3 call and persists as we go into Q4" while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; and (3) ICON's biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Brennan omitted material facts necessary to make the statement not misleading in the context in which it was made.

362. In addition, Brennan indicated that ICON's full-service and FSP businesses had similar margins, stating:

We obviously have a blended margin of -- in the 29% to 30% gross margin profile as an organization. *It is fair to say that our pure full service work is a couple of percent higher than that in terms of its margin profile. It's also fair to say that our FSP work is a couple of percent below that. So one is in the kind of in the mid-to high 20s and the other one is in the kind of low 30s.*

This statement was materially false because ICON's margins on FSP and full-service work are not "in the mid-to high 20s" and "low 30s," and neither is within "a couple of percent" of 29–30% gross margin. Instead, ICON's actual margins on FSP work are only around 15%, compared to 40–50% for full-service work.

#### 4. November 2023 Evercore ISI Conference

363. On November 29, 2023, Defendant Brennan attended Evercore ISI's HealthCONx Conference. At the conference, analyst Elizabeth Hammell Anderson asked, "any sort of changes in RFP flow as we're thinking about 4Q?" Defendant Brennan responded:

*No, at this stage, it remains solid. And we talked about being up nicely year-over-year on a trailing 12-month basis. That persists into Q4.* I think the mix of it is pretty decent as well. So it's not -- we've seen obviously -- *as I mentioned, we saw kind of good recovery in biotech and emerging biotech, small biotech, particularly in Q3. That remains stable, is the best way to put it as we go into Q4.*

This statement was materially false because ICON was not "up nicely year-over-year on a trailing 12-month basis" and had not seen a "good recovery in biotech . . . particularly in Q3," and biotech was not "stable . . . as we go into Q4." Instead, ICON's overall RFPs and biotech customer RFPs declined throughout 2023. This statement was also materially misleading because it touted an increase in ICON's RFPs, a "good recovery in biotech," and that biotech was "stable . . . as we go into Q4," while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA

funding, such that only one study would materialize; and (3) ICON's biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Brennan omitted material facts necessary to make the statement not misleading in the context in which it was made.

## 5. 4Q23 Earnings Call

364. On February 22, 2024, ICON hosted a conference call with analysts to discuss the Company's 4Q23 and full-year 2023 financial results. In his prepared remarks, Defendant Cutler stated:

***In totality, across all segments, our overall trailing 12-month RFP activity increased in the high single digits in quarter 4, consistent with quarter 3 and this appears to be continuing or even accelerating early in 2024.***

This statement was materially false because ICON's overall RFPs declined throughout 2023. This statement was materially misleading because it claimed ICON's "overall trailing 12-month RFP activity increased in the high single digits in quarter 4" and that "this appears to be continuing or even accelerating early in 2024," while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; and (3) ICON's biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

365. Later in the call, analyst Elizabeth Hammell Anderson from Evercore ISI asked, "Can you talk about sort of the level of visibility on your strategic partnerships with large pharma and how kind of you -- maybe they help you get a sense of sort of where their pipelines are going, and can help give people a little bit more confidence in the trajectory there?"

366. Defendant Cutler replied:

***I'm not hearing again at this stage any further concerns on funding or on their R&D spend. If anything, based on the RFP of opportunities we've got over the last couple of months and even last quarter, last year and the second and third quarter was strong as well, we're seeing more opportunities.*** So I guess I keep saying it, but as their budgets become perhaps a little bit more constrained or they watch where they're spending their dollars, ***they do appear to becoming [sic] more open to outsourcing and outsourcing even more than they're doing at the moment. . .***

This statement was materially false because, contrary to Defendant Cutler's statement that "I'm not hearing again at this stage any further concerns on funding or on their R&D spend" and "they do appear to [be] becoming more open to outsourcing and outsourcing even more," (1) Pfizer had stopped awarding new full-service business to ICON as part of a "strategic refresh," and Cutler had internally admitted that ICON had lost the "Pfizer opportunity" and was no longer a preferred partner of Pfizer; (2) Pfizer had materially decreased the amount and dollar value of its awards to ICON, such that ICON's win rate was near zero and ICON was closed out of 85% of Pfizer's most lucrative Phase 2 and 3 business; (3) Pfizer had demanded—and Cutler had personally approved—significant budget cuts for ICON's existing studies; (4) ICON's PSBU continuously decreased in size from 2022; (5) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (6) Pfizer and other large customers were switching to nearly 100% FSP, slashing ICON's profit margins; and (7) the PRA Merger had led to large customers' overconcentration that caused them to reduce their business with ICON. This statement was also materially misleading because it omitted these existing, material, negative facts, as well as the facts that (8) many of ICON's purported RFPs were issued only for price discovery and/or duplicative because they involved proposed studies that were competing for limited BARDA funding; and (9) ICON's biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts,

Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

367. Later in the call, analyst Jailendra P. Singh of Truist asked, “It seems you’re encouraged by data points and trends you’ve seen in Q1 thus far, but you’re maintaining your outlook, which assume[s] slower CRO industry growth. So is it fair to say that you’re not reflecting recent trends in your outlook? And if these trends continue, would you say that will be kind of upside to your expectations for the year?” Defendant Cutler replied:

Yes. I’d characterize it this way, Jailendra, that I think as we said early in January on the RFP front, biotech was a little more muted. Large pharma was strong. *As we’ve gone into the first half of the first quarter of this year, we’ve probably seen the RFPs tick up and the environment sort of move up a notch. A lot of that [is] through strength in large pharma*, some of the strategic partnerships we’ve talked about are bearing fruit in terms of opportunities. *But we’re also seeing a modest uptick around mid-single digits in the biotech space as well. So we talked about biotech stabilizing and improving. And that seems to be playing out in the first -- as I say, the first very early part of this year.*

This statement was materially false because the Company did not “see[] the RFPs tick up and the environment sort of move up a notch” due to “strength in large pharma” and “upticks around mid-single digits in the biotech space.” Instead, ICON’s biotech customer RFPs declined throughout 2023 and 2024. This statement was also materially misleading because it claimed that the purportedly increasing RFP activity was due to “strength in large pharma” and “upticks around mid-single digits in the biotech space” while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; (3) ICON’s biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations; and (4) ICON was losing significant business from Pfizer and other large pharma customers, with the majority declining from early 2023 through 2024. By failing to disclose these existing,



material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

368. Later in the call, analyst Luke England Sergott of Barclays asked, “as you guys have shifted more towards large pharma, given the lack of biotech funding and RFPs out there, the large CROs are competing on fewer projects. So are you guys seeing fewer projects across large pharma?” Defendant Cutler replied:

*Well, we’re certainly seeing more opportunities in large pharma. No question about that. The RFP dollars that are coming through are very solid. And then driving that, as I say, that early ’24 mid-teens increase in RFP on a trailing 12-month basis. And we’re seeing more opportunities as well. . . . I would say that in our -- with our opportunities, because we’re strategic with a number of these customers, our win rate tends to be higher in that part of the market as well. So we win a greater proportion of those dollars and we do in other parts of the market where we’re competing with a number of different organizations and there are different perspectives on large versus small CROs, et cetera, et cetera. So we’d certainly like that large pharma space.*

This statement was materially false because rather than “seeing more opportunities in large pharma” and having a higher “win rate . . . in that part of the market,” (1) Pfizer had stopped awarding new full-service business to ICON as part of a “strategic refresh,” and Cutler had internally admitted that ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer; (2) Pfizer had materially decreased the amount and dollar value of its awards to ICON, such that ICON’s win rate was near zero and ICON was closed out of 85% of Pfizer’s most lucrative Phase 2 and 3 business; (3) Pfizer had demanded—and Cutler had personally approved—significant budget cuts for ICON’s existing studies; (4) ICON’s PSBU continuously decreased in size from 2022; (5) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (6) Pfizer and other large customers were switching to nearly 100% FSP, slashing ICON’s profit margins; and (7) the PRA Merger had led to large customers’ overconcentration that caused them to reduce their business with ICON. This

statement was also materially misleading because it omitted these existing, material, negative facts, as well as the facts that (8) many of ICON's purported RFPs were issued only for price discovery and/or duplicative because they involved proposed studies that were competing for limited BARDA funding; and (9) ICON's biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

## 6. March 2024 TD Cowen Conference

369. On March 5, 2024, Defendant Brennan attended TD Cowen's Health Care Conference. At the conference, analyst Charles Rhyee asked, "Obviously, one of the big topics has been the funding environment in the biotech. You guys have generally been pretty resilient through all of this, right? And I think this is despite the concerns and perhaps that's sort of a testament to your relationship with particularly a lot of large pharma companies. Maybe talk about sort of how that relationships -- those have changed or evolved particularly with the acquisition of PRA." Defendant Brennan responded:

... in the large and midsized pharmas, it's worked well over the last couple of years. *We've seen good traction. We've seen the evolution of existing relationships and development of new relationships in that space.* I would say the biotech, our biotech business has been a bit more challenged over that period of time. *That's just the market for, obviously, the biotech funding. But we see good positive signs as we come into this year. Obviously, sequentially, RFP flow was up well from Q4 -- sorry, Q3 to Q4. . . we see decent traction from all of our business units and all of our customer segments even in the first couple of months of the year from a business development perspective.*

This statement was materially false because ICON's "RFP flow" was not "up" from "Q3 to Q4"; instead, ICON's overall RFPs declined throughout 2023. This statement was also materially misleading because it omitted the existing, material, negative facts that (1) Pfizer had stopped awarding new full-service business to ICON as part of a "strategic refresh," and Cutler had

internally admitted that ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer; (2) Pfizer had materially decreased the amount and dollar value of its awards to ICON, such that ICON’s win rate was near zero and ICON was closed out of 85% of Pfizer’s most lucrative Phase 2 and 3 business; (3) Pfizer had demanded—and Cutler had personally approved—significant budget cuts for ICON’s existing studies; (4) ICON’s PSBU continuously decreased in size from 2022; (5) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (6) Pfizer and other large customers were switching to nearly 100% FSP, slashing ICON’s profit margins; (7) the PRA Merger had led to large customers’ overconcentration that caused them to reduce their business with ICON; (8) many of ICON’s purported RFPs were issued only for price discovery and/or duplicative because they involved proposed studies that were competing for limited BARDA funding; and (9) ICON’s biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Brennan omitted material facts necessary to make the statement not misleading in the context in which it was made.

370. Later during the conference, Rhyee asked, “I know on the call, you mentioned sort of this uptick in sort of activity, good RFP flow starts for the start of ’24 here and continued strength in the large pharma segment. At the same time, right, we’ve all seen the news of pharma kind of retrenching cost-cutting and concerns with the large customers. Maybe kind of reconcile those two a little bit. I guess some people are worried, maybe does that flow into then the R&D budgets? Or maybe those two are a little distinct from each other?” Defendant Brennan responded:

*. . . Like the thinking around what the model should look like has been done. Even some of the new selections of partners has been done.* And I think what I’d like to see now is more of a traction. *They are all saying that they’re going to increase spending*, even some of the -- I think, some of the companies that have been more troubled over the last period have even said in their own press releases

over the last while that Q4 was probably at a later point and they want to continue to increase R&D spend as they go forward.

This statement was materially false because ICON's large pharmaceutical partners were not "all saying that they're going to increase spending." Instead, (1) Pfizer had stopped awarding new full-service business to ICON as part of a "strategic refresh," and Cutler had internally admitted that ICON had lost the "Pfizer opportunity" and was no longer a preferred partner of Pfizer; (2) Pfizer had materially decreased the amount and dollar value of its awards to ICON, such that ICON's win rate was near zero and ICON was closed out of 85% of Pfizer's most lucrative Phase 2 and 3 business; (3) Pfizer had demanded—and Cutler had personally approved—significant budget cuts for ICON's existing studies; (4) ICON's PSBU continuously decreased in size from 2022; (5) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (6) Pfizer and other large customers were switching to nearly 100% FSP, slashing ICON's profit margins; and (7) the PRA Merger had led to large customers' overconcentration that caused them to reduce their business with ICON. This statement was also materially misleading because Defendant Brennan claimed that "[e]ven some of the new selections of partners has been done" while omitting the existing, material, negative facts that Pfizer had stopped awarding new full-service business to ICON and had decided to award the vast majority (85%) of its lucrative Phase 2 and 3 business to another CRO. By failing to disclose these existing, material, negative facts, Defendant Brennan omitted material facts necessary to make the statement not misleading in the context in which it was made.

## **7. March 2024 Barclays Conference**

371. On March 12, 2024, Defendant Cutler attended Barclays' Global Healthcare Conference. At the conference, analyst Luke England Sergott asked, the "biotech funding market has kind of started to unlock a little bit, but you guys have seen continued strength in large pharma.

Give us kind of the lay of the lands [sic] right now as you exited the year and then into 1Q, how that's kind of playing out versus your expectations?" Defendant Cutler responded:

***Yes. I think we're seeing overall a very constructive environment, fueled for us mainly by large pharma. We've certainly seen some significant upticks in opportunity in large pharma over the last 3 to 6 months . . . So overall the demand environment for us is strong.***

This statement was materially misleading because it touted "a very constructive environment, fueled for us mainly by large pharma" and "some significant upticks in opportunity in large pharma over the last 3 to 6 months" while omitting the existing, material, negative facts that (1) Pfizer had stopped awarding new full-service business to ICON as part of a "strategic refresh," and Cutler had internally admitted that ICON had lost the "Pfizer opportunity" and was no longer a preferred partner of Pfizer; (2) Pfizer had materially decreased the amount and dollar value of its awards to ICON, such that ICON's win rate was near zero and ICON was closed out of 85% of Pfizer's most lucrative Phase 2 and 3 business; (3) Pfizer had demanded—and Cutler had personally approved—significant budget cuts for ICON's existing studies; (4) ICON's PSBU continuously decreased in size from 2022; (5) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (6) Pfizer and other large customers were switching to nearly 100% FSP, slashing ICON's profit margins; and (7) the PRA Merger had led to large customers' overconcentration that caused them to reduce their business with ICON. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

372. Defendant Cutler further responded to the same question:

***The biotech front has also been positive. We see RFPs in the mid-single digits, up [on] a trailing 12-month basis.***

This statement was materially false because ICON's biotech customer RFPs declined throughout 2023 and 2024. This statement was also materially misleading because it omitted the existing,

material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; and (3) ICON's biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

## 8. 1Q24 Earnings Call

373. After the close of trading on April 24, 2024, ICON filed a press release on Form 6-K with the SEC reporting the Company's 1Q24 financial results. On April 25, 2024, ICON hosted a conference call to discuss the results. In his prepared remarks, Defendant Cutler stated:

The market trends we saw early in quarter 1 continued throughout the balance of the quarter, characterized by *stabilizing demand within the biotech customer base as well as a continuation of the robust demand we have consistently seen from large pharma customers*. . . . Proposal volumes are at healthy levels, *with overall RFP volume increasing low double digits on a trailing 12-month basis*.

374. Later in the call, analyst Maxwell Andrew Smock from William Blair asked, "Maybe just to clarify quickly on RFPs. You mentioned up low double digits in total. Do you have that breakdown or how that breaks down between biotech and large pharma? And then how does each of those buckets compare to where they were at, at the end of last year? And then it sounds like, based on your prior answer a few minutes ago, you would actually expect RFPs to get better from here given the lag between funding and that ultimately, showing up in RFP flow. I just wanted to make sure I understood that commentary correctly." Defendant Cutler responded:

[W]e don't really split out too much the RFP data. But qualitatively, certainly, *large pharma continues to be strong, and we've seen that. The biotech's also been solid*, perhaps not quite as strong, *but it does seem to be on the uplift*. So if I look at, say,

*low double digits, large pharma is well above that. Biotech is probably more in the mid-singles if I had to put a number on it.* And it's -- as I say, it's solid, strong.

375. Later in the call, analyst Michael Leonidovich Ryskin of BofA Securities asked, “in your prepared remarks, you called out a continuation of robust demand. You talked about R&D for the group for 2024 seems to be pretty stable, in line with prior. I just want to get a sense of how much of that is already locked in when we think where we are in the year in April. Is there a risk of that changing as you go forward?” Defendant Cutler responded:

As you said, *we've seen pretty strong demand in the large pharma space.* And it's not just this quarter. *It's been really over the last 12, 18 months. Nothing has changed in that for now . . .* Overall, *we see a very stable and very strong demand in the large pharma.*

Defendant Brennan also responded:

Yes. No, I think just reflecting on it, one of the things that we talked about at the start of our call is *we have actually seen pretty decent traction from the large pharma group and probably more on the full service side of the house as well as we've come into '24,* and that's been heartening.

376. The statements identified in Paragraphs 373–375 were materially false because ICON had not seen “stabilizing demand within the biotech customer base as well as a continuation of the robust demand we have consistently seen from large pharma customers,” “very stable and very strong demand in the large pharma” over “the last 12, 18 months,” “pretty decent traction from the large pharma group and probably more on the full service side of the house,” “solid” biotech performance, or a “mid-singles” increase in biotech RFPs. Instead, ICON’s overall RFPs declined throughout 2023 and biotech customer RFPs declined throughout 2023 and 2024, and with respect to large pharma customers, (1) Pfizer had stopped awarding new full-service business to ICON as part of a “strategic refresh,” and Cutler had internally admitted that ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer; (2) Pfizer had materially decreased the amount and dollar value of its awards to ICON, such that ICON’s win rate was near

zero and ICON was closed out of 85% of Pfizer’s most lucrative Phase 2 and 3 business; (3) Pfizer had demanded—and Cutler had personally approved—significant budget cuts for ICON’s existing studies; (4) ICON’s PSBU continuously decreased in size from 2022; (5) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (6) Pfizer and other large customers were switching to nearly 100% FSP, slashing ICON’s profit margins; and (7) the PRA Merger had led to large customers’ overconcentration that caused them to reduce their business with ICON. These statements were also materially misleading because Defendants Cutler and Brennan claimed “demand” was “stabilizing” for “biotech customer[s],” touted “the robust demand we have consistently seen from large pharma customers” and “very stable and very strong demand in the large pharma,” adding that “[n]othing has changed in that for now,” and asserted that ICON had received increased RFPs in large pharma, biotech, and overall, all while omitting these existing, material, negative facts, as well as the facts that (8) many of ICON’s purported RFPs were issued only for price discovery and/or duplicative because they involved proposed studies that were competing for limited BARDA funding; and (9) ICON’s biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendants Cutler and Brennan omitted material facts necessary to make the statements not misleading in the context in which they were made.

377. During the April 25, 2024 call, Cutler stated in his prepared remarks: “One of our important strategic initiatives as we came into 2024 was the focused rebranding of our dedicated biotech solutions business, ICON biotech. . . . Following the rebrand activity in quarter 4 last year, I am pleased to report that *we are already seeing* positive momentum in terms of customer receptivity and *an increased win rate in this segment.*”



378. Later in the call, in response to an analyst question, Defendant Cutler stated: “We’ve been successful. ***Our win rate in that biotech space has gone up over the last quarter or so.***”

379. In response to another analyst question about “your improved win rate in biotech,” Defendant Cutler stated: “Dan, I could give you a million reasons why we’ve improved that. It’s a multifactorial thing. . . . And it’s, as I say, turned into a -- ***gave us a nice uptick on the win rate.***”

380. The statements identified in Paragraphs 377–379 were materially false because ICON’s biotech win rate was decreasing, as Cutler admitted at a Company-wide town hall in February 2024 and Chris Smyth reiterated at a biotech town hall in the first quarter of 2024.

## 9. May 2024 Investor Day

381. On May 30, 2024, ICON hosted an Investor Day. During the Investor Day, Defendant Balfe stated the following in his prepared remarks:

The rate at which we’ve managed to add new alliances in the space and to expand the alliances we already have into new business areas has increased. One of the founding pillars of the deal rationale for the merger between ICON and PRA was that we would advance our position in this sector, and I’m pleased to say that is borne out by the data. ***We have seen in the last 18 months, in my 25 years, the most sustained and intense period of realignment or refreshing of large pharma preferred partnerships. And it’s particularly encouraging that ICON has come out of that period with all of the alliances we had before, many of them expanded,*** and a number of new alliances where we’ve either replaced an incumbent or added ourselves into the mix where previously we didn’t compete.

This statement was materially misleading because Balfe touted that “ICON has come out” of a period of “intense” large pharma “realignment or refreshing . . . with all of the alliances we had before, many of them expanded” while omitting the existing, material, negative facts that (1) Pfizer had stopped awarding new full-service business to ICON as part of a “strategic refresh,” and Cutler had internally admitted that ICON had lost the “Pfizer opportunity” and was no longer a preferred

partner of Pfizer; (2) Pfizer had materially decreased the amount and dollar value of its awards to ICON, such that ICON's win rate was near zero and ICON was closed out of 85% of Pfizer's most lucrative Phase 2 and 3 business; (3) Pfizer had demanded—and Cutler had personally approved—significant budget cuts for ICON's existing studies; (4) ICON's PSBU continuously decreased in size from 2022; (5) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (6) Pfizer and other large customers were switching to nearly 100% FSP, slashing ICON's profit margins; and (7) the PRA Merger had led to large customers' overconcentration that caused them to reduce their business with ICON. By failing to disclose these existing, material, negative facts, Defendant Balfe omitted material facts necessary to make the statement not misleading in the context in which it was made.

382. Later during the conference, analyst Patrick Donnelly of Citi asked, “Steve, maybe just on kind of the market growth rate. It seems like your confidence has been building this year. January was maybe a little softer. And then obviously, 1Q, the bookings trends were really strong. Today, to have the confidence that you have, is it just based on what you’re seeing on the RFP flow, the bookings still?” Defendant Cutler responded:

Yeah, Patrick, I think our confidence on the business development going forward and the new business awards is based on a couple of things. RFPs, we’ve talked about, and *we’ve been in a pretty good place on RFPs, both in the large pharma and the biotech space over the last several quarters.*

This statement was materially false because ICON was not “in a pretty good place on RFPs . . . over the last several quarters.” Instead, ICON's overall RFPs declined throughout 2023 and biotech customer RFPs declined throughout 2023 and 2024. This statement was also materially misleading because Defendant Cutler claimed that “we’ve been in a pretty good place on RFPs, both in the large pharma and the biotech space over the last several quarters” while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery,

not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; (3) ICON's biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

#### 10. June 2024 Jefferies Conference

383. On June 6, 2024, Defendant Cutler attended Jefferies' Global Healthcare Conference. At the conference, analyst Dave Windley asked, "maybe you could talk about the sources of that demand across customer cohorts, where you're seeing the real strength at the moment between large pharma and biotech?" Defendant Cutler responded:

Yes, if we look at *large pharma first, Dave, we've certainly seen continuing solid demand in that space*. We've traditionally been known as a large pharma CRO. We've worked with all of the big organizations, big pharma organization, and we continue to do that. We have partnerships with something like 16 of the top 20.

This statement was materially false because the Company had not "seen continuing solid demand" from large pharma customers. Instead, (1) Pfizer had stopped awarding new full-service business to ICON as part of a "strategic refresh," and Cutler had internally admitted that ICON had lost the "Pfizer opportunity" and was no longer a preferred partner of Pfizer; (2) Pfizer had materially decreased the amount and dollar value of its awards to ICON, such that ICON's win rate was near zero and ICON was closed out of 85% of Pfizer's most lucrative Phase 2 and 3 business; (3) Pfizer had demanded—and Cutler had personally approved—significant budget cuts for ICON's existing studies; (4) ICON's PSBU continuously decreased in size from 2022; (5) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (6) Pfizer and other large customers were switching to nearly 100% FSP, slashing

ICON's profit margins; and (7) the PRA Merger had led to large customers' overconcentration that caused them to reduce their business with ICON. This statement was also materially misleading because it omitted these existing, material, negative facts, disclosure of which was necessary to make the statement not misleading in the context in which it was made.

## 11. 2Q24 Earnings Call

384. On July 25, 2024, ICON hosted a conference call with analysts to discuss the Company's 2Q24 financial results. In his prepared remarks, Defendant Cutler stated:

We remain encouraged by the leading indicators in our market that support a solid demand environment, including *continued growth in RFP flow and the overall consistent level of opportunities we are seeing across our customer segments*. While biotech funding levels attenuated slightly in quarter two from a robust start in quarter one, *we see this market continuing to stabilize and have seen a modest uptick in RFPs on a trailing 12-month and sequential basis within this segment*.

This statement was materially false because ICON was not seeing the biotech "market continue to stabilize" and had not seen "a modest uptick in RFPs on a trailing 12-month and sequential basis within this segment." Instead, ICON's biotech customer RFPs declined throughout 2023 and 2024. This statement was also materially misleading because Defendant Cutler touted "continued growth in RFP flow" while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; (3) ICON's biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

385. Later in the call, analyst Dave Windley from Jefferies asked, "Biotech, you had both at [our conference] in June and then again on the call, talked about attenuation in funding. I

wanted to understand, is that just a funding comment or did you also see that flow through to your activity?” Defendant Cutler responded:

Interestingly, as we look at the cancellations in the biotech and the RFP area, we typically talk about biotech dollars coming through and not so much what actually gets decided on. *So we’ve seen actually in quarter two, a reduction in the number of cancels in the pending side of things.* In other words, proposals that come to us, and we bid on, a proportion of those always get canceled never actually come to a decision. *We’ve seen a reduction in that. And that I think gives me some encouragement in terms of the rigor and the robustness of our pending pipeline.*

This statement was materially false because the Company had not experienced “a reduction in the number of cancels in the pending side of things” in biotech. Instead, up to 40% of RFPs to ICON were merely for price discovery and did not result in awards, and there was no “reduction” in this figure in 2Q24. This statement was also materially misleading because Defendant Cutler touted a “reduction” in cancellations and the “rigor and the robustness of our pending pipeline” while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; and (3) ICON’s biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

## 12. September 2024 Baird Conference

386. On September 10, 2024, Defendant Cutler attended the Robert W. Baird Global Healthcare Conference. At the conference, analyst Eric Codwell asked, “There’s been some interesting moves in the stock, in the sector. And I think we’re going to shift gears away from some of the canned Q&A and just jump right into what the heck is going on and maybe give us a little lay of the land on what’s on your mind.” Defendant Cutler responded:

The funding environment, first part of the year quarter or so, was very positive. That seems to have attenuated a little bit. And then also, that seems to us at least what we're seeing in the business is it's translated into a little bit of delay or some delays into the decision making around that biotech space which has some potential for impact. ***But overall, the number -- the percentage of RFPs that are coming through, the dollar amounts that are coming through remain strong, remain good,*** and we feel positive about that. In our large pharma segment as it's publicly disclosed, we've talked about this for a year now. One or two of our larger customers are restructuring their business and going through some budget cuts. So there's nothing new there. We certainly haven't -- that's not news to anybody. . . .

Our nature as an organization is to be honest and open with shareholders and with analysts and try to give you a perspective of what our business. We don't try to sugarcoat things too much. We like to be upfront, and that's what we're trying to do. ***No material changes really to the environment or to our business apart from, as I said, some of the biotech slowdown and some of the biotech decision making, which is having potentially some impact in the very short term.***

387. In response to Cutler's answer, Codwell asked, "were all of the topics that you just highlighted, topics that you had considered when you gave the recent update and the recent guidance?" Defendant Cutler responded:

***Yeah, yeah. Absolutely.*** Really, over the last sort of six, eight week -- and summer's also a bit of a challenging time. August, not much happens in our business, and September is a big month for us. So we have a lot of work to chop obviously in September to get our quarter-three number done. So there's a little bit of that playing in. ***But there's nothing that's fundamentally changed that we hadn't already thought about or included in our guidance. We are seeing a little bit of what we thought we were thinking, and those predictions if you like or that planning, is coming to fruition, if that makes sense. So we're seeing what we thought we'd see,*** and we just wanted to be specific and honest and open about that.

388. Codwell also asked, "I think I have to throw out there, it's September 10. So we found out from a few times this year across the industry that what happens from the second week of the quarter to the end of the quarter can change, but it sounds like there's really no notable change in frankly much of anything since you talked last quarter." Defendant Cutler responded:

***No, that's exactly right. No material, no really material changes,*** but we are trying to be, as you say, honest and open around some of the perhaps slow down, parents [sic] slowing down in decision making, particularly in the biotech and the challenges that we're addressing in our large pharma, in our top large pharma.

389. The statements identified in Paragraphs 386–388 were materially false because contrary to Defendant Cutler’s claim that ICON had experienced a “strong” or “good” “percentage of RFPs [and] dollar amounts that that are coming through,” many of ICON’s purported RFPs were issued only for price discovery and/or duplicative because they involved proposed studies that were competing for limited BARDA funding. Further, ICON had experienced a “material” and “fundamental[.]” “change[.]” that ICON “hadn’t already . . . included in our guidance” because the Pfizer COVID-flu vaccine had failed its Phase 3 trial, meaning ICON would lose a significant amount of money, and ICON’s guidance did not include the impact of this loss or the following facts known to Defendants at the time: (1) Pfizer had stopped awarding new full-service business to ICON as part of a “strategic refresh,” and Cutler had internally admitted that ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer; (2) Pfizer had materially decreased the amount and dollar value of its awards to ICON, such that ICON’s win rate was near zero and ICON was closed out of 85% of Pfizer’s most lucrative Phase 2 and 3 business; (3) Pfizer had demanded—and Cutler had personally approved—significant budget cuts for ICON’s existing studies; (4) ICON’s PSBU continuously decreased in size from 2022; (5) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (6) Pfizer and other large customers were switching to nearly 100% FSP, slashing ICON’s profit margins; (7) the PRA Merger had led to large customers’ overconcentration that caused them to reduce their business with ICON; and (8) ICON’s biotech segment was subject to a “revenue sweep” to attempt to close a \$100 million “gap” in the third quarter of 2024. These statements were also materially misleading because they omitted these existing, material, negative facts, as well as the facts that (9) many of ICON’s purported RFPs were issued only for price discovery and/or duplicative because they involved proposed studies that were competing for

limited BARDA funding, and (10) ICON's biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statements not misleading in the context in which they were made.

### 13. 3Q24 Earnings Call

390. On October 24, 2024, ICON hosted a conference call with analysts to discuss the Company's 3Q24 financial results.

391. During the call, analyst Michael Cherny of Leerink Partners asked what gives Cutler comfort about the pace of the biotech recovery, "given that obviously . . . it's been a bit slower than we all would have anticipated?" Defendant Cutler responded:

. . . We do see, as I say, some optimism in the segment *in terms of the RFPs numbers we're seeing through the solid, certainly solid enough.*

This statement was materially misleading because it omitted the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; and (3) ICON's biotech business was experiencing declining RFPs and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

392. Later in the call, analyst Max Smock of William Blair asked, "I just wanted to make sure I understand the drivers behind the miss on gross bookings versus the miss on revenue here because a lot of the factors you mentioned at the top of the call, the only one that really struck me as being more tied to new bookings and not burn rate was the award from small biotech. So -- can



you just walk through kind of whatever the key drivers of that shortfall in net bookings specifically?” Defendant Cutler responded:

We’re looking hard at the business, certainly over the next three or four months and will provide a guidance in January as we normally do. Having said that, as I indicated in my comments, there are some good opportunities in the pipeline. ***And the RFP flow continues to be solid across both segments of our market, both large pharma and biotech.***

This statement was materially false because the Company had not experienced “solid” “RFP flow” for “both large pharma and biotech.” Instead, ICON’s biotech customer RFPs declined throughout 2023 and 2024. This statement was also materially misleading because Defendant Cutler touted “solid” “RFP flow” for “both large pharma and biotech” while omitting the existing, material, negative facts that (1) many of these RFPs were issued only for price discovery, not to award actual business to ICON; (2) many of these RFPs were duplicative because they involved proposed studies that were competing for limited BARDA funding, such that only one study would materialize; and (3) ICON’s biotech business was experiencing declining RFPs, a lower win rate, and increased cancellations. By failing to disclose these existing, material, negative facts, Defendant Cutler omitted material facts necessary to make the statement not misleading in the context in which it was made.

#### 14. November 2024 Jefferies Conference

393. On November 21, 2024, Defendant Cutler attended the Jefferies London Healthcare Conference. At the conference, during his prepared remarks, Defendant Cutler stated:

We had a disappointing quarter three for some specific reasons relating to, particularly, our top two customers. And we’ll talk about that a bit more in the fireside chat. And that’s been an area that we’ve been aware of. But ***there are certainly [a] confluence of circumstances that hit us rather hard and rather late in quarter three leading to us reducing our guidance. I would say though, with the guidance we gave or the revised guidance we gave in quarter three stands, and we reiterate that firmly. For 2024, nothing’s changed in that respect.*** We are a company that’s had something like 50 quarters of good, solid progression in terms of earnings and progress on revenues. ***And the last quarter was something of an***

*anomaly, due, as I said, to particularly to a couple of our larger customers.* But we do feel that we are on the path back, and we'll be back within a couple of quarters going forward. So just a firm -- we are reiterating our guidance for 2024. That's the revised guidance that we gave on the Q3 call. . . . So overall, we see a very solid and constructive view of the industry going forward from a mid- to long-term point of view.

This statement was materially false because ICON's negative 3Q24 performance was not due to a "confluence of circumstances that hit us rather hard and rather late in quarter three leading to us reducing our guidance" or "an anomaly" related "to a couple of our larger customers." Instead, as detailed herein, for well over a year before 3Q24, ICON had been losing significant business from its largest customers, including that (1) Pfizer had stopped awarding new full-service business to ICON as part of a "strategic refresh," and Cutler had internally admitted that ICON had lost the "Pfizer opportunity" and was no longer a preferred partner of Pfizer; (2) Pfizer had materially decreased the amount and dollar value of its awards to ICON, such that ICON's win rate was near zero and ICON was closed out of 85% of Pfizer's most lucrative Phase 2 and 3 business; (3) Pfizer had demanded—and Cutler had personally approved—significant budget cuts for ICON's existing studies; (4) ICON's PSBU continuously decreased in size from 2022; (5) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (6) Pfizer and other large customers were switching to nearly 100% FSP, slashing ICON's profit margins; and (7) the PRA Merger had led to large customers' overconcentration that caused them to reduce their business with ICON.

#### **15. Materially Misleading Statements Concerning Risk Factors That Were a Known Certainty**

394. ICON's FY22 Form 20-F was filed on February 24, 2023, and incorporated by reference into ICON's 2Q23 and 3Q23 Form 6-Ks, filed on July 28, 2023 and October 27, 2023, respectively. ICON's FY23 Form 20-F was filed on February 23, 2024, and incorporated by reference into ICON's 1Q24, 2Q24 and 3Q24 Form 6-Ks, filed on April 25, 2024, July 25, 2024,

and October 25, 2024, respectively. ICON's FY22 Form 20-F and FY23 Form 20-F were signed by Defendant Brennan and certified by Brennan and Cutler, and each stated:

***The potential loss or delay of our large contracts, or of multiple contracts, could adversely affect our results.***

Our clients may discontinue using our services completely or cancel some projects either without notice or upon short notice. ***The termination or delay of a large contract, or of multiple contracts, could have a material adverse effect on our revenue and profitability.*** . . . [T]he loss, early termination or delay of a large contract or contracts could adversely affect our revenues and profitability.

***If we do not generate new business awards, or if new business awards are delayed, terminated, reduced in scope or fail to go to contract, our business, financial conditions, results of operations or cash flows may be materially adversely affected.***

Our business is dependent on our ability to generate new business awards from new and existing customers and maintain existing customer contracts. ***If we were unable to generate new business awards on a timely basis and contract for those awards, that could have a material impact on our business, financial condition, results of operations or cash flows.***

395. ICON's 2022 Form 20-F stated:

***We depend on a limited number of customers and a loss of, or significant decrease in, business from one or more of them could affect our business.***

While no customers individually contributed more than 10% of our revenues during the years ended December 31, 2022 and December 31, 2021, our top five customers represented 28.3% and 31.6% of our revenues, respectively.

***The loss of, or a significant decrease in, business from one or more of these key customers could have a material adverse impact on our results of operations and financial results.***

396. ICON's 2023 Form 20-F stated:

***We depend on a limited number of customers and a loss of, or significant decrease in, business from one or more of them could affect our business.***

While no customers individually contributed more than 10% of our revenues during the years ended December 31, 2023 and December 31, 2022, our top five customers represented 26.8% and 28.3% of our revenues, respectively. ***The loss of, or a significant decrease in, business from one or more of these key customers could have a material adverse impact on our results of operations and financial results.***

397. The statements identified in Paragraphs 394–396 were materially misleading because, in purportedly warning investors about various risks and hypothetical future events that “could” or “may” have “a material adverse impact” on ICON, they omitted the existing, material negative facts that ICON had already lost significant business from its largest customers, including that (1) Pfizer had stopped awarding new full-service business to ICON as part of a “strategic refresh,” and Cutler had internally admitted that ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer; (2) Pfizer had materially decreased the amount and dollar value of its awards to ICON, such that ICON’s win rate was near zero and ICON was closed out of 85% of Pfizer’s most lucrative Phase 2 and 3 business; (3) Pfizer had demanded—and Cutler had personally approved—significant budget cuts for ICON’s existing studies; (4) ICON’s PSBU continuously decreased in size from 2022; (5) ICON was losing significant business from other large customers, with the majority declining from early 2023 through 2024; (6) Pfizer and other large customers were switching to nearly 100% FSP, slashing ICON’s profit margins; and (7) the PRA Merger had led to large customers’ overconcentration that caused them to reduce their business with ICON. By portraying the loss of business from ICON’s large customers as merely hypothetical risks, rather than known certainties, these statements omitted material facts necessary to make the statements not misleading in the context in which they were made.

**B. Misstatements about ICON’s Book-to-Bill Ratio and Gross and Net Business Wins**

398. Defendants also materially overstated ICON’s book-to-bill ratio (purportedly ICON’s net business wins divided by revenue), and its gross and net business wins, during the Class Period.

399. ICON's 2Q23 Form 6-K, filed on July 26, 2023, stated: "**Gross business wins in the second quarter were \$2,860 million** and cancellations were \$441 million. **This resulted in net business wins of \$2,419 million and a book to bill of 1.20.**"

400. During ICON's July 27, 2023 earnings call, Defendant Cutler stated that "**net bookings grew 4% over quarter 2 2022, resulting in a net book-to-bill of 1.2x,**" and Defendant Brennan stated: "In quarter 2, **ICON achieved gross business wins of \$2.86 billion** and recorded \$441 million worth of cancellations. **This resulted in a net awards [sic] in the quarter of \$2.42 billion and net book-to-bill of 1.2x.**"

401. ICON's 3Q23 Form 6-K, filed on October 25, 2023, stated: "**Gross business wins in the third quarter were \$3,055 million** and cancellations were \$474 million. **This resulted in net business wins of \$2,581 million and a book to bill of 1.26.**"

402. During ICON's October 26, 2023 earnings call, Defendant Cutler stated: "**Net bookings increased 10% year-over-year, resulting in a good book-to-bill of 1.26x revenue in the quarter,**" and Defendant Brennan stated: "In quarter 3, **ICON achieved gross business wins of \$3.06 billion** and recorded \$474 million worth of cancellations. **This resulted in an impressive level of net awards in the quarter of \$2.58 billion, and net book-to-bill of 1.26x.**"

403. ICON's 4Q24 Form 6-K, filed on February 21, 2024, stated: "**Gross business wins in the fourth quarter were \$2,992 million** and cancellations were \$461 million. **This resulted in net business wins of \$2,531 million and a book to bill of 1.22.**"

404. During ICON's February 22, 2024 earnings call, Defendant Brennan stated: "In quarter 4, **ICON achieved gross business wins of \$2.99 billion** and recorded \$461 million worth of cancellations. **This resulted in a solid level of net awards in the quarter of \$2.53 billion, and net book-to-bill of 1.22x.**"

405. ICON's 1Q24 Form 6-K, filed on April 24, 2024, stated: "***Gross business wins in the first quarter were \$3,114 million and cancellations were \$460 million. This resulted in net business wins of \$2,654 million and a book to bill of 1.27.***"

406. During ICON's April 25, 2024 earnings call, Defendant Cutler stated: "In quarter 1, net bookings grew 10% on a year-over-year basis, ***resulting in a book-to-bill of 1.27x in the quarter and increasing our trailing 12-month book-to-bill ratio to 1.24,***" and Defendant Brennan stated: "In quarter 1, ***ICON achieved gross business wins of \$3.11 billion***, and recorded \$460 million worth of cancellations. ***This resulted in a solid level of net awards in the quarter of \$2.65 billion and a net book-to-bill of 1.27.***"

407. During ICON's April 25, 2024 earnings call, analyst Luke England Sergott of Barclays asked, "Can you talk about like the pass-throughs, the trends that you're seeing here in the current quarter and the elevated booking -- your bookings that you had for this quarter? Anything to step up there? We're just trying to find anything, I guess, to pick at or find issue with." Defendant Brennan responded:

No luck there, Luke. Brendan here. ***Obviously, we had a very solid quarter in terms of bookings, but that wasn't based on elevated pass-throughs or anything like that. We had a very solid direct fee book-to-bill as well, up to similar. So no, nothing there to particularly get you guys worried about.*** It was a very solid quarter across the organization and very much in terms of direct fee also.

408. ICON's 2Q24 Form 6-K, filed on July 24, 2024, stated: "***Gross business wins in the second quarter were \$3,072 million and cancellations were \$493 million. This resulted in net business wins of \$2,579 million and a book to bill of 1.22. . . . Gross business wins year to date were \$6,185 million and cancellations were \$953 million. This resulted in net business wins of \$5,232 million and a book to bill of 1.24.***" The 2Q24 Form 6-K also reported "a ***trailing twelve month net book to bill of 1.24.***"

409. During ICON’s July 25, 2024 earnings call, Defendant Cutler stated, “Turning to financial performance in quarter two, net bookings grew 7% on a year-over-year basis, **resulting in a book-to-bill of 1.2 times in the quarter and sustaining our trailing 12-month book-to-bill ratio of 1.24 times**,” and Defendant Brennan stated: “In quarter two, **ICON achieved gross business wins of \$3.07 billion**, an increase of 7.4% on a year-over-year basis. In addition, we recorded \$493 million worth of cancellations **resulting in net awards in the quarter of \$2.58 billion and net book to bill of 1.22 times**.”

410. ICON’s 3Q24 Form 6-K stated: “**Gross business wins in the third quarter were \$2,832 million** and cancellations were \$504 million. **This resulted in net business wins of \$2,328 million and a book to bill of 1.15**. . . . **Gross business wins year to date were \$9,017 million** and cancellations were \$1,457 million. **This resulted in net business wins of \$7,560 million and a book to bill of 1.21**.” The 3Q24 6-K also reported “**a trailing twelve month net book to bill of 1.21**.”

411. During ICON’s October 24, 2024 earnings call, Defendant Brennan stated: “In quarter three, **ICON achieved gross business wins of \$2,832 million**, a decrease of 7.3% on a year-over-year basis. In addition, we recorded \$504 million worth [of] cancellations, **resulting in net awards in the quarter of \$2,328 million [and] a net book-to-bill of 1.15 times**.”

412. The statements identified in Paragraphs 399–411 were materially false and misleading because ICON’s gross business wins, net business wins, and book-to-bill ratio during the Class Period were significantly inflated by (1) large numbers of customer “awards” entered into Salesforce that lacked signed contracts or were otherwise highly unlikely to materialize, and (2) Cutler’s directions to book awards at larger dollar amounts than sponsors had actually approved. Further, when asked about ICON’s purported 1.27 book-to-bill ratio in 1Q24,



Defendant Brennan falsely claimed that ICON “had a very solid quarter in terms of bookings” and there was “nothing there to particularly get you guys worried about,” while misleadingly omitting the existing, material, negative fact that ICON’s gross business wins, net business wins, and book-to-bill ratio were significantly inflated.

**C. Misstatements about ICON’s Purported GAAP Compliance, Revenue Recognition, and Accounting Methodology**

413. ICON’s FY23 Form 20-F stated:

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing: *U.S. GAAP* ☒ . . .

Unless otherwise indicated, ICON plc’s financial statements and other financial data contained in this Form 20-F are presented in United States dollars (“\$”) and *are prepared in accordance with generally accepted accounting principles in the United States* (“U.S. GAAP”). . . .

*We prepare our financial statements in accordance with generally accepted accounting principles in the United States of America* (“U.S. GAAP”) which are revised on an on-going basis by the authoritative bodies. . . .

*The consolidated financial statements have been prepared in accordance with U.S. GAAP.*

414. ICON’s Forms 6-K released July 28, 2023, October 27, 2023, April 26, 2024, and July 25, 2024 (each signed by Brennan) each stated:

These condensed consolidated financial statements *which have been prepared in accordance with United States Generally Accepted Accounting Principles* (‘US GAAP’) have not been audited.

415. The statements identified in Paragraphs 413–414 were materially false and misleading because the financial statements and other financial data contained in the FY23 Form 20-F and 2Q23, 3Q23, 1Q24, and 2Q24 Forms 6-K were not prepared “in accordance with U.S. GAAP,” and GAAP was not the “basis of accounting” ICON “used to prepare [its] financial statements.” Instead, Defendants violated GAAP because they (1) extended ICON’s reporting periods to overstate billing and cash received, and recognize additional revenue and profit;



(2) deliberately created fake invoices to inflate ICON's purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON's revenue, income, profit, and margins by not "loading" project costs that had "overburned" ICON's budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast "efficiencies" to boost margins, as detailed herein. These GAAP violations inflated ICON's reported revenue, net income, adjusted EBITDA, gross margin, and cash generated from operating activities. By failing to disclose these existing, material, negative facts, Defendants omitted material facts necessary to make the statements not misleading in the context in which they were made.

416. The FY23 Form 20-F also stated:

*Revenue is recognized over time as the single performance obligation is satisfied. The progress towards completion for clinical service contracts is measured based on an input measure being total project costs incurred (inclusive of pass-through/reimbursable expenses) at each reporting period as a percentage of forecasted total project costs. . . .*

*Revenue from long term contracts is recognized on a proportional performance method based on the relationship between cost incurred and the total estimated costs of the trial or on a fee-for-service basis according to the particular circumstances of the contract. . . .*

Contract fees are generally payable in installments based on the achievement of certain performance targets or "milestones" (e.g. target patient enrollment rates, clinical testing sites initiated or case report forms completed), such milestones being specific to the terms of each individual contract, *while revenues on contracts are recognized as contractual obligations are performed. . . .*

*Revenue from contracts is generally recognized as income on the basis of the relationship between costs incurred and the total estimated contract costs. . . .*

*The progress towards completion for clinical service contracts is measured based on total project costs (direct fees are therefore inclusive of third party costs). . . .*

*Revenue is recognized on a percentage completion basis as the single performance obligation is satisfied. The progress towards completion for clinical service contracts is measured based on an input measure being total project costs (inclusive of third party costs) at each reporting period. . . .*

As discussed in Note 2 to the consolidated financial statements, *clinical trial service revenue is recognized over time, using an input measure, being total project costs (inclusive of third-party costs, principally pass-through/reimbursable expenses) incurred at each reporting period as a percentage of forecasted total project costs*, to measure progress towards satisfying the Company's performance obligation. . . .

*The progress towards completion for clinical service contracts is measured based on total project costs* (including reimbursable costs).

417. ICON's Forms 6-K released July 28, 2023, October 27, 2023, April 25, 2024, and July 25, 2024 (each signed by Brennan) each further stated:

*Revenue is recognized over time as the single performance obligation is satisfied. The progress towards completion for clinical service contracts is measured based on an input measure being total project costs incurred (inclusive of pass-through/reimbursable expenses) at each reporting period as a percentage of forecasted total project costs. . . .*

*Revenue from long term contracts is recognized on a proportional performance method based on the relationship between cost incurred and the total estimated costs of the trial or on a fee-for-service basis according to the particular circumstances of the contract. . . .*

Contract fees are generally payable in installments based on the achievement of certain performance targets or "milestones" (e.g. target patient enrollment rates, clinical testing sites initiated or case report forms completed), such milestones being specific to the terms of each individual contract, *while revenues on contracts are recognized as contractual obligations are performed. . . .*

*Revenue from contracts is generally recognized as income on the basis of the relationship between time incurred and the total estimated contract duration or on a fee-for-service basis.*

418. The statements identified in Paragraphs 416–417 were materially false and misleading because ICON did not recognize revenue "over time as the single performance obligation is satisfied," based on "total project costs incurred," or "as contractual obligations are performed," and did not accurately calculate "total project costs." Instead, Defendants, in violation of GAAP, (1) extended ICON's reporting periods to overstate billing and cash received, and recognize additional revenue and profit; (2) deliberately created fake invoices to inflate ICON's

purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON's revenue, income, profit, and margins by not "loading" project costs that had "overburned" ICON's budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast "efficiencies" to boost margins, as detailed herein. These GAAP violations overstated ICON's percentage of completion on clinical trials and inflated ICON's reported revenue, net income, adjusted EBITDA, gross margin, and cash generated from operating activities. By failing to disclose these existing, material, negative facts, Defendants omitted material facts necessary to make the statements not misleading in the context in which they were made.

**D. Misstatements about ICON's Internal Controls over Financial Reporting and Disclosure Controls**

419. ICON's FY23 Form 20-F, signed by Defendant Brennan and certified by Brennan and Cutler, stated:

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2023. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control – Integrated Framework 2013*. ***Based upon the assessment performed, we determined that, as of December 31, 2023 the Company's internal control over financial reporting was effective.*** There have been no changes in the Company's internal control over financial reporting during 2023 that have materially affected, or are reasonably likely to affect materially, the Group's internal control over financial reporting.

420. The FY23 Form 20-F also stated:

An evaluation was carried out under the supervision and with the participation of the Company's management, including the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO), of the effectiveness of our disclosure controls and procedures as at December 31, 2023. ***Based on that evaluation, the CEO and CFO have concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.*** Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure

that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

421. Exhibit 12.1 to the FY23 Form 20-F contains Cutler's and Brennan's respective Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, pursuant to which Cutler and Brennan each certified that:

2. Based on my knowledge, *this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;*

3. Based on my knowledge, *the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;*

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) *Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;*

b) *Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;*

c) *Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and*

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting.

422. Exhibit 12.2 to the FY23 Form 20-F contains Cutler's and Brennan's Certifications Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, pursuant to which Cutler and Brennan each certified that:

(1) the [Annual Report of ICON plc (the "Company") on Form 20-F for the year ending December 31, 2023] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the *information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.*

423. The statements identified in Paragraphs 419–422 were materially misleading because the FY23 Form 20-F did not “fairly present[], in all material respects, the financial condition and result of operations of the Company,” and ICON's internal controls over financial reporting and disclosure controls and procedures were materially deficient. As detailed herein, Defendants violated GAAP because they (1) extended ICON's reporting periods to overstate billing and cash received, and recognize additional revenue and profit; (2) deliberately created fake invoices to inflate ICON's purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON's revenue, income, profit, and margins by not “loading” project costs that had “overburned” ICON's budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast “efficiencies” to boost margins, as detailed herein. Further, in the fourth quarter of 2023, ICON's senior management falsely allocated \$350 million in revenue to ICON's biotech segment to prop it up. In addition, Defendants inflated ICON's reported gross business wins, net business wins, and book-to-bill ratio during the Class Period by including large numbers of customer “awards” entered into Salesforce that lacked signed contracts or were otherwise highly

unlikely to materialize, and through Cutler's directions to book awards at larger dollar amounts than sponsors had actually approved. ICON's deficient internal controls over financial reporting and deficient disclosure controls and procedures allowed these GAAP violations and manipulations to occur. By failing to disclose these existing, material, negative facts, Defendants omitted material facts necessary to make the statements not misleading in the context in which they were made. Further, given the flagrant and pervasive nature of Defendants' GAAP violations and manipulations, and their material impact—for example, holding reporting periods open beyond their stated close boosted ICON's purported quarterly revenue by 5–10%—Defendants Cutler and Brennan did not, and had no basis to, believe that ICON's internal control over financial reporting or disclosure controls and procedures were effective.

#### **E. Misstatements about ICON's Financial Performance**

##### **1. 2Q23 Filings**

424. After the close of trading on July 26, 2023, ICON filed a press release on Form 6-K with the SEC reporting the Company's 2Q23 financial results. The Form 6-K was signed by Defendant Brennan. In the press release, the Company reported:

*Quarter two adjusted EBITDA of \$414.2 million* or 20.5% of revenue, an increase of 16.9% on quarter two 2022. *YTD adjusted EBITDA of \$813.4 million* or 20.3% of revenue, representing a year on year increase of 17.0%. . . .

*Quarter two adjusted net income* attributable to the Group was *\$256.9 million* or \$3.11 per diluted share, an increase of 8.7% on quarter two 2022 adjusted earnings per share. *Year to date adjusted net income* attributable to the Group of *\$496.7 million* or \$6.01 per diluted share, an increase of 6.9% year on year. . . .

*Cash generated from operating activities for the quarter was \$203.9 million.*

425. The next day, on July 27, 2023, ICON hosted a conference call with analysts to discuss the Company's 2Q23 financial results. In his prepared remarks, Defendant Brennan stated:

*Gross margin for the quarter was 29.6%* compared to 29.8% in quarter 1, 2023.

426. On July 28, 2023, ICON filed its 2Q23 quarterly financial report on Form 6-K. The 2Q23 Form 6-K was signed by Defendant Brennan. ICON's 2Q23 Form 6-K reported quarterly revenue of \$2.02 billion and year-to-date revenue of \$4.00 billion; quarterly GAAP net income of \$115.6 million or \$1.40 per diluted share and year-to-date GAAP net income of \$232.3 million or \$2.81 per diluted share; and year-to-date net cash from operating activities of \$379.4 million and year-to-date cash and cash equivalents of \$270.2 million.

427. The 2Q23 Form 6-K further stated that ICON's financial results—including its condensed consolidated balance sheets, condensed consolidated statements of operations, condensed consolidated statements of comprehensive income, and condensed consolidated statements of cash flows; ICON's net income per ordinary share and diluted net income per ordinary share; changes in ICON's revenue and income from operations; ICON's cash and short term investment balances; and ICON's net cash provided by operating activities—were each reported for periods ending “June 30, 2023.”

428. The statements identified in Paragraphs 424–427 were materially false and misleading because Defendants, in violation of GAAP, (1) extended ICON's reporting periods to overstate billing and cash received, and recognize additional revenue and profit; (2) deliberately created fake invoices to inflate ICON's purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON's revenue, income, profit, and margins by not “loading” project costs that had “overburned” ICON's budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast “efficiencies” to boost margins, as detailed herein. These GAAP violations inflated ICON's reported revenue, net income, adjusted EBITDA, gross margin, and cash generated from operating activities. By failing to disclose these existing, material,



negative facts, Defendants omitted material facts necessary to make the statements not misleading in the context in which they were made.

## 2. 3Q23 Filings

429. After the close of trading on October 25, 2023, ICON filed a press release on Form 6-K with the SEC reporting the Company's 3Q23 financial results. The Form 6-K was signed by Defendant Brennan. In the press release, the Company reported:

***Quarter three adjusted EBITDA of \$432.5 million*** or 21% of revenue, an increase of 13.9% on quarter three 2022. ***YTD adjusted EBITDA of \$1,245.9 million*** or 20.6% of revenue, representing a year on year increase of 16.0%. . . .

***Quarter three adjusted net income*** attributable to the Group was ***\$273.9 million*** or \$3.30 per diluted share, an increase of 10.0% on quarter three 2022 adjusted earnings per share. ***Year to date adjusted net income*** attributable to the Group of ***\$770.7 million*** or \$9.31 per diluted share, an increase of 8.0% year on year. . . .

***Cash generated from operating activities for the quarter was \$341.5 million.***

430. The next day, on October 26, 2023, ICON hosted a conference call with analysts to discuss the Company's 3Q23 financial results. In his prepared remarks, Defendant Brennan stated:

***Gross margin for the quarter was 29.8%*** compared to 29.6% in quarter 2, 2023.

431. On October 27, 2023, ICON filed its 3Q23 quarterly financial report on Form 6-K. The 3Q23 Form 6-K was signed by Defendant Brennan. ICON's 3Q23 Form 6-K reported quarterly revenue of \$2.06 billion and year-to-date revenue of \$6.05 billion; quarterly GAAP net income of \$163.7 million or \$1.97 per diluted share and year-to-date GAAP net income of \$395.9 million or \$4.79 per diluted share; and year-to-date net cash from operating activities of \$720.9 million and year-to-date cash and cash equivalents of \$313.1 million.

432. The 3Q23 Form 6-K further stated that ICON's financial results—including its condensed consolidated balance sheets, condensed consolidated statements of operations, condensed consolidated statements of comprehensive income, and condensed consolidated



statements of cash flows; ICON’s net income per ordinary share and diluted net income per ordinary share; changes in ICON’s revenue and income from operations; ICON’s cash and short term investment balances; and ICON’s net cash provided by operating activities—were each reported for periods ending “September 30, 2023.”

433. The statements identified in Paragraphs 429–432 were materially false and misleading because Defendants, in violation of GAAP, (1) extended ICON’s reporting periods to overstate billing and cash received, and recognize additional revenue and profit; (2) deliberately created fake invoices to inflate ICON’s purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON’s revenue, income, profit, and margins by not “loading” project costs that had “overburned” ICON’s budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast “efficiencies” to boost margins, as detailed herein. These GAAP violations inflated ICON’s reported revenue, net income, adjusted EBITDA, gross margin, and cash generated from operating activities. By failing to disclose these existing, material, negative facts, Defendants omitted material facts necessary to make the statements not misleading in the context in which they were made.

434. The 3Q23 Form 6-K also stated:

***The increase in net cash provided by operating activities of \$98.2 million is primarily due to an increase in underlying operating activity and improved working capital.***

This statement was materially false and misleading because ICON’s increase in net cash provided by operating activities was attributable to how Defendants, in violation of GAAP, (1) extended ICON’s reporting periods to overstate billing and cash received, and recognize additional revenue and profit; (2) deliberately created fake invoices to inflate ICON’s purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON’s revenue, income, profit, and

margins by not “loading” project costs that had “overburned” ICON’s budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast “efficiencies” to boost margins, as detailed herein. These GAAP violations inflated ICON’s reported revenue, net income, adjusted EBITDA, gross margin, and cash generated from operating activities. By stating that ICON’s increase in net cash provided by operating activities was “primarily due to an increase in underlying operating activity and improved working capital,” while failing to disclose these existing, material, negative facts, Defendants omitted material facts necessary to make the statement not misleading in the context in which it was made.

### 3. 4Q23 and FY23 Filings

435. After the close of trading on February 21, 2024, ICON filed a press release on Form 6-K with the SEC reporting the Company’s 4Q23 and full-year 2023 financial results. The Form 6-K was signed by Defendant Brennan. In the press release, the Company reported:

***Quarter four revenue of \$2,066.2 million*** representing an increase of 5.3% on prior year revenue. ***Full year revenue of \$8,120.2 million*** representing a year on year increase of 4.9%.

***Quarter four adjusted EBITDA of \$448.2 million*** or 21.7% of revenue, an increase of 10.7% on quarter four 2022. ***Full year adjusted EBITDA of \$1,694.1 million*** or 20.9% of revenue, representing a year on year increase of 14.5%.

***GAAP net income for the quarter of \$216.4 million or \$2.60 per diluted share. . . .***

***Quarter four adjusted net income was \$287.5 million*** or \$3.46 per diluted share, an increase of 10.5% on quarter four 2022 adjusted earnings per share. ***Full year adjusted net income of \$1,058.2 million*** or \$12.79 per diluted share, an increase of 8.9% on the prior year adjusted earnings per share. . . .

***Cash generated from operating activities for the quarter was \$440.1 million.***

436. The next day, February 22, 2024, ICON hosted a conference call with analysts to discuss the Company’s 4Q23 financial results. In his prepared remarks, Defendant Brennan stated:

**Gross margin for the quarter was 30.4%** compared to 29.8% in quarter 3, 2023. Gross margin increased 50 basis points of gross margin of 29.9% in quarter 4 2022. **Full year 2023 gross margin was 29.9%**, and we anticipate this to be a similar level for the full year 2024.

437. On February 23, 2024, ICON filed its full-year 2023 financial report on Form 20-F. The FY23 Form 20-F was signed by Defendant Brennan and certified by Brennan and Cutler. ICON's FY23 Form 20-F reported FY23 revenue of \$8.12 billion; FY23 GAAP net income of \$612.3 million or \$7.40 per diluted share; and FY23 net cash from operating activities of \$1.16 billion and cash and cash equivalents of \$378.1 million.

438. The FY23 Form 20-F further stated that ICON's financial results—including its condensed consolidated balance sheets, condensed consolidated statements of operations, condensed consolidated statements of comprehensive income, and condensed consolidated statements of cash flows; ICON's net income per ordinary share and diluted net income per ordinary share; changes in ICON's revenue and income from operations; ICON's cash and cash equivalents and available for sale investments; and ICON's net cash provided by operating activities—were each reported for periods ending “December 31, 2023.”

439. The statements identified in Paragraphs 435–438 were materially false and misleading because Defendants, in violation of GAAP, (1) extended ICON's reporting periods to overstate billing and cash received, and recognize additional revenue and profit; (2) deliberately created fake invoices to inflate ICON's purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON's revenue, income, profit, and margins by not “loading” project costs that had “overburned” ICON's budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast “efficiencies” to boost margins, as detailed herein. These GAAP violations inflated ICON's reported revenue, net income, adjusted EBITDA, gross margin,

and cash generated from operating activities. By failing to disclose these existing, material, negative facts, Defendants omitted material facts necessary to make the statements not misleading in the context in which they were made.

440. ICON's FY23 Form 20-F attributed the 4.9% increase in revenue in 2023 "to the continued organic growth across the Company's markets."

441. The FY23 Form 20-F also stated:

***The increase in net cash provided by operating activities of \$597.7 million is primarily due to an increase in underlying operating activity and improved working capital management.***

442. The statements identified in Paragraphs 440–441 were materially false and misleading because ICON's increased revenue and increase in net cash provided by operating activities were attributable to how Defendants, in violation of GAAP, (1) extended ICON's reporting periods to overstate billing and cash received, and recognize additional revenue and profit; (2) deliberately created fake invoices to inflate ICON's purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON's revenue, income, profit, and margins by not "loading" project costs that had "overburned" ICON's budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast "efficiencies" to boost margins, as detailed herein. These GAAP violations inflated ICON's reported revenue, net income, adjusted EBITDA, gross margin, and cash generated from operating activities. By stating that ICON's increase in revenue was due "to the continued organic growth across the Company's markets" and that ICON's increase in net cash provided by operating activities was "primarily due to an increase in underlying operating activity and improved working capital," while failing to disclose these existing, material, negative facts, Defendants omitted material facts necessary to make the statements not misleading in the context in which they were made.

#### 4. 1Q24 Filings

443. After the close of trading on April 24, 2024, ICON filed a press release on Form 6-K with the SEC reporting the Company's 1Q24 financial results. The Form 6-K was signed by Defendant Brennan. In the press release, the Company reported:

***Quarter one adjusted EBITDA of \$444.0 million*** or 21.2% of revenue, an increase of 11.3% on quarter one 2023. . . .

***Quarter one adjusted net income was \$288.5 million*** or \$3.47 per diluted share, an increase of 19.7% on quarter one 2023 adjusted earnings per share. . . .

***Cash generated from operating activities for the quarter was \$327.1 million.***

444. The next day, on April 25, 2024, ICON hosted a conference call with analysts to discuss the Company's 1Q24 financial results. In his prepared remarks, Defendant Brennan stated:

***Gross margin of 29.9%*** increased 10 basis points over quarter 1 2023.

445. On April 26, 2024, ICON filed its 1Q24 quarterly financial report on Form 6-K. The 1Q24 Form 6-K was signed by Defendant Brennan. ICON's 1Q24 Form 6-K reported quarterly revenue of \$2.09 billion; quarterly GAAP net income of \$187.4 million or \$2.25 per diluted share; and year-to-date net cash from operating activities of \$151.6 million and year-to-date cash and cash equivalents of \$396.1 million.

446. The 1Q24 Form 6-K further stated that ICON's financial results—including its condensed consolidated balance sheets, condensed consolidated statements of operations, condensed consolidated statements of comprehensive income, and condensed consolidated statements of cash flows; ICON's net income per ordinary share and diluted net income per ordinary share; changes in ICON's revenue and income from operations; ICON's cash and cash equivalents and available for sale investment balances; and ICON's net cash provided by operating activities—were each reported for periods ending “March 31, 2024.”

447. The statements identified in Paragraphs 443–446 were materially false and misleading because Defendants, in violation of GAAP, (1) extended ICON’s reporting periods to overstate billing and cash received, and recognize additional revenue and profit; (2) deliberately created fake invoices to inflate ICON’s purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON’s revenue, income, profit, and margins by not “loading” project costs that had “overburned” ICON’s budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast “efficiencies” to boost margins, as detailed herein. These GAAP violations inflated ICON’s reported revenue, net income, adjusted EBITDA, gross margin, and cash generated from operating activities. By failing to disclose these existing, material, negative facts, Defendants omitted material facts necessary to make the statements not misleading in the context in which they were made.

448. The 1Q24 6-K also stated:

***The increase in net cash provided by operating activities of \$151.6 million is primarily due to an increase in underlying operating activity and improved working capital.***

This statement was materially false and misleading because ICON’s increase in net cash provided by operating activities was attributable to how Defendants, in violation of GAAP, (1) extended ICON’s reporting periods to overstate billing and cash received, and recognize additional revenue and profit; (2) deliberately created fake invoices to inflate ICON’s purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON’s revenue, income, profit, and margins by not “loading” project costs that had “overburned” ICON’s budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast “efficiencies” to boost margins, as detailed herein. These GAAP violations inflated ICON’s reported revenue, net income, adjusted EBITDA, gross

margin, and cash generated from operating activities. By stating that ICON's increase in net cash provided by operating activities was "primarily due to an increase in underlying operating activity and improved working capital," while failing to disclose these existing, material, negative facts, Defendants omitted material facts necessary to make the statement not misleading in the context in which it was made.

## 5. 2Q24 Filings

449. After the close of trading on July 24, 2024, ICON filed a press release on Form 6-K with the SEC reporting the Company's 2Q24 financial results. The Form 6-K was signed by Defendant Brennan. In the press release, the Company reported:

***Quarter two adjusted EBITDA of \$450.4 million*** or 21.2% of revenue, an increase of 8.7% on quarter two 2023. . . .

***Quarter two adjusted net income was \$312.6 million*** or \$3.75 per diluted share, an increase of 20.6% on quarter two 2023 adjusted diluted earnings per share. . . .

***Cash generated from operating activities for the quarter was \$218.6 million.***

450. The next day, on July 25, 2024, ICON hosted a conference call with analysts to discuss the Company's 2Q24 financial results. In his prepared remarks, Defendant Brennan stated:

***Gross margin for the quarter was 29.9%***, consistent with quarter one, 2024, as expected.

451. Also on July 25, 2024, ICON filed its 2Q24 quarterly financial report on Form 6-K. The 2Q24 Form 6-K was signed by Defendant Brennan. ICON's 2Q24 Form 6-K reported quarterly revenue of \$2.120 billion and year-to-date revenue of \$4.210 billion; quarterly GAAP net income of \$146.9 million or \$1.76 per diluted share and year-to-date GAAP net income of \$334.3 million or \$4.02 per diluted share; and year-to-date net cash from operating activities of \$545.7 million, and year-to-date cash and cash equivalents of \$506.6 million.

452. The 2Q24 Form 6-K further stated that ICON’s financial results—including its condensed consolidated balance sheets, condensed consolidated statements of operations, condensed consolidated statements of comprehensive income, and condensed consolidated statements of cash flows; ICON’s net income per ordinary share and diluted net income per ordinary share; changes in ICON’s revenue and income from operations; ICON’s cash and cash equivalents; and ICON’s net cash provided by operating activities—were each reported for periods ending “June 30, 2024.”

453. The statements identified in Paragraphs 449–452 were materially false and misleading because Defendants, in violation of GAAP, (1) extended ICON’s reporting periods to overstate billing and cash received, and recognize additional revenue and profit; (2) deliberately created fake invoices to inflate ICON’s purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON’s revenue, income, profit, and margins by not “loading” project costs that had “overburned” ICON’s budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast “efficiencies” to boost margins, as detailed herein. These GAAP violations inflated ICON’s reported revenue, net income, adjusted EBITDA, gross margin, and cash generated from operating activities. By failing to disclose these existing, material, negative facts, Defendants omitted material facts necessary to make the statements not misleading in the context in which they were made.

454. The 2Q24 6-K also stated:

***The increase in net cash provided by operating activities of \$166.3 million is primarily due to an increase in underlying operating activity.***

This statement was materially false and misleading because ICON’s increase in net cash provided by operating activities was attributable to how Defendants, in violation of GAAP, (1) extended



ICON's reporting periods to overstate billing and cash received, and recognize additional revenue and profit; (2) deliberately created fake invoices to inflate ICON's purported billing to clients and recognize additional revenue; (3) manipulated and inflated ICON's revenue, income, profit, and margins by not "loading" project costs that had "overburned" ICON's budget; and (4) prematurely recognized revenue from draft, unsigned change orders, prematurely recognized revenue before meeting contractual milestones, and forecast "efficiencies" to boost margins, as detailed herein. These GAAP violations inflated ICON's reported revenue, net income, adjusted EBITDA, gross margin, and cash generated from operating activities. By stating that ICON's increase in net cash provided by operating activities was "primarily due to an increase in underlying operating activity," while failing to disclose these existing, material, negative facts, Defendants omitted material facts necessary to make the statement not misleading in the context in which it was made.

## **VII. SUMMARY OF SCIENTER ALLEGATIONS**

455. Together with the above-alleged facts, the Individual Defendants acted with scienter in that each knew or recklessly disregarded the true facts in making the materially false and misleading statements identified in Section VI above. The key allegations that support a strong inference of scienter are summarized below.

### **A. Cutler's and Brennan's Unusual, Highly Profitable Insider Sales Support a Strong Inference of Scienter**

456. CEO Cutler and CFO Brennan capitalized on ICON's inflated stock price by selling over 126,000 shares of their ICON ordinary shares at inflated prices to reap net profits of nearly \$30 million. The fact that two senior ICON executives made unusual, large stock sales as ICON's stock price approached its Class Period high supports a strong inference of scienter—particularly given Cutler's internal "\$500 by 2025" goal of boosting ICON's stock price to \$500 by 2025.

457. Each executive's insider sales of ICON ordinary shares during the Class Period, and the resulting proceeds and profits, are set forth below:<sup>11</sup>

**Stephen Cutler: Insider Sales of ICON Stock During Class Period**

<b>Date</b>	<b>Shares Sold</b>	<b>Share Price</b>	<b>Sale Proceeds</b>	<b>Estimated Net Profits</b>
7/31/2023	5,202 (from RSUs/PSUs)	\$251.21	\$1,306,776.73	\$1,306,776.73
9/14/2023	13,500 (from options)	\$265.48	\$3,583,971.90	\$2,516,661.90
9/15/2023	2,500 (from options)	\$265.36	\$663,396.00	\$465,746.00
11/21/2023	18,517 (from RSUs/PSUs)	\$271.03	\$5,018,732.87	\$5,018,732.87
3/6/2024	15,442 (from RSUs/PSUs)	\$335.98	\$5,188,132.13	\$5,188,132.13

<b>Gross Sale Proceeds</b>	\$15,761,009.63
<b>Estimated Total Net Profits</b>	\$14,496,049.63
<b>Total Shares Sold</b>	55,161
<b>Total Shares and Vested Options<sup>12</sup></b>	238,014
<b>Shares Sold as a % of Total Shares and Vested Options</b>	23.2%

<sup>11</sup> These transactions are drawn from the Forms 144 that each insider filed with the SEC. These tables exclude transactions occurring on or near the vesting dates for Cutler and Brennan (March 3, 2022; March 3, 2023; and March 3, 2024), which are presumed to be effected for tax withholding purposes. Estimated Net Profits for transactions involving RSUs (Restricted Stock Units) or PSUs (Performance Stock Units) are identical to their Sale Proceeds. Estimated Net Profits for transactions involving options is the difference between the stock's market price at the time of exercise and the exercise price (determined from ICON's Annual Reports from 2022–2024). Share Price is rounded to the nearest cent.

<sup>12</sup> Total Shares and Vested Options are equal to shares held at the start of the Class Period, plus RSUs, PSUs, and options that vested during the Class Period, less shares sold on or near vesting dates. Option grants are assumed to vest over five years at a rate of 20% per year.

**Brendan Brennan: Insider Sales of ICON Stock During Class Period**

<b>Date</b>	<b>Shares Sold</b>	<b>Share Price</b>	<b>Sale Proceeds</b>	<b>Estimated Net Profits</b>
11/16/2023	25,926 (from options)	\$267.79	\$6,942,625.02	\$4,074,950.16
11/16/2023	4,280 (from RSUs)	\$267.79	\$1,146,124.94	\$1,146,124.94
2/26/2024	7,021 (from private acquisition)	\$316.33	\$2,220,929.06	\$2,220,929.06
5/10/2024	7,930 (from RSUs)	\$316.43	\$2,509,319.24	\$2,509,319.24
7/29/2024	18,518 (from options)	\$325.99	\$6,036,706.89	\$2,736,428.93
7/29/2024	7,546 (from PSUs)	\$325.99	\$2,459,930.35	\$2,459,930.35

<b>Gross Sale Proceeds</b>	\$21,315,635.50
<b>Estimated Total Net Profits</b>	\$15,147,682.68
<b>Total Shares Sold</b>	71,221
<b>Total Shares and Vested Options</b>	72,224
<b>Shares Sold as a % of Total Shares and Vested Options</b>	98.6%

458. Cutler's and Brennan's insider sales were highly unusual and suspicious.

459. First, these insider sales realized unusually large profits. Cutler's and Brennan's estimated net profits were \$14,496,050 and \$15,147,683, respectively, for a combined total of \$29,643,733. Cutler's net profits were twice his total 2023 compensation of \$7.2 million, and Brennan's net profits were seven times his total 2023 compensation of \$2.1 million.

460. Second, Cutler and Brennan each sold large percentages of their total holdings. As detailed above, Cutler and Brennan respectively divested 23.2% and 98.6% of their total holdings during the Class Period. Significantly, Brennan sold most of his holdings (52.3%) prior to the announcement of his resignation on April 3, 2024.

461. Third, Cutler's and Brennan's insider sales were unusual compared to their sales before and after the Class Period. Cutler made *no* non-tax sales in 2022, the first six months of

2023, or after the Class Period. Brennan's Class Period sales dwarf his pre-Class Period sales. In 2022, Brennan sold only 18,991 shares in non-tax transactions, compared to 30,206 shares in 2023 and 41,015 shares in 2024. Brennan has sold zero shares since the Class Period.

462. Fourth, the timing of Cutler's and Brennan's insider sales was unusual. The sales occurred near peaks in ICON's stock price (which was artificially inflated due to their misstatements), making them highly profitable. The majority of Brennan's sales occurred at prices well over \$300 per share.

463. In addition, several sales occurred shortly after Cutler and Brennan made false statements to investors. For example, Cutler made his first insider sale (for net profits of \$1.3 million) on July 31, 2023—just two business days after he made the first misstatements in this action on July 27, 2023. Brennan made his first and largest insider sale (for net profits of \$5.2 million) on November 16, 2023—just two days after the November 14, 2023 Jefferies conference where he falsely claimed there was “definitely” a “significant kind of uptick [in RFPs] from our biotech customers.” On March 6, 2024—the day after misstatements at the March 5, 2024 TD Cowen Health Care Conference—Cutler sold shares for \$5.2 million of net profits. On July 29, 2024—just two business days after ICON's July 25, 2024 earnings call—Brennan sold shares to reap net profits of \$5.2 million.

464. Further, shortly after the fraud began to unravel, Cutler's and Brennan's sales quickly stopped: neither sold a single share after July 29, 2024 through the end of the Class Period on January 13, 2025. Thus, Cutler's and Brennan's suspicious and unusual insider sales appear calculated to maximize their personal profits from their fraud.

465. Fifth, none of Cutler's and Brennan's insider sales were conducted through a Rule 10b5-1 insider trading plan. These sales were entirely discretionary.

466. Finally, Cutler's and Brennan's insider sales occurred when both were uniquely situated to profit from knowing the truth they concealed from investors.

467. As detailed above, Cutler and Brennan knew ICON's biotech customer RFPs were continuously declining through 2023 and 2024, while biotech cancellations increased, totaling several hundred million dollars in 2023 alone. They were aware of significant issues with ICON's large customers, including (i) Pfizer's decision in 2023 to stop awarding new full-service awards and at least 85% of its Phase 2 and 3 studies to ICON, causing ICON's win rate with Pfizer to drop near zero; (ii) ICON's effort to begin shutting down its Pfizer-dedicated PSBU by early 2024 given the lack of business from Pfizer; (iii) Cutler's personal approval in January 2024 of a \$50 million budget cut on ICON's remaining Pfizer studies; and (iv) Pfizer's and other large customers' shift to nearly 100% FSP, decimating ICON's profits and margins.

468. Indeed, Cutler's single largest sale (on March 6, 2024, yielding \$5.2 million in net profits) occurred shortly after he internally admitted, at an ICON town hall in February 2024, that ICON had lost the "Pfizer opportunity" and was no longer a preferred partner of Pfizer—a highly material, non-public fact that would significantly reduce ICON's share price once it was revealed.

469. That Defendants Cutler and Brennan profited nearly \$30 million from selling ICON stock, while concealing the truth about ICON's declining business, is strong evidence of scienter.

#### **B. Former Employee Allegations**

470. Former ICON employees provided information on a confidential basis supporting the strong inference that the Individual Defendants acted with scienter in making the alleged materially false and misleading statements. The former employees' accounts corroborate one another and the additional facts alleged herein.

## 1. FE-1

471. FE-1 initially worked at ICON as a technical project manager for product development between November 2011 and March 2017, and a senior technical project manager for product management until June 2017. FE-1 rejoined ICON in January 2020 as a senior project manager for the IRT (Interactive Response Technologies) division. In March 2021, FE-1 became a director of business development for ICON's IRT and Clinical Supplies Management ("CSM") Solutions divisions and remained at ICON in that role until September 1, 2024. FE-1's role involved sales for the IRT and CSM businesses for the whole company, maintaining clients, and cultivating new business. FE-1 was ICON's salesperson responsible for the IRT and CSM sales for most of FE-1's second employment term. During the period from January 2023 to September 2024, FE-1 reported to Executive Director Sales Strategy, Biometrics & Pharmacovigilance Amanda Cohen; Cohen initially reported to Senior Vice President Yves Grenon and later reported to current Vice President of Business Development Eloise Harris. Grenon and Harris reported to Executive Vice President and Chief Commercial Officer George McMillan. According to FE-1, based on personal knowledge:

- i. **Cutler Was the Pfizer Executive Sponsor:** Pfizer was ICON's largest customer. Based on regularly working with Pfizer for over a decade, FE-1 explained that Pfizer has always been ICON's "number one since day one" and was a "centerpiece" of ICON's business. Further, CEO Cutler was Pfizer's "executive sponsor." FE-1 recalled that ICON internal documents listed top customers with the assigned business development lead and an executive-level sponsor. Cutler was the executive sponsor for Pfizer and certain other customers.
- ii. **Pfizer Slowdown:** FE-1 described a trend of Pfizer reducing its business with ICON starting in 2023. During a 2023 "strategic refresh," Pfizer informed ICON that it was not getting any full-service work. This was a negative development for ICON given the higher margins for full-service work and the lower margins on FSP work.
  - a. In 2023, Pfizer stopped awarding new full-service business to ICON as part of a "strategic refresh."

- i. FE-1 explained that in the “strategic refresh,” Pfizer asked ICON to bid on mock studies under several models, ranging from FSP to full-service to a combination of both. FE-1 worked on preparing the bids submitted to Pfizer, together with Michael Ohrwashel, Karen Tormey, and other ICON executives, including CCO McMillan. FE-1 recalled that McMillan was “always involved in anything strategic,” and based on working with ICON’s full-service personnel, FE-1 explained that any budgets over \$9 or \$10 million required executive approval and review by McMillan. The Pfizer “strategic refresh” involved hundreds of millions of dollars.
  - ii. ICON provided the bids in 2023. In response, Pfizer responded that ICON was not getting any full-service work. ICON’s full-service work for Pfizer had previously involved large, global Phase 3 studies of \$20 to \$30 million each.
  - iii. The Pfizer “strategic refresh” was completed by mid- to late 2023.
- b. FE-1 confirmed that Pfizer was not awarding a lot of new business to ICON throughout 2023 and 2024.
  - i. For context, ICON had enjoyed a 50% win rate for Pfizer’s studies through approximately 2021, but saw a trend of a declining Pfizer win rate over the next several years.
  - ii. Once Pfizer’s “strategic refresh” was completed in mid- to late 2023, ICON’s win rate with Pfizer dropped near zero.
- c. FE-1 was aware of the declining Pfizer business from participating in monthly business development calls dedicated to Pfizer, which included representatives from each of ICON’s functional groups on the sales side, including Ohrwashel (for the full-service business), Tormey, and sometimes Mark Cooper (then head of ICON FSP).
  - i. During the calls, the participants reviewed detailed Salesforce reports (maintained by Ohrwashel) that included, among other things, Pfizer’s backlog, awards, pipeline, all open RFPs, and ICON’s chance of winning those RFPs.
  - ii. FE-1 explained that during these monthly meetings, no one offered positive projections for the Pfizer relationship. Instead, the most positive development concerning Pfizer was an IRT award of about \$2.5 million that FE-1 achieved shortly before he left ICON in September 2024. While this award was “small dollars,” FE-1 explained that it stood out given the lack of other new awards from Pfizer.
- d. On the FSP side, ICON’s standard contracts generally required 90 days advance notice for staffing changes.

- iii. **Biotech Slowdown:** FE-1 described a trend of slowdown in ICON’s biotech business in 2023 and 2024 based on decreasing biotech RFPs, increasing cancellations, numerous “awards” without signed contracts driving ICON’s revenue forecasts, and RFPs that were premature or duplicative.
- iv. **Brennan, Balfe and Other Senior Executives Knew about ICON’s Decreasing Biotech Customer RFPs in 2023 and 2024:** ICON saw a decreasing number of biotech customer RFPs through 2023 and 2024. These declining biotech RFPs in 2023 and 2024 were shown in quarterly business development meetings that FE-1 attended with Brennan, Balfe, and McMillan.
  - a. The quarterly business development meetings were led by McMillan as CCO. FE-1 attended these meetings, which were held by video and typically lasted an hour; FE-1 believed the meetings were recorded. Brennan was a regular attendee at these quarterly meetings, and Cutler sometimes attended.
  - b. During the quarterly meetings, Brennan and Balfe presented a company-wide dashboard in Salesforce that contained 10 or 15 datapoints.
  - c. ICON’s biotech customer RFPs continued to decline through 2023 and 2024 and did not increase at any point through FE-1’s departure in September 2024.
  - d. FE-1 also knew the trends in ICON’s biotech area from participating in weekly meetings that included reports on open and closed RFPs, and from accessing the Salesforce system, both as described below.
  - e. FE-1 explained that ICON’s full-service RFPs with an IRT component—which were largely biotech and covered more than half of ICON’s full-service biotech work—peaked by 2021 or 2022 at close to 50 per month. FE-1 personally tracked these RFPs and confirmed that they showed a year-over-year decline in 2023, and average RFPs per month were also dropping. By 2024, they had dropped to the low 30s each month.
  - f. FE-1 confirmed that there was always a direct relationship between trends in these RFPs and the broader set of ICON’s biotech customer RFPs based on seeing reports for both categories.
- v. **Increasing Biotech Cancellations Throughout 2023 and 2024:** Starting in late 2022, ICON saw a “trend” of increasing study cancellations—especially in the biotech area.
  - a. FE-1 learned about ICON’s increasing cancellations from attending weekly meetings to review Salesforce reports with Cohen and other colleagues. These reports were visible from logging in to Salesforce and were also circulated as screenshots for the meetings. The reports contained standard metrics, including how many open RFPs were in the pipeline, the percentage chance of winning the RFPs (as low as 30 percent), total awards, cancellations, and actual year-to-date numbers.



- b. During the weekly meetings, the participants discussed ICON's pipeline, open and closed RFPs, win and loss rates, and the reasons why opportunities were lost. At the meetings, Cohen, FE-1, and the other attendees "went over every win or loss and the cancellations."
  - c. By June 2023, FE-1 explained, it was clear that the elevated cancellations were a trend. From that point, the trend never improved, and ICON's biotech cancellations progressively worsened into 2024.
  - d. FE-1 emphasized that the "cancellations were a big thing because we realized they were going up" and that the number of cancellations "was a big concern." FE-1 noted that out of 30 or 40 full-service studies awarded by biotech customers to ICON over the course of a year, "five to 10 canceled."
  - e. The canceled studies were financially significant, as most biotech studies ranged from \$8 million to \$30 million—and some were much larger. FE-1 estimated that ICON's total biotech cancellations were at least several hundred million dollars in 2023 alone.
  - f. In addition to the weekly meetings, FE-1 learned from Cohen, Harris, and Grenon that "we need" the cancellation "numbers because it is going all the way up to the top and they are reviewing it." Thus, Cohen aggregated the cancellation data for her team, and passed it up to her managers for further aggregation. FE-1 understood that the roll-up of cancellation data extended to McMillan and Cooper, who then submitted the data to Cutler and Brennan.
- vi. **CFO Brennan Personally Presented ICON's Increasing Biotech Cancellations:** FE-1 confirmed that Brennan, Balfe, and McMillan were aware of ICON's increasing biotech cancellations based on their attendance and presentations at quarterly meetings with FE-1 in 2023 and 2024, described above, where the increasing cancellations were consistently discussed.
- a. Brennan and Balfe presented ICON's cancellation data in multiple quarterly business development meetings using a company-wide dashboard; cancellations were a "fixed piece" on the dashboard that was always presented.
    - i. From the middle of 2023 onward, ICON's cancellations were discussed consistently at these quarterly meetings and reflected in the dashboards, and the number was always "very high."
    - ii. Between mid-2023 and FE-1's departure in September 2024, there was no quarter with a reduction in ICON's biotech cancellation rate.
    - iii. The message Brennan and Balfe delivered during the quarterly meetings was that high cancellations were really hurting ICON's numbers.
  - b. ICON's increasing biotech cancellations were also discussed at an annual sales meeting that Cutler and FE-1 attended in April 2024 in Tampa, Florida.

- i. The April 2024 sales meeting was held at a Westin resort in Tampa and included the full service and FSP sales staff, as well as CEO Cutler and other executives. Cutler had consistently attended the sales meeting in prior years, while CFO Brennan sometimes attended. FE-1 specifically recalled one year when Brennan forgot his wallet, and FE-1 had to pay for Brennan's drinks.
- vii. **ICON Forecast Revenue from "Awards" without Signed Contracts:** Heightening the impact of ICON's increasing biotech cancellations, ICON's forecasts had included revenue from studies without signed contracts in place.
  - a. As FE-1 explained, once a study was marked as "awarded" in ICON's Salesforce system, the revenue from that study was included in ICON's financial forecast for the duration of the study.
  - b. FE-1's manager Cohen had concerns that some of the full-service sales representatives were marking contracts in Salesforce as "awarded" to improve their numbers—even before receiving the necessary assurances and/or documentation that the studies would materialize.
  - c. From personally accessing the Salesforce system, FE-1 confirmed that there were numerous studies marked as "awarded" in Salesforce, even though the contract was not signed. For example, FE-1 noticed that Salesforce was showing a larger amount of "awards" than FE-1 tracked in his own Excel file of awards.
  - d. These "awards" without signed contracts were included in Salesforce dashboards, and FE-1 believed they were also included in ICON's public forecasts, revenues and earnings guidance, despite the absence of signed contracts.
  - e. Many of the "awarded" studies without signed contracts were later canceled. FE-1 knows this because he was the client account manager for the IRT component of ICON's full-service studies (covering more than half of ICON's full-service work for biotech customers), and thus had access to those full-service awards in the Salesforce system and tracked whether they materialized into work and revenue or whether they were canceled. FE-1 also received automatic email notifications from Salesforce when cancellations or other changes were made to these studies.
- viii. **Duplicative RFPs for Limited BARDA Funding:** Finally, FE-1 identified another issue with ICON RFPs. In 2023 and 2024, ICON bid on several relatively large studies, in the \$30 to \$50 million range, to be funded by BARDA. However, in each case, multiple companies were competing for the same BARDA funding for the same study, so even where ICON responded to three or four RFPs for a given study, there would ultimately only be one study and one award. Thus, for example, what appeared to be "\$1 million" in RFPs could all relate to a single \$250,000 study. As a result of this duplication, ICON's volume of RFPs from BARDA-funded studies was several times higher than the maximum possible award.

## 2. FE-2

472. FE-2 was Director of Clinical Operations, Oncology/Director of Clinical Research from summer 2022 to February 2024. In this role, FE-2 ran ICON's oncology projects for Pfizer and also worked on projects for Elicio Therapeutics and Janssen. FE-2 reported to Vice President, Global Project Management Martin Lachs, who reported in parallel to a Senior Vice President and to CEO Cutler. According to FE-2, based on personal knowledge:

- i. **ICON's Oncology Division:** FE-2 explained that ICON's oncology division was the second-largest division in the company (and had been the largest before the COVID-19 pandemic). FE-2 estimated that one-third of ICON's overall business came from the oncology area.
- ii. **Pfizer's Oncology Business Had Slowed for Years:** Upon starting at ICON in summer 2022, FE-2 was informed that ICON's oncology business with Pfizer was decreasing.
  - a. During FE-2's entire tenure, Pfizer had largely stopped giving ICON new late-phase awards (which involved the largest and most financially significant studies). Over FE-2's tenure, FE-2 participated in 5 to 6 bid defenses with Pfizer that ICON did not win.
  - b. Further, in late 2023, Pfizer dropped various oncology studies with ICON. For the remaining studies, ICON's margins eroded. FE-2 described four multiple myeloma studies (ranging from \$4 to \$15 million each) that Pfizer decided to continue because the drug was headed for approval. However, ICON was "overburning on the budgets and eating the costs" because its staff was incurring extensive overtime that was not being billed to Pfizer. FE-2 estimated that the unbilled overtime was tens of thousands of dollars per month, per study.
  - c. Overall, Pfizer's oncology business with ICON decreased substantially during FE-2's tenure. FE-2 estimated the reduction as \$30 to \$40 million, stating that "the portfolio was dying" and "they weren't giving us a lot to replace it with," coupled with the impact of Pfizer's shift to FSP (described below). FE-2's supervisor Lachs described the situation as "like a dying dinosaur."
- iii. **Other Large Customers Also Reduced Their ICON Oncology Studies:** FE-2 stated that ICON's oncology business from Pfizer and BMS was declining throughout 2023 and through FE-2's departure in February 2024.
  - a. Further, by October 2023, several large pharma companies, including GSK and Sanofi, were shutting down their studies in the oncology area. FE-2 learned of this from his direct reports who had worked on those studies and indicated that they had

time available for other projects. However, ICON did not have other active studies to assign them.

- iv. **Janssen Stopped All New Awards in Fall 2023:** Janssen was dissatisfied with ICON due to performance issues, such as delays in study start-up and issues with quality and performance in terms of monitoring. Lachs and West had to meet face-to-face with Janssen in an effort to smooth things over, as FE-2 learned from Lachs and the Janssen project manager, Mary McKay. Nonetheless, in fall 2023, Janssen advised that it would not award any new studies to ICON until the issues were fully resolved. As of FE-2's departure in February 2024, the issues were not fully resolved, and Janssen was not awarding any further studies to ICON.
- v. **Cutler Headed ICON's Pfizer Liaison Team:** Cutler headed a special Pfizer "liaison team" at ICON, which also included Sarah Gore (Executive Director of Project Management for the Pfizer oncology business) and Heather West (Vice President, Strategic Alliance Management), who dealt with Pfizer and other strategic partnerships.
- vi. **Cutler Personally Approved Pfizer's Demand for a \$50 Million Budget Cut:** In mid-September 2023, Pfizer came to ICON and its other CROs demanding that each CRO cut \$50 million from the budget for its portfolio of Pfizer studies. In January 2024, CEO Cutler approved the \$50 million cuts for Pfizer. FE-2 knows this from seeing emails where Cutler approved the cuts, as well as an electronic notification from ICON's computer system that Cutler had given final approval to the cuts.
  - a. The cuts affected all of the approximately 19 oncology studies FE-2 oversaw at the time, as well as Pfizer studies in other therapeutic areas. After the budget cuts were prepared in FE-2's department, approved by Lachs, and reviewed by ICON's finance department, the final package was presented to Cutler.
  - b. Cutler also approved other requests from Pfizer and other top 10 customers to reduce ICON's project budgets. FE-2 knows this from seeing emails with Cutler, which also included Lachs, Gore, West, and Senior Director, Business Development Michael Ohrwashel, where Cutler approved budget cuts.
  - c. For example, if an ICON budget included 40% of the budget for project management, Cutler would state something along the lines of "this is too much. They are not going to approve it. Take another \$1 million out." The frequency of these emails increased towards the end of FE-2's tenure in February 2024.
  - d. FE-2 emphasized that Cutler was extensively involved in approving final budgets related to Pfizer and was "always undercutting margin" in an effort to obtain more business from Pfizer.
- vii. **In 2023, ICON Lost Much of Pfizer's Most Lucrative Work:** In fall 2023, Pfizer directed ICON and its other CRO providers (PPD, Parexel, and Syneos) to participate in a "mock bid defense" so Pfizer could decide how to allocate its CRO business.

- a. FE-2 participated in preparing ICON's submission to Pfizer, which described ICON's plan for study sites, use of technology, proposed vendors and their costs, and other information.
  - b. CEO Cutler approved the final budget forecasting and "pitch" presentation to Pfizer. FE-2 knows this from seeing the email where Cutler reviewed and approved the "pitch" to Pfizer.
  - c. Shortly before Christmas 2023, Pfizer communicated the results to ICON via Gore and West, whose messaging to FE-2 indicated that Cutler and other senior executives had already been informed. The outcome was that:
    - i. Pfizer would no longer award business to PPD.
    - ii. Pfizer would award its Phase 1 business to Syneos.
    - iii. Pfizer would award 85% of Phase 2 and 3 business to Parexel.
    - iv. Pfizer would award 15% of the Phase 2 and 3 business to ICON.
  - d. FE-2 explained that these results effectively capped ICON's opportunities with Pfizer, as ICON was shut out of the vast majority of Pfizer's Phase 2 and 3 studies, which are the largest and most financially significant.
- viii. **Pfizer, BMS and Another Large Customer All Switched to FSP by Early 2024, Slashing ICON's Margins:** In late 2023 and early 2024, Pfizer, BMS, and another large ICON customer all switched from FSO to FSP for both new studies and existing awards.
- a. FE-2 indicated that these customers switched from nearly 100% FSO to nearly 100% FSP. This was a huge loss for ICON, since FSP profit margins were only around 15%, compared to 40–50% margins for FSO.
  - b. FE-2 was aware of Pfizer's switch from working with Pfizer and losing CRAs who were reassigned from Pfizer full-service to FSP work in January or early February 2024. FE-2 knew about BMS's switch because ICON's protocols in the oncology area were affected.
  - c. One of the catalysts for BMS's shift to FSP was a "crisis" in fall 2023 when an ICON CRA fraudulently claimed to have performed monitoring that she did not perform. BMS discovered the issue when the study reached database lock and the data was wrong, although the monitor had falsely marked it as clean. In response to the fraudulent monitoring, Lachs asked FE-2 to perform an internal audit.
- ix. **Pfizer's Strategic "Refresh" to FSP:** FE-2 confirmed that by January 2024, Pfizer had notified ICON that it was moving to an FSP model to reduce costs. ICON's shift to FSP for Pfizer, called a "refresh" or "reset," was to be completed by March 2024. Cutler was aware of Pfizer's switch to FSP because he reviewed and approved ICON's internal

announcement of the change. FE-2 noted that the FSP announcement was made by email, which was sent by Gore but signed by Cutler.

- a. FE-2 explained that Gore and West managed ICON's transition from FSO to FSP for Pfizer and prepared multiple presentations describing the organization, treatment of benefits, and other issues.
- b. FE-2 explained that there were meetings in late 2023 and early 2024 involving Cutler and the Pfizer "liaison team," as well as Lachs. These were "lengthy meetings," during which the attendees had to "approve all this information – messaging" around the change, "how it would roll out to the team, when it would roll out."
- c. In early 2024, Gore held regular meetings with ICON's Director-level employees, including FE-2, assigned to Pfizer studies. Later, Gore's meetings expanded to "town halls," held via Teams, that included both ICON Director and VP-level personnel. By February 2024, in advance of Wave 1 (described below), Gore conducted internal training sessions with slide decks to explain the FSP rollout.
- d. Based on email updates from Gore and regular meetings with Gore, FE-2 learned that Cutler was meeting with Pfizer regularly to work out the details of the transition to FSP. FE-2 explained that Cutler and his management team had to "work out what the finances were going to be" and "approve what the structure was going to look like."
- e. Pfizer's transition to FSP was scheduled to occur in three "waves," each affecting a group of studies:
  - i. Wave 1 was to occur in mid- to late February 2024.
  - ii. Wave 2 was scheduled to be completed in March 2024.
  - iii. Wave 3 was initially scheduled to be finished in March 2024, but was extended to start on April 8, 2024 and to be completed by the end of April 2024.
- f. While Pfizer sought to retain the ICON staff members from the FSO side, the FSP positions did not pay as well. FE-2 pointed out that on the FSO side, a project manager might make \$185,000 per year, while the FSP side only paid \$130,000 with no benefits, vacation, or job security, since their employment would end with the study for which they were engaged. As a result, ICON had to "scramble" to adjust compensation to fill the positions on the FSP side.
- x. The combination of losing Pfizer's Phase 2 and 3 studies and simultaneously losing "a huge chunk of margin" because of Pfizer's switch to the FSP model, as detailed above, was a "huge blow to ICON."



- xi. **Cutler Participated in “Brutal” Monthly VP Meetings to Review Detailed Financial Data:** FE-2’s supervisor, Lachs, participated in monthly VP meetings with Cutler, Brennan, Balfe and other members of senior management to convey the status of the oncology division and defend its performance. FE-2 added that these meetings “could be brutal.”
- a. FE-2 explained that the monthly VP meetings were scheduled through a standing calendar invite to Cutler, Brennan, Balfe and other members of senior management.
  - b. In advance of the meetings, Lachs prepared a slide deck; FE-2 was involved in preparing the decks, which included financial information (such as revenue and margins), wins and losses, the studies’ needs, problems, and upcoming deadlines and milestones.
  - c. As Lachs explained to FE-2, the slide decks were transmitted to Cutler and other executives in advance. Cutler and other senior management received and reviewed the materials because they came to the meetings with questions about specific studies. FE-2 knows this because Lachs sent FE-2 instant messages during the meetings with specific questions, such as “Steve [Cutler] wants to know what the problem is with study startup.”
- xii. **Cutler Participated in “End Gate” Meetings for Underperforming Studies:** In addition to the monthly VP meetings, ICON held periodic Teams meetings for studies with quality problems, such as Janssen and BMS. Cutler, Brennan, Balfe, McMillan, and other senior executives (including in biotech, study startup, and data management) attended at various times.
- a. FE-2 explained that the directors had to complete Excel-based slides maintained on an internal portal. The slides captured numerous metrics about each study, and if the numbers were not where ICON wanted, the director was called to a meeting.
  - b. During the meeting, each presenter was given a 15-minute slot. The executives in attendance asked difficult questions about why the study numbers were not where they were supposed to be and whether more resources were required. FE-2 emphasized that the attendees “would run you through the wringer about why you were not where you needed to be.”
  - c. FE-2 presented at two such “end gate” meetings around October and December 2023; Cutler attended the October 2023 meeting, which related to a study for Pfizer, and an SVP attended the December meeting in Cutler’s place.
- xiii. **Cutler Monitored the Pfizer Business “in Near Real Time”:** As FE-2 summarized, “[t]here is no way that Cutler or any member of leadership could say they didn’t know what was happening or they didn’t have access to it.” FE-2 said Cutler was “aware in near real time” what the status of business was with Pfizer. As FE-2 put it, Cutler was “aware of everything as soon as we were.” For example, FE-2 had regular calls with Lachs to provide updates on the Pfizer business. Lachs then had to provide updates to Cutler in the monthly VP meetings described above.

- xiv. **ICON’s “Close Canceled” RFPs:** FE-2 confirmed that customers sent RFPs to ICON merely to get a sense of ICON’s pricing; once ICON responded, the customers indicated that they did not wish to move forward with the study.

### 3. FE-3

473. FE-3 worked as an Executive Director of Project Delivery at ICON from early 2023 until November 2024. In this role, FE-3 oversaw 15 Directors of Project Delivery and served as ICON’s senior leadership client contact for clients within FE-3’s portfolio. FE-3’s portfolio encompassed 25 to 28 sponsors and ranged from 50 to 70 studies. Overall, FE-3’s portfolio generated about \$350 million in revenue per year. FE-3 reported to Vice President Mary Frances Sassaman, who reported to Brandon Early (VP of Project Delivery until December 2023, then SVP, Global Project Delivery—ICON Biotech through November 2024). Early reported to ICON Biotech President Chris Smyth, who reported to CEO Cutler. According to FE-3, based on personal knowledge:

- i. **Cutler’s Internal Goal of “\$500 by 2025”:** FE-3 explained that Cutler had an internal goal of boosting ICON’s stock price to \$500 per share by 2025, a strategy called “\$500 by 2025.” FE-3 heard about Cutler’s “\$500 by 2025” strategy from Early and explained that it drove many of ICON’s business practices, like extensive offshoring and cost-cutting.
- ii. **Cutler and Other Senior Executives Admitted ICON’s Lower Biotech Win Rate by Early 2024:** FE-3 attended a Company-wide town hall in February 2024 where CEO Cutler spoke about ICON’s lower biotech win rate, indicating that the biotech RFPs that ICON received were not converting to wins at the same rate as in the past. During the town hall, Cutler also stated that ICON had missed its revenue and new business award targets and presented a slide deck that showed ICON had missed its targets.
  - a. In addition, FE-3 attended a town hall for ICON’s biotech division in the first quarter of 2024 where Chris Smyth, who headed the biotech division at the time, similarly announced that the biotech RFPs that ICON received were not converting to wins at the same rate in the past. As FE-3 stated, it was clear that ICON’s win rate had declined and not improved: Smyth explained that the fourth quarter of 2023 had been “difficult” and that instead of winning 1 of 3 RFPs, ICON was now only winning 1 of 5 or 6 RFPs.
  - b. During the town hall, Smyth attributed the lower conversion rate to sponsors going to more vendors than in the past and price shopping across six or more CROs (compared to three in the past).



- c. FE-3 noted that the biotech town hall was “demoralizing” and that Smyth blamed ICON’s biotech personnel for not delivering results.
- iii. **ICON Lost Business from Pfizer and Other Large Customers by Early 2024:** During the quarterly town hall in February 2024, Cutler announced that ICON had lost its contract with Pfizer as a result of softening in the COVID vaccine space. As FE-3 recalled, Cutler indicated ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer. FE-3 noted that Cutler’s town hall presentation was a pre-recorded video.
  - a. After the February 2024 town hall, FE-3 discussed the negative impact of losing the Pfizer preferred partnership in meetings with Sassaman and Early. FE-3 and colleagues also exchanged instant messages discussing this news.
  - b. Further, FE-3 explained that BMS had not awarded ICON any new business during FE-3’s entire tenure at ICON (January 2023 through November 2024). FE-3 also confirmed the issue with ICON’s fraudulent monitoring for BMS.
  - c. FE-3 noted that another large customer, Gilead, had allocated all of its new work to ICON’s competitors in late 2022. Throughout 2023, ICON was on a Performance Improvement Plan, or PIP, and not allowed to bid for new Gilead studies because Gilead had previously given studies to both ICON and PRA, and was concerned about the overconcentration that resulted from the PRA Merger. FE-3 explained that the PIP was widely known within ICON because ICON was required to provide Gilead with quarterly reporting against certain KPIs. ICON was allowed to resume bidding for Gilead’s studies in 2024, but Gilead did not award any new work to ICON through FE-3’s departure.
- iv. **ICON’s Increasingly Frequent “Revenue Sweeps” Sought Up to \$100 Million:** FE-3 explained that Chris Smyth demanded quarterly “revenue sweeps” when ICON’s actual performance in the biotech segment was not meeting its targets. The “revenue sweeps” occurred twice in 2023 and initially involved shortfalls of about \$10 million. However, in the first three quarters of 2024, the sweeps continued every quarter, with increasingly large shortfalls—culminating with a “gap” of \$100 million in the third quarter of 2024.
  - a. FE-3 explained that the \$100 million “revenue sweep” was initiated in late August 2024 on a Thursday night and demanded responses by Monday morning Irish time. FE-3 noted that the request was “ridiculous” given the short time remaining in the third quarter and the large dollar amount. The “gap” of \$100 million compared to total quarterly revenues of approximately \$750 million for ICON’s biotech segment.
  - b. FE-3 noted that although the revenue sweep instructions formally came from Smyth, ICON employees widely understood that the sweeps were directed by Cutler given his extensive involvement in the details of ICON’s operations. For example, FE-3 noted that all new awards above a certain dollar threshold are reviewed by Cutler, who often dictated changes to the terms. FE-3 worked on a potential award over \$50 million, involving an Asian client, that Cutler personally

reviewed in May 2024. After Cutler insisted that the award should exclude trial sites in Asia because ICON's margins were not high enough in the region, ICON lost the work.

- c. The "revenue sweeps" started with emails announcing the "sweep," which linked to or attached a spreadsheet identifying the studies where additional revenue could be recognized (*e.g.*, by pulling billable work forward or adding work from ICON's out-of-scope logs). These revenue sweep emails were sent by Smyth or one of his SVPs and signed by Smyth, who was always copied, and included all of ICON's Project Delivery personnel, from SVPs down to junior levels.
  - d. Next, the recipients (including FE-3) responded with their updates to the spreadsheet identifying additional revenue. FE-3 noted that the spreadsheet covered ICON's biotech segment, and FE-3 saw the updates that others were sending.
  - e. At the conclusion of the process, the spreadsheet "always" matched the revenue target, as FE-3 learned via oral reports from Sassaman. As FE-3 stated, "people would do anything to find revenue" in these "sweeps."
- v. **ICON's Aggressive Accounting Practices:** FE-3 stated that ICON engaged in three practices to boost financial performance. These practices affected FE-3's full portfolio, which generated \$350 million in revenue per year and accounted for about 10% of ICON's biotech division. FE-3 estimated that these practices added \$5 to \$10 million per year to FE-3's portfolio and contributed up to \$1 million to a single study.
- a. First, ICON's treatment of change orders increased its revenue and margins. FE-3 explained that the first draft of a change order typically provides for a much larger amount of revenue than the client ultimately approves, and that obtaining a final, signed change order could take six months. However, ICON used the draft, unsigned change order to recognize revenue. FE-3 emphasized that this was "standard operating procedure" at ICON during 2023 and 2024.
    - i. FE-3 estimated that the final change orders were typically 20–30% smaller than the first draft that ICON used to recognize revenue, and this variance increased over time. FE-3 noted that these are large change orders of \$5–6 million, with some exceeding \$10 million. FE-3's studies generally had one to two change orders of \$5 million or more per quarter.
    - ii. Recognizing revenue from draft, unsigned change orders raised the risk that ICON would not recover the full amount. For example, FE-3 noted that for one large customer, Gilead, ICON regularly wrote off 50% of the amounts it initially sought via change orders.
    - iii. FE-3 stated that the instructions as to change orders were communicated by Aine McGill, VP Client Contract Services. McGill convened weekly meetings about change orders with FE-3, other project leaders with change orders and VPs of Project Delivery, and Sassaman. FE-3 explained that

McGill (who was located in Ireland) reported to CFO Brennan or CEO Cutler and always framed her instructions as “the directive is.” During each weekly meeting, the attendees provided updates about what they were able to achieve in accordance with the directive; McGill then consulted with either Cutler or Brennan and returned the next week with new marching orders.

- b. Second, FE-3 indicated that when ICON needed to “find revenue” for the quarter, it recognized revenue in advance of contractual milestones. For example, FE-3 explained, if the contract only allowed ICON to claim revenue upon site activation, and ICON planned to activate the site in September but encountered challenges that delayed activation to October, ICON still recognized the revenue in September.
- c. Third, when studies experienced cost overruns, ICON forecasted offsetting “efficiencies” near the end of the studies. As FE-3 explained, this led to an overly positive margin because it assumed that the future “efficiencies” would offset the near-term cost overruns.

#### 4. FE-4

474. FE-4 was employed by ICON from 2019 until November 2024, based in Ireland. FE-4 was initially an Associate Finance Manager and was promoted to Senior Finance Manager in September 2023. FE-4’s role involved billing and cash matters for large pharma customers. FE-4 reported to Ronan Flood, Senior Director of Finance. Flood reported to Vice President of Finance Pat O’Grady, who reported to Senior Vice President of Finance Alan Sheehan. Sheehan reported to CFO Brennan. According to FE-4, based on personal knowledge:

- i. **ICON Manipulated Financial Metrics:** At ICON, FE-4 observed a focus on cash and billing at all costs given ICON’s cost to acquire PRA and pay interest on the resulting debt. To that end, ICON manipulated financial metrics, particularly during the last year of FE-4’s employment (*i.e.*, November 2023 to November 2024). As detailed below, to boost ICON’s financial performance, ICON extended reporting periods to overstate billing and cash received; deliberately created fake invoices to inflate ICON’s purported billing to clients; and recognized large amounts of unbilled revenue.
- ii. **ICON Held Periods Open to Inflate Billing and Cash:** ICON regularly *held the books open for 10–14 days after month or quarter-end* to increase its billing and cash numbers.
  - a. Specifically, FE-4 received monthly and quarterly targets for billing and cash. When the targets weren’t met by the end of the month or quarter, the period was simply held open—typically by 10 to 14 days—until the targets were reached.

- b. Holding the periods open led to a cycle where the next period was effectively shortened by 10 to 14 days, preventing ICON from hitting the targets for that period, which was then held open in turn.
  - c. ICON's practice of holding periods open by 10 to 14 days *added approximately \$100 to \$200 million* to ICON's billing and cash each quarter.
  - d. Sheehan communicated the "directive" to hold periods open to FE-4. Sheehan "took a hard line" on the issue in meetings; as FE-4 explained, "there's no way" Sheehan would have done that if CFO Brennan was unaware.
  - e. FE-4 described a "*mad scramble*" at ICON to find "anything" that could be counted towards the cash and billing targets. Sheehan, O'Grady and Flood relayed to FE-4 that it was Brennan's "priority one, two and three to get cash in the door," and that Brennan was aware of the "anemic" cash ICON was actually receiving at times.
  - f. Further, ICON recorded clients' mere *promises* to pay as cash that ICON had *received*; ICON included those promised amounts in the cash it had purportedly received when it closed a period.
- iii. **ICON Issued Fake Invoices Before Performing Work:** Under Sheehan's direction, ICON "deliberately" created "*fake*" *invoices* for future work that ICON had not performed. For example, ICON issued invoices during a given period where the contractual billing milestone was in the first 10 days of the *next* period. These fake invoices served to get "invoices on the books."
- a. The fake invoices were *marked with an asterisk* because they were "*known to be fake*" and were not intended to be sent to ICON clients.
  - b. However, ICON's offshored billing function in India accidentally sent some fake invoices—showing work that ICON had not yet performed—to clients ahead of time.
  - c. FE-4 explained that ICON's Finance Department was given a "firm directive that this had to happen." The fake invoices were widely discussed within the Finance Department; the only reason FE-4 and his colleagues could identify for this practice is that CFO Brennan and CEO Cutler were probably about to leave ICON and wanted to "jack up" its share price.
  - d. Similar to the issue of holding periods open, described above, FE-4 explained that ICON's creation of fake invoices created a "hole" in the next month, which continued over time.
  - e. The issue came to a head in Christmas 2023, when ICON fell significantly short of its targets. FE-4 described a "mad scramble" as employees worked 14- to 16-hour days to try to find cash. "The billing practices got pretty ropey" as ICON issued fake invoices to clients, such as Celgene.

- f. ICON finally began to stop the fake invoicing in early 2024 because it was causing too many problems.
- iv. **ICON's High Unbilled Revenue:** ICON recognized substantially more revenue than it had billed, resulting in large amounts of unbilled revenue, described internally as “being ahead of your skis.” One manager said to FE-4 that she had \$50 million in unbilled revenue on her studies—while others in her group had even larger amounts.
- v. **ICON's Decline in Business from Pfizer and Other Large Customers:** FE-4 worked on large pharma customers, which accounted for most of ICON's revenue, and saw billing and revenue information for ICON's top 5 to 10 customers. Within this group of customers, FE-4 confirmed that ICON experienced a decrease in business from its largest customer, Pfizer, and all other large clients—with only two exceptions—in early 2023 through 2024.
  - a. Evidencing the decline in ICON's large customers, FE-4 described an incident where CEO Cutler sacrificed margin to gain new business. FE-4 functioned as business operations lead for a customer that was ICON's tenth-largest client at the time and one of FE-4's main clients. Over time, the margins on the customer's business shrank substantially. Nonetheless, as ICON was negotiating rates and other terms with the customer, late in 2Q24, CEO Cutler met with the customer's CEO and accepted all of the customer's terms in exchange for allowing ICON to handle investigative fee work (with no margin) and an upcoming trial in China. As FE-4 explained, Cutler had further reduced ICON's margin with the customer—which was “already the weakest” among large clients—to “boost” ICON's book through new business at an even lower margin.
  - b. Ultimately, FE-4 explained, ICON was winning less work at a lower margin. FE-4 noted that in the past, ICON's Pfizer work had approached 50% margin.
- vi. **ICON's Biotech Business Was “Dying on the Vine”:** After ICON acquired PRA and its book of business, ICON's biotech business was “dying on the vine” because ICON did not build on PRA's customer relationships. At the same time, ICON assigned revenue and cash flow targets to Bridget Hennessy (Senior Finance Director) that were impossible to meet with a diminishing portfolio; no one listened to the notion that ICON should report realistic numbers.

## 5. FE-5

475. FE-5 worked as a Project Financial Analyst from spring 2022 until August 2024. In this role, FE-5 initially reported to Justin Mason, Director, Finance Business Partnering, and then to Matt Doran, Supervisor, Financial Planning. According to FE-5, Mason was one or two levels below Brennan. FE-5's responsibilities included managing portfolio studies, working with

different teams to manage how well they were sticking to the project budgets, and conferring with the project managers to fine-tune budgets. FE-5 worked on over 20 studies, mostly biotech with some large pharma. The budgets for his studies averaged between \$1 million and \$3 million but he had one study with a \$15 million budget. According to FE-5, based on personal knowledge:

- i. **Through “Cost Not Loaded,” ICON Omitted Certain Project Costs to “Hold the Margins”:** FE-5 explained that on a monthly basis, he entered information into ICON’s “Revenue” platform, used for financial reporting. He stated that he was instructed by his managers Mason and Doran (Supervisor, Financial Planning) not to “load” certain project costs to prevent margins from declining. ICON internally referred to this practice as “cost not loaded,” or “CNL.”
  - a. Specifically, FE-5 explained that Mason and Doran indicated that they wanted no change in margins. Thus, whenever additional project costs caused margins to decline, even by 0.2%, Mason and Doran instructed FE-5 to apply a “CNL” entry in ICON’s Revenue software to prevent the increased costs from impacting margins.
  - b. These instructions were typically given to FE-5 via Teams chat. Mason also held Teams meetings and explained that the “CNL” practice came from Mason’s supervisor or ICON’s CFO, explaining that the “instructions from above” were that “we need to hold margin for the studies.”
  - c. FE-5 reported that the use of CNL was discussed in meetings, and he was taught how to calculate the CNL as a part of his training. According to FE-5, this was a standardized practice. FE-5’s friends at ICON worked on large pharma studies, including for Janssen and Pfizer, and reported that the CNL practice was also applied on their studies.
- ii. **Identifying “Costs Not Loaded” to “Hold the Margins” in ICON’s Revenue Software:** FE-5 explained that the CNL process had three steps:
  - a. First, FE-5 used an Excel workbook with a “CNL” tab that calculated the dollar amount of costs that had to be omitted to hold the margins.
  - b. Second, ICON’s Revenue software had a button to add costs to a study, with a drop-down menu that allowed the user to select “Costs Not Loaded.” FE-5 selected the “Costs Not Loaded” option and entered the dollar amount from the Excel workbook. The software also required a mandatory text comment, which FE-5 entered as “CNL to hold the margins.”
  - c. Finally, FE-5 submitted the Revenue entry for approval. FE-5 explained that if the entry showed even a small drop in margin, Mason rejected it and instructed FE-5 to add a CNL entry.



- iii. **“Costs Not Loaded” Significantly Impacted Margin:** FE-5 confirmed that the CNL practice substantially impacted ICON’s current margin on studies.
  - a. FE-5 stated that the use of CNL greatly impacted at least half of his studies, resulting in up to a 10% to 20% difference in margin. FE-5 further stated that for one study, without CNL, the margin was negative.
  - b. FE-5 noted that margins declined over time for most projects; as a result, the amount of CNL grew to keep the margins the same. Several of FE-5’s studies had margins that worsened by a few percent each month, so applying CNL to hold the margins had a large impact over a year.
- iv. **The “Costs Not Loaded” Practice Was Used for at Least Two Years:** FE-5 was uncomfortable with ICON’s use of CNL. The explanation provided by FE-5’s supervisors was that they would “fix it next month,” which never happened. Instead, FE-5 was provided with the same CNL and “hold the margins” instruction the next month. The CNL practice continued until FE-5 left ICON in August 2024.
- v. **ICON Overstated Percentage of Completion on Studies:** FE-5 noted that five or six of his studies were still ongoing but reported 100% completion in ICON’s Revenue software (which calculated percentage of completion from a forecast in Salesforce). FE-5 explained that the studies were ongoing and still incurring costs, but ICON was not forecasting them out. The Revenue software’s “100%” completion was significantly different than the studies’ actual status at the time. For example, one study marked as 100% complete was only 75% complete, while another marked as 100% complete was subject to repeated change orders and months of additional work.
- vi. **Layoffs Quickly Followed CFO Brennan’s Abrupt Departure:** FE-5 learned of CFO Brennan’s departure when Brennan abruptly sent an internal email announcing it. Cutler responded to the email. FE-5 indicated that the CFO’s sudden departure raised concerns internally. Shortly after that email exchange, FE-5 learned during a Teams meeting in April 2024 that he would be let go in August 2024.

## 6. FE-6

476. FE-6 worked as a Finance Manager at ICON from 2021 to November 2023. In this role, FE-6 reported to Justin Mason (Director, Finance Business Partnering) and then to Bridget Hennessy (Senior Finance Director). FE-6’s day to day responsibilities included leading a team of 9 to 12 analysts. FE-6 reviewed and approved the analysts’ revenue entries before submitting the entries for the month, and reviewed cost change orders. FE-6 also discussed forecasts and

budgets with project sponsors. FE-6 worked on ICON's Janssen partnership. According to FE-6, based on personal knowledge:

- i. **Using "Costs Not Loaded" to Hold ICON's Margins:** FE-6 was instructed to hold the margins for different projects by using the cost not loaded, or CNL, procedure. FE-6 stated that the instruction to hold the margins was communicated by Bridget Hennessy (via email or phone), although FE-6 believed that Hennessy was new to the role and inexperienced, so the actual instruction came from the person above her, Ronan Flood (Director of Finance).
  - a. FE-6 explained that ICON used a "reserve workbook" to calculate the amount of costs that were necessary to remove to keep the margin the same. The calculation was based on hours and an average rate. For example, the spreadsheet included an average hourly rate for North America-based workers to facilitate calculation of how many hours needed to be removed to preserve the study's margin. The workbook was saved in ICON's Revenue system as audit support.
  - b. Finally, FE-6 entered the CNL amount into the Revenue system and inserted comments that "per Bridget [Hennessy]," he was adding a reserve to hold the margins.
  - c. FE-6 explained that the "CNL" treatment applied to most or all Janssen studies and noted that ICON had at least five to six large Janssen studies, which totaled about \$150 to \$300 million and averaged about \$1.5 to \$2 million in revenue per month. The reserves on these studies fluctuated in size, but could be as large as \$1 million for a given study.
- ii. **"Costs Not Loaded" Instructions Increased in Late 2023:** FE-6 explained that the number of CNL instructions increased towards the end of his tenure in October and November 2023, and he became uncomfortable that ICON was "pushing the line." As a result, FE-6 decided to add comments indicating the source of the CNL instruction so more junior team members would not get into trouble.
- iii. **"Costs Not Loaded" Impacted ICON's Financial Reporting:** FE-6 confirmed that the CNL procedure impacted ICON's financial reporting: ICON's revenue team used the results of the "CNL" for ICON's financial reporting and also had access to the reserves and comments indicating to hold the margin, including the workbook showing the calculation of the "CNL" amount.
- iv. **ICON Used a "Management Reserve" for Overburn:** FE-6 explained that in addition to the "CNL" process, ICON consistently included a "management reserve" to account for an assumption of 2% overburn at the beginning of each study. Specifically, because ICON consistently bid studies too low, ICON included a reserve to accommodate 2% overburn through the end of the study startup phase (when the last site was activated). This reserve prevented overburn from reducing margin in the early stages of the study. FE-6 explained



that this 2% management reserve was “company standard” and affected each study FE-6 worked on.

## 7. FE-7

477. FE-7 worked as a Senior Proposal Manager at ICON from April 2018 to November 2023. He reported to Joseph Luke, a Senior Director in Proposals, who reported to Heather Carter Castleberry, VP of Global Proposals. FE-7 was part of the team responsible for large pharma from April 2022 until his departure. In this role, FE-7 was involved in responding to RFPs from large pharma sponsors, preparing budgets for the proposals, and drafting the text document that explained the proposals. According to FE-7, based on personal knowledge:

- i. **Cutler Directed ICON to Book Inflated “Awards”:** FE-7 stated that Cutler directed ICON to book awards at larger dollar amounts than sponsors had actually approved. FE-7 knows this because he was copied on emails from Cutler, and sometimes was standing in Cutler’s office, when Cutler gave the direction to book the awards at the larger value in ICON’s system. FE-7 believed that the awards were booked in Salesforce and in internal Excel-based financial systems.
  - a. FE-7 explained that sponsors often gave ICON awards with caveats about reducing the size or scope of a study before a contract was signed. For example, if ICON bid for a \$100 million study with 500 patients, the sponsor might award the study with the caveat that the sponsor was only approving a \$60 million study with 300 patients. At Cutler’s direction, ICON would book the \$100 million award reflected in its bid.
  - b. When booking the larger award amounts, ICON knew the award amounts would decrease because ICON had agreed to the reductions during the bid defense phase, or because the award itself referenced a reduction in costs.
  - c. FE-7 explained that ICON engaged in this practice regularly, especially near the end of the quarter, when ICON would “creatively get there” to hit the numbers. FE-7 confirmed that ICON used this practice in the second and third quarters of 2023.
  - d. FE-7 noted that within the subset of ICON’s awards that he personally observed, this practice occurred with respect to one or two opportunities per quarter. These awards tended to be larger opportunities and raised ICON’s claimed award numbers by \$20 to \$30 million for the quarter.
  - e. FE-7 noted that Cutler and McMillan were also aware of the practice because of the large dollar amounts involved. Cutler’s sign-off was required for opportunities

of \$30 million and above, while McMillan's sign-off was required for opportunities of \$15-\$20 million and above.

- ii. **ICON's Overall Decline in RFPs Was Known to Cutler in 2023:** FE-7 described internal emails, sent consistently toward the end of each quarter in 2023, to call out a decline in ICON's customer RFPs. FE-7 indicated that the emails usually came from the head of sales, consistently copied Cutler and McMillan, and sometimes came from Cutler or McMillan themselves. The emails stated that ICON's RFPs and awards were declining across the board. At the time of receiving these emails in 2023, FE-7 questioned why Cutler publicly stated that ICON's RFPs were increasing when they were actually decreasing. FE-7 described the emails as "calls to action" that urged employees' full attention to each RFP given the diminishing number. FE-7 further stated that the emails described the gap between ICON's current numbers and target, indicating that ICON needed to "book X amount more."
- iii. **Price Discovery RFPs:** FE-7 stated that up to 40% of the large pharma RFPs ICON received in 2023 were just "testing the waters"—*i.e.*, intended merely for price discovery. He stated that in about one-third of these cases, sponsors actually told ICON that the RFPs were just for price discovery purposes. In other cases, the sponsors sent three RFPs, reflecting three scenarios for the same study, which indicated to FE-7 and ICON that the sponsors were just "fishing" to discover ICON's pricing. FE-7 confirmed that the price discovery RFPs happened throughout 2022 and 2023 and increased towards the end of his tenure. FE-7 believed that Cutler and McMillan were both aware of the price discovery RFPs given their prevalence and because Cutler and McMillan were both "very hands on."

## 8. FE-8

478. FE-8 was employed as a Clinical Trial Manager in ICON's Pfizer Strategic Business Unit (PSBU) from March 2022 until September 2024. FE-8 reported to Greg Homentaler. FE-8's role as a Clinical Trial Manager involved managing trial sites and ICON CRAs who visited the sites, including issues like ensuring site compliance, confirming that patients were enrolled, and ensuring proper data entry. According to FE-8, based on personal knowledge:

- i. **The Pfizer Strategic Business Unit:** ICON's PSBU was "huge," with hundreds of employees in the Clinical Trial Manager position alone. Employees in the PSBU used Pfizer computers and email addresses but received their benefits and pay from ICON.
- ii. **ICON Dissolves the PSBU as Pfizer Moves Work In-House:** FE-8 explained that the PSBU was initially handling several large Phase 3 trials for Pfizer, with at least four or five Pfizer trials active. During FE-8's tenure, however, the PSBU continuously decreased in size.
  - a. FE-8's first supervisor, Cecilia Gomez de la Torre, left ICON in October 2022.

- b. By early 2024, ICON was “dissolving” the PSBU because Pfizer was moving the work in-house. In February or March 2024, FE-8’s supervisor encouraged FE-8 to apply to Pfizer in-house positions.
  - c. CEO Cutler and CFO Brennan were aware that ICON was dissolving the PSBU. For one thing, in March 2024, ICON made significant layoffs, including from the PSBU.
  - d. Cutler and Brennan also participated in periodic town halls, conducted by Zoom, where they answered questions from ICON employees submitted by Zoom chat. FE-8 explained that by early 2024, these questions expressed concern about bonuses and why ICON was laying off employees.
    - i. FE-8 noted that the Zoom town hall meetings were recorded. FE-8 watched the recorded versions to learn as much as possible about the situation at ICON given FE-8’s concern for his job.
    - ii. The PSBU itself also held separate Zoom town hall meetings, which FE-8 attended.
  - e. FE-8 confirmed that there wasn’t much work within the PSBU in the first half of 2024 and emphasized, “Everyone was applying for jobs outside of the PSBU.”
  - f. FE-8 applied for a new job (outside ICON) in June 2024 and began interviewing in early August 2024. FE-8 noted that he joined ICON with three friends, and all four left ICON within two years.
- iii. **Pfizer’s Key COVID-Flu Vaccine Trial Fails:** FE-8 had been hired into the PSBU to work on COVID trials and specifically worked on Pfizer’s COVID/flu “combo” vaccine and RSV vaccine studies. The COVID/flu “combo” vaccine study was a large Phase 3 trial that involved about 8,800 participants; FE-8 supervised 15 trial sites that collectively enrolled about 1,000 patients.
- a. FE-8 noted that over 50 ICON personnel within the PSBU worked on the trial, which had an estimated contract value of at least \$60 million.
  - b. By early August 2024, however, FE-8 and ICON learned that the Pfizer COVID-flu vaccine had failed its Phase 3 trial. FE-8 recalls learning of the trial failure by early August 2024 from discussing it in connection with his job interviews at the time.
  - c. FE-8 noted that under its contract with Pfizer, ICON would lose a significant amount of money from the COVID-flu vaccine trial’s failure. Further, once a trial fails, enrollment stops immediately and Pfizer’s staffing needs decrease.
  - d. FE-8 explained that there was “nowhere for me to go” in terms of another study with Pfizer. FE-8 saw that there were no Pfizer jobs posted on ICON’s job board

and no more active studies with Pfizer. The absence of other Pfizer studies to work on confirmed the dry spell with Pfizer in the first half of 2024.

- iv. **Overburn on Pfizer Studies:** FE-8 confirmed that ICON's studies for Pfizer experienced overburn on the CRA monitoring component, which is among the most expensive aspects of any trial. FE-8 noted that ICON closely tracked this cost and that Pfizer was not happy with the overburn, requiring ICON to reduce monitoring visits by lengthening the duration between visits.

## 9. FE-9

479. FE-9 was a department head of one of ICON's clinical research divisions within the full-service segment from prior to the Class Period until late 2024. In this role, FE-9's team supported studies, including providing support operations, monitoring clinical research onsite, developing protocols, and writing up reports. FE-9 reported to two successive Senior Vice Presidents during his employment; in turn, the Senior Vice Presidents reported to Ute Berger, who reported to Cutler. According to FE-9, based on personal knowledge:

- i. **CEO Cutler's Bullying Brought ICON Personnel to Tears:** FE-9 indicated that Cutler is a bully. On internal calls, Cutler regularly reviewed internal projects, and his comments and behavior often left ICON personnel in tears. FE-9 recalled that very senior ICON personnel resigned after interacting with Cutler, and FE-9 was also subjected to Cutler's behavior at times.
- ii. **In Late 2023, ICON's Failing Biotech Business Required a \$350 Million Bailout:** According to FE-9, ICON's biotech business was performing very poorly in 2023 and 2024. During the fourth quarter of 2023, \$350 million in revenue was transferred to ICON's biotech business from another business unit within ICON. FE-9's supervising SVP explained that ICON's biotech business was "doing miserably" and "dying," requiring a transfer of \$350 million in revenue to prop biotech up and make it appear to be doing better than it actually was. FE-9 understood that the transfer was communicated to the SVP from a more senior level, and the revenue was moved in ICON's Oracle system. The significant decline in ICON's biotech business also continued into 2024.
- iii. **ICON's Unusual Financial Practices:** FE-9 indicated that ICON's financial practices were unusual. For example, ICON management was constantly shifting revenue between divisions to make one department look better than it actually was. FE-9 personally experienced this when P&L was taken from his own division, in addition to the \$350 million transfer to biotech in late 2023.
  - a. FE-9 also stated that ICON's financial functions, which had been outsourced to India, were inept. Customers paid for work that was never performed, while in

other cases, large amounts were never collected. One of FE-9's clients owed \$1.6 million, but the India team never advised FE-9, who had to discover it and collect the debt on his own.

- b. After repeatedly complaining about the problems, in mid- to late 2023, FE-9's supervising SVP indicated that an ICON employee, internally called an "accounting rockstar," had been assigned to resolve the issues. FE-9 spoke to the "accounting rockstar," but after this individual conducted an initial review of the problems, he gave up and announced that he would retire.
- iv. **ICON's Slowdown in Business from Large Customers and Eroding Profit Margins:** FE-9 learned from his supervising SVP that large customers like Pfizer, Janssen/Johnson & Johnson, Eli Lilly, and Roche were reducing their business with ICON, including in the full-service area, from late 2023 and onward.
  - a. In late 2023, around the time of the \$350 million revenue transfer to ICON biotech, FE-9's supervising SVP explained that "FSP was keeping us afloat."
  - b. To FE-9, that was a major concern, since the margins on the FSP business were significantly lower than those of the full-service segment. Specifically, ICON's full-service projects had margins of 40% to 50% (or higher), while FSP margins were closer to 15%. As FE-9 put it, "FSP was much lower profitability, so FSP keeping us afloat means your core business is in real, serious trouble."
- v. **ICON's Inflated Book-to-Bill Ratios:** FE-9 learned from an ICON employee that ICON has publicly reported inflated book-to-bill ratios for at least three years based on ICON sales representatives entering "wins" into Salesforce that they knew were highly unlikely to materialize, and were later canceled. Without these "wins," ICON's actual book-to-bill ratios for 2023 and 2024 were 0.9 or lower. FE-9 noted that any book-to-bill ratio below 1 is a serious problem and means ICON's pipeline is below the level necessary to sustain the business in the medium term.
  - a. FE-9 explained that ICON's sales representatives are paid a percentage of the contract value for their "wins" as a commission. They are also given sales targets: (1) the dollar value of new contracts, and (2) the dollar value of change orders (called "upselling" at ICON).
  - b. As a result of this compensation structure, the sales representatives are incentivized to record "wins," even without a signed contract. FE-9 noted that ICON's Salesforce system shows whether a given "win" has a signed contract and recalled seeing many "wins" recorded in Salesforce, without signed contracts, during FE-9's tenure at ICON.
- vi. **Cutler's Offshoring Strategy Failed:** ICON extensively offshored its services to places like India and Mexico in an attempt to improve margins and profitability. ICON had a program where countries were classified as "high," "medium" or "low" based on worker cost, and new hires had to be made from "low" countries (including Mexico and Tunisia).

- a. FE-9 understood from discussions with his supervising SVPs and human resources that this offshoring strategy came from Cutler. Hiring employees with low hourly wages allowed ICON to charge much higher rates to clients, with flexibility for ICON to reduce rates if necessary to satisfy large customers.
- b. However, the strategy backfired. The “low” cost countries lacked the necessary skill set to perform CRO work. As a result, FE-9 explained, customers hated it. They went from having experienced, English-speaking ICON personnel to new workers who lacked English comprehension and relevant training, knowledge, and experience.

## 10. FE-10

480. FE-10 worked for ICON from July 2021 until November 2024 as a director of operations for real world solutions. At the end of FE-10’s tenure, he reported to Senior Director of Operations Ray Kaczmarek, who reported to Senior Director, Project Operations Kay Price. In turn, Price reported to Vice President RWS Project Management Harpreet Gill. Gill reported to Chief Medical Officer and President of ICON Development Solutions Ute Berger, who reported to CEO Cutler. FE-10 provided oversight to late-stage trials, functioned as a “line manager” who provided support for proposals, and oversaw studies across multiple therapeutic areas in ICON’s delivery of full-service trial management. According to FE-10, based on personal knowledge:

- i. **ICON Regularly Underbid Projects:** At the direction of senior management, ICON regularly made “lean” bids for projects that were “not enough to get the work done.” FE-10 explained that ICON’s senior leadership was involved in directing lower bids to win business; senior leadership, including senior financial personnel, held “bid review meetings” to review bid proposals over a certain dollar amount.
- ii. **ICON’s Low Bids Yield “Overburn”:** Given ICON’s low bids, it was relatively common for projects to exceed the budgets ICON had agreed to with sponsors. This scenario—where ICON’s actual costs exceeded ICON’s budget—was called “overburn.” About 60% of the studies that FE-10 “inherited” (*i.e.*, trials that were already underway) had “budget challenges,” including studies for Teva, Ionis Pharmaceuticals, and Tenaya Therapeutics. These studies were “way under our margin” due in part to ICON’s low bids.
  - a. For example, the Tenaya study—an \$8 to \$10 million project—suffered from additional costs due to high turnover among ICON employees and technical database issues in late 2023 and the first half of 2024. The sponsor Tenaya did not pay ICON additional money for the first issue, and covered less than half of the cost of the second issue, reducing ICON’s margins.



- iii. **ICON Tracked Overburn and Other Financial Metrics in Tableau:** ICON used the Tableau tool within Salesforce to track and manage overburn. Specifically, ICON tracked the actual hours for each project, as well as “units” based on the number of hours for a given task, and compared these figures to ICON’s budget to assess overburn. Further, the Tableau tool provided dashboard reports, including a “finance” report and a report that flagged each study as being in “red,” “amber” or “green” status. Red and amber meant the project was underperforming.
  - a. For example, underperforming studies like Tenaya were constantly in the red in the Tableau dashboard. Tableau also indicated each study’s current margin, and ICON’s finance team provided the variance to the margin in ICON’s bid.
- iv. **ICON Closely Reviewed Underperforming Studies:** When a study’s margin changed in excess of a certain amount, ICON required director-level review, and the reviewing director was required to enter a comment in Tableau about why the actual margin was different than ICON’s expected margin. ICON’s finance team also reviewed underperforming studies and reached out to project managers (including FE-10) with questions, then escalated the inquiry to directors when necessary.
  - a. In addition, FE-10 believes that Kaczmarek and other managers had access to a Tableau report showing all studies in red or amber status, since they contacted FE-10 with questions and appeared to know which studies were underperforming and required explanations for their status. Each project also had an assigned financial analyst who contacted FE-10 with questions.
- v. **ICON Tracked Contracts, Change Orders, and Bids:** FE-10 explained that ICON continuously and regularly tracked contracts, change orders, and new bids. For example, FE-10 updated a “contracts tracker” maintained on ICON’s SharePoint site with any “change orders and new bids.” By early 2024, ICON formed a new “contracts group” that checked with FE-10 and his colleagues to provide updates about the status of bids, change orders, and new contracts, paying especially close attention to larger projects.
- vi. **ICON Lost Business from Large Customer Johnson & Johnson in Early 2023:** FE-10 explained that Johnson & Johnson (J&J) is among ICON’s largest customers. FE-10 had insight into the J&J business because one of his direct reports, Senior Project Manager, Clinical Operations Nadia Longo, was assigned to J&J. FE-10 reported that Longo managed two J&J studies where ICON was overburning and requested “more and more money” from J&J. By January 2023, however, J&J objected to ICON’s excessive costs and stated that it would only pay for approximately half of the work. For example, where J&J was previously paying for six hours for a site visit, J&J was only willing to pay for three hours going forward. FE-10 was informed that CFO Brennan approved for ICON to continue performing the same amount of work for J&J without having the full budget.
- vii. **Quarterly Employee Updates:** FE-10 explained that Cutler, Brennan and other ICON executives provided “quarterly updates” to employees, including updates on ICON’s performance, “the target and where we were trending based on close of the quarter.” At the October 2024 quarterly meeting, the executives were “not excited” and informed

employees that they had to “reforecast the sales target” from around “\$8.6 billion” to “closer to \$8.2 billion.”

## 11. FE-11

481. FE-11 worked at PRA in its FSP group from 2011 to 2013; his role included FSP and M&A work. After leaving in 2013, FE-11 returned to PRA in 2014. ICON acquired PRA in 2021 and FE-11 became Vice President and General Partner in ICON’s FSP (Functional Service Provider) division, reporting to Samir Shah (former President of ICON Strategic Solutions (previously defined as “ISS”). Shah reported to Cutler. FE-11 left ICON in February 2023. According to FE-11, based on personal knowledge:

- i. Within FSP, FE-11 represented Novartis, which was one of ICON’s five largest accounts, with over 2,000 ICON employees embedded. The last award FE-11 obtained from Novartis was for three years and \$780 million.
  - a. In addition to Novartis, ICON’s largest FSP customers included Janssen/Johnson & Johnson (a relationship that involved 3,000 ICON employees and generated about \$500 million per year); Merck; and Sanofi.
- ii. **Cutler Was Central to the Pfizer Relationship:** CEO Cutler has always managed the Pfizer account given its prominence and size. Barry Balfe (current ICON COO), Debbie Gilmore, and other senior ICON executives have also been intimately involved with the Pfizer relationship. FE-11 described Pfizer as their “baby.”
- iii. **Cutler Personally Interacted with Pfizer Executives:** Cutler personally led “Partner of Choice” meetings where ICON invited senior executives from Pfizer, Novartis and other large accounts to ICON’s US headquarters in Blue Bell, PA. FE-11 attended these POC meetings together with Cutler, Samir Shah, and others.
  - a. The POC meetings’ goal was to create a think tank or whiteboard session to discuss challenges in the industry and issues related to ICON’s business—including Pfizer’s move from FSO to FSP, which threatened ICON’s margins because the FSP work was less profitable for ICON.
- iv. **Artificially Boosting ICON’s Margins:** At ICON, FE-11 saw a sustained focus on financials and driving numbers up. While Samir Shah was a mouthpiece for these instructions, FE-11 added that the underlying direction was coming from ICON’s most senior leadership. Tony Southers, who now runs ICON FSP, would have sent emails directing the improvements. There was a push to improve margins artificially. For example:



- a. FE-11 described ICON's practice of overbilling Sanofi by using CRAs from ICON's FSP business but charging Sanofi ICON's higher full-service rates – a 13-14% markup. As FE-11 explained, a 13-14% rate increase for over 2,000 employees makes a big difference in the financials.
  - b. FE-11 was told to reduce G&A labor by 5% or otherwise find 5% improvement.
- v. **Customers Pressure ICON's Margins After the PRA Merger:** FE-11 noted that ICON's FSO and FSP businesses cannibalize each other. FE-11 cited Janssen, where the PRA merger led to Janssen's overconcentration with ICON. FE-11 confirmed that Janssen was unhappy with the concentration and ultimately used it as leverage to demand lower pricing, reducing ICON's margins.
- vi. **QBR Meetings Highlighted the Risk of Losing Business from ICON's Key Customers:** FE-11 described Quarterly Business Review (QBR) meetings where ICON's senior leadership discussed business performance and risks, including issues with large contracts, in detail.
  - a. The QBR meetings were very structured, two-and-a-half-day meetings. FE-11 attended the QBR meetings with Balfe, Shah and other executives. FE-11 recalled that CEO Cutler attended once during FE's tenure.
  - b. FE-11 explained that the QBR meetings were intended to identify issues ahead of time and serve as a barometer of the state of the business, its financial health, and where it is going. The QBR meetings focused on ICON's FSP business and covered issues like headcount, G&A expenses, and business opportunities.
  - c. The QBR meetings were coordinated by ICON administrative assistants with calendar invites.
    - i. FE-11 had to submit draft QBR materials a week in advance of the meetings for review.
    - ii. In advance of the meetings, the administrative assistants transmitted the final PowerPoint presentations by email; Cutler received these presentations and was copied on the same emails FE-11 received.
  - d. The QBR meetings primarily focused on 7 to 8 key accounts. At the QBR meetings, FE-11 presented for approximately 90 minutes on the Novartis account, together with a business development person who covered contract-related issues. FE-11 recalled that Maria DiPietro presented the Pfizer account at the QBR meetings during FE-11's tenure, while Karen Tormey and Hope Fitzsimmons currently cover Pfizer.
  - e. FE-11 confirmed that the prospect of a large customer significantly reducing headcount with ICON would be flagged in the QBR presentations. For example, FE-11 explained that Novartis reduced its headcount at ICON by about 200 people,

or about 10% of the total. FE-11 started to discuss these possible reductions with Novartis in May and flagged the issue in at least two QBRs before Novartis implemented the reductions at year-end—seven months after FE-11 raised the issue at ICON.

- f. FE-11 explained that the QBR presentation included detailed operational metrics for each key account, including:
  - i. ICON’s actual performance, down to the gross profit per FTE (full-time equivalent), accounts receivable, accounts payable, days sales outstanding (DSO), revenue, and margin to date. These figures were reported as actuals for the prior quarter and as forecasts for the next two quarters.
  - ii. The status of the customer’s contract and renewals. For example, the presentations identified a given contract as three years and that ICON was 1.5 years through the performance period.
  - iii. A “Risk Factors” slide that identified the customer’s contract as red, yellow, or green based on potential threats to the relationship. The risks identified in the presentations included contract termination, other material threats like significantly reducing headcount, and issues like having excessive staffing in a given area.
  - iv. Key Performance Indicators under ICON’s Service-Level Agreements, classified as red, yellow or green. These metrics were tracked because ICON was penalized for falling short on quality metrics like retention and time to fill, triggering payments to the sponsor. FE-11 recounted that ICON had paid Novartis in some years.
- g. The QBR presentations also covered sales, including RFPs and ICON’s efforts to expand in geographies and existing markets.
  - i. Finally, the QBR presentations also included slides on ICON’s financial health and the implications of potential changes in headcount and other issues, covering downside scenarios for the year, such as a scenario where ICON’s expenses increased by more than 100 basis points a year.
- vii. FE-11 rejects Defendants’ public explanation that ICON’s issues with two large customers arose suddenly late in the third quarter of 2024. In particular, FE-11 described the notion that CEO Cutler only learned about Pfizer’s cuts in September 2024 as “bullshit.”
  - a. FE-11 explained that a business reduction of that magnitude was known to Cutler and ICON’s other executives 12 to 18 months ahead of time, and they simply decided to delay public disclosure in an effort to generate other business to make up for the known loss.
  - b. FE-11 added that it is the GP’s job to report whether ICON was at risk and to proactively identify issues or changes that could have a material impact on ICON

and to review the financial implications at QBRs. FE-11 again cited Novartis' 10% headcount reduction, which was extensively discussed internally starting seven months before it happened.

## 12. FE-12

482. FE-12 was employed by ICON as a Resource Manager from June 2022 to August 2023. FE-12 was assigned to ICON Strategic Solutions (previously defined as "ISS"), which represented the legacy PRA business and provided embedded employees to study sponsors, similar to ICON's FSP business. FE-12 responded to RFPs and executed study plans in the vaccine area for Sanofi Pasteur. His responsibilities included building study budgets, managing change orders and study staffing, and negotiating contracts, including working with Sanofi's legal counsel to finalize study contracts. FE-12 reported to Tim Saxton and Sue Stefko, both of whom reported to SVP, Business Development Maria DiPietro. In turn, DiPietro reported to ISS President Samir Shah. According to FE-12, based on personal knowledge:

- i. **ICON ISS's Significant Relationship with Sanofi:** FE-12 explained that ICON ISS provided embedded solutions to Sanofi: ISS employees had access to Sanofi's systems, but were paid via ICON. As of August 2023, FE-12 estimated that ISS had between \$900 million and \$1 billion in committed multi-year contracts with Sanofi. These contracts ranged between one-and-a-half and five years in duration, with an average duration of about three years. FE-12 confirmed that Sanofi was one of ICON's top 10 customers, and potentially among the top five.
- ii. **ICON FSP Loses Business to ISS:** FE-12 explained that the PRA Merger left ICON ISS and FSP to compete for similar business from the same sponsors, including Sanofi. FE-12 noted that ICON ISS and FSP "were constantly bidding against" each other. FE-12 knew this because Sanofi would allocate a yearly study budget and sent FE-12 a list of approximately 40 studies for ICON ISS to bid on each quarter. Based on that list and discussions with FSP and Sanofi staff, FE-12 estimated that ICON bid against itself on roughly half of Sanofi's RFPs, or approximately 20 RFPs per quarter.
  - a. Further, ICON FSP consistently lost awards to ISS because ISS was cheaper for Sanofi. FE-12 said this trend continued throughout his employment at ICON. FE-12 knew ISS was winning the awards because he interacted with ICON FSP personnel who were "really mad that we were bidding on the same projects," and he received weekly updates that identified every award FSS won.

- iii. **Despite Being Warned in Writing Not to Commit “Fraud,” Cutler Misled Sanofi About ICON FSP Pricing:** In early 2023, CEO Cutler tried to mislead Sanofi by falsely indicating that ICON FSP and ISS had similar pricing, even though FSP was 25% more expensive—even after FE-12 warned Cutler that doing so was “essentially fraud.”
- a. The issue arose in fall 2022, when Sanofi executives asked ICON to compare FSP and ISS pricing for a hypothetical vaccine study. FE-12 recalled that the request originated from Sanofi VP, Global Head of Clinical Development Sanjay Gurunathan; Tim Saxton at ICON asked FE-12 via email to perform the analysis.
  - b. FE-12’s pricing analysis showed that ICON FSP was about 25% more expensive than ISS. FE-12’s price comparison for the ISS and FSP bids included salaries per position, different bill rates for the five different countries involved in the study, hours required by the study protocol, and other key data points.
  - c. In late December 2022, FE-12 emailed his analysis to Saxton, and it ultimately reached Cutler and Brennan. FE-12 knew Cutler and Brennan received the analysis because Cutler responded by email, and Saxton forwarded Cutler’s response to FE-12. Cutler stated, in substance, that the report “cannot leave the Company” and that the ISS and FSP pricing needed to look “more even,” such that the bids were within 5% of each other.
  - d. FE-12 warned that Cutler’s request was “essentially fraud” and unethical, and his warning was forwarded to Cutler and Brennan. Specifically, in January or early February 2023, FE-12 sent Saxton a lengthy email refusing to modify the analysis because Cutler’s request was “essentially fraud,” unethical, and would cause problems if ICON were ever investigated. FE-12 confirmed that his email used the term “fraud.” Saxton then forwarded FE-12’s email to Cutler and Brennan. FE-12 knows that Cutler saw the email, because two to three weeks later, Saxton told FE-12 during a weekly one-on-one call that Cutler had mentioned it to Saxton and said he “was not amused.”
  - e. Nonetheless, shortly thereafter, ICON presented Sanofi with a misleading PowerPoint slide that “fudged” the pricing analysis to show that ISS’s and FSP’s pricing appeared to be within five percent of each other. FE-12 learned about the presentation from either Saxton or Stefko, who attended the meeting with Sanofi and described it to FE-12, and provided FE-12 with a PowerPoint slide presented to Sanofi. The numbers on the slide had been “fudged” by reducing the hours for clinical research associates (CRAs) at ICON FSP (but not ISS) until ISS’s and FSP’s overall pricing appeared to be within five percent of each other, which was not true. FE-12 explained that the study would require double the CRA hours indicated in ICON’s presentation to Sanofi. FE-12 confirmed that the analysis had been altered at Cutler’s direction based on Cutler’s email he received.
- iv. **The Drop in Vaccine Spending Was Foreseeable:** FE-12 said that he noticed two business trends during his tenure that indicated that ICON would lose vaccine-related revenue.

- a. First, as discussed above, Sanofi was alienated by the competition between ICON's ISS and FSP units. Sanofi's revenue was concentrated in COVID and flu vaccines, so less Sanofi business meant less vaccine-related revenue.
  - b. Second, Sanofi lost significant funding from BARDA. BARDA reduced its funding for COVID-related vaccine research six months before FE-12 departed in August 2023. Accordingly, Sanofi lost approximately \$150–\$200 million in COVID vaccine funding from BARDA across two major studies, which involved thousands of patients in 15-25 countries. As FE-12 said, ICON “was not going to get \$300 to \$400 million per year” in vaccine revenue after the COVID vaccine funding cuts began.
- v. **ICON's Heavy Offshoring of Labor:** FE-12 confirmed that ICON attempted to cut costs by offshoring study staff and administrative roles to countries with lower labor costs, such as India and Bulgaria. For example, FE-12 stated that in approximately 2022, ICON eliminated its entire U.S. “invoicing team,” which was previously based in Virginia, and moved the invoicing function to India.
- a. Despite ICON's heavy offshoring, FE-12 explained that ICON FSP told customers, such as Sanofi, that their project staff were U.S.-based, even as the personnel were actually located in India or other low-cost countries.
  - b. To make matters worse, ICON FSP billed customers for these non-U.S. employees at U.S. rates. FE-12 knew this because he saw proposals to customers where ICON would bill the India staff at the rates charged for U.S. staff.

### 13. FE-13

483. FE-13 was ICON's Vice President, Scientific Affairs from spring 2019 to September 2023. In this role, FE-13 organized a team that supported sales to laboratory services clients and supervised management of ICON's specialty testing labs. FE-13 reported to Jim Miskel, President of Laboratory Services, who reported directly to CEO Cutler for most of FE-13's tenure. From approximately September 2022, Miskel reported to Chief Medical Officer and President of ICON Development Solutions Ute Berger, who reported to Cutler. FE-13 worked in the same Blue Bell, PA office as Cutler and saw him regularly in the office. According to FE-13, based on personal knowledge:

- i. **By Early 2023, ICON Saw Declining RFPs in Lab Services:** On the laboratory services side, RFPs to ICON from biotech and large pharma customers were noticeably down, by at least 20%, starting from January 2023.

- a. FE-13 explained that ICON struggled to integrate PRA's business on the laboratory services side. The ICON and PRA sales representatives were paid on a transactional basis, leading to an "us vs. them" mentality and a lack of coordination. For example, PRA and ICON bioanalytical labs salespeople would talk over each other on calls with potential clients.
  - b. Customers found the situation confusing and didn't want to deal with it, leading to lost business for ICON. While these concerns were communicated to Miskel, the situation did not improve, as ICON's sales compensation model remained unchanged.
- ii. **CEO Cutler Personally Reviewed ICON's Expenses:** Cutler was a "micro-manager CEO" whose "approval was required for everything." For example, FE-13 explained that Cutler was heavily involved in approving even relatively small expenses, such as purchases over \$10,000, which required Cutler's approval via email. FE-13 found CEO Cutler's detailed involvement in expense approvals to be unusual for a company of ICON's size.
  - a. Further, larger expenses, such as all laboratory equipment purchases over \$100,000, had to be approved by Cutler in expense review meetings. These meetings occurred approximately quarterly and were held via Zoom. Cutler, Brennan, FE-13 and others participated, and Balfe sometimes attended.
  - b. The meetings covered expenses in multiple areas of ICON, such as full-service, IT, and laboratory services.
  - c. FE-13 covered the laboratory services area. In advance of each meeting, FE-13 prepared an extensive slide deck that identified each proposed equipment purchase, listed what customers would be using it, and provided a detailed financial analysis, including how much revenue the equipment would generate in the first five years.
  - d. The slides were due two weeks before the meetings. FE-13 emailed the slides to Cutler's administrative assistant, who organized the meetings, prepared agendas, and distributed the materials to Cutler, Brennan, and other executives.
  - e. During the meetings, FE-13 personally presented the lab equipment purchases to Cutler and Brennan, continuing into the last year of his employment (September 2022 to September 2023). It was clear to FE-13 that Cutler had reviewed the presentations in advance because he was ready with questions for FE-13 about the proposed equipment purchases.
  - f. Cutler approved the expenses verbally during the meetings; afterward, his administrative assistant sent an official approval number that had to be used for any requisition.
- iii. **Cutler Personally Approved Hiring Decisions:** FE-13 explained that in addition to expenses, Cutler's approval was required to add headcount or replace employees who departed. This process involved Miskel raising the issue with Ute Berger, who obtained Cutler's approval. Further, in the last year of FE-13's employment (September 2022 to



September 2023), any departing employees had to be replaced with workers in low-salary areas like India and Mexico.

- iv. **Cutler's Detailed Meetings with His Direct Reports:** FE-13 noted that in the period when Miskel reported directly to Cutler, Miskel and Cutler held weekly meetings that were very detailed. Despite Miskel's title, FE-13 explained that he had no freedom to operate.

#### 14. FE-14

484. FE-14 was a Director of Business Development for ICON's clinical trial services from 2021 through early 2023. In this role, FE-14 handled ICON's external relationships with pharmaceutical companies, also called sponsors, and was responsible for forging new partnerships and maintaining existing relationships with sponsors. On a day-to-day basis, FE-14 managed accounts, handled proposals and bids, met with customers to support their needs and forecast their pipelines, and engaged in remediation for projects that were not going well. FE-14 worked with three large pharmaceutical companies—Eli Lilly, Daiichi Sankyo, and Teva Pharmaceuticals—and 30 to 40 small biotech companies. FE-14 reported to Beth Moeller, Vice President of Finance, and then to Wendy Bulgrin, Executive Director, Global Business Development Lead. According to FE-14, based on personal knowledge:

- i. **Senior Management Was Directly Involved with ICON's Large Customer Relationships and Reviewed Large Revenue Opportunities:** FE-14 explained that senior ICON executives, including Cutler and McMillan, had direct involvement in ICON's business dealings with Pfizer and other large sponsors because they were the "bread and butter" that kept ICON's revenue rolling. FE-14 confirmed Pfizer, Janssen, and Eli Lilly were among ICON's largest customers.
  - a. FE-14 recalled that ICON senior leadership reviewed any revenue opportunity worth approximately \$30 million or more.
    - i. First, revenue opportunities were entered into Salesforce, and revenue opportunities of \$30 million or more generated an email to ICON senior leadership to alert them and trigger their involvement in the process; FE-14 was copied on these emails sent to McMillan. FE-14 also knows that some of ICON's target deals with Eli Lilly were presented to Cutler based on seeing email threads that went to Cutler.

- ii. Second, ICON senior leadership had calls with the account representatives to “grill” them on strategy and discuss the budget to ensure that it was competitive. Further, it was common for ICON senior leadership to green-light discounts on \$30 million-plus deals to get the work. FE-14 recalled that a member of ICON’s senior leadership said ICON would never lose a deal due to pricing.
  - iii. Third, when ICON “pitched” to customers, McMillan attended as an executive presence to speak to customers, such as Eli Lilly. McMillan also sometimes met with customers by himself, even flying to meet customers for dinner and in-person meetings to win the deals. ICON senior leadership also participated in bid defense meetings with customers.
- b. FE-14 expressed skepticism about ICON’s claim that two large customers suddenly reduced their business in 3Q24. He said that as a large CRO, ICON’s management should be well entrenched with two large key customers and have executive steering committees and governance in place to make forecasts and ensure visibility of issues with the business.
- ii. **The PRA Merger Was a Failure:** FE-14 characterized the merger with PRA as a “terrible merger” and a “failure.” FE-14 explained that following the Merger, ICON continued to promise strong biotech partnerships, but in reality, ICON was losing ground with its biotech customers.
  - a. FE-14 stated that ICON acquired PRA because it was a leader in biotech—meaning that everything at PRA was built for biotech. PRA was also known for its culture, while ICON was very numbers-driven. ICON had a minimal biotech business before the Merger, so ICON saw the acquisition as a way to build out its biotech arm.
  - b. After the PRA Merger, although ICON tried to “spruce it up,” customers eventually began to “see through the façade” and realize that ICON did not have biotech solutions. For example, ICON’s Standard Operating Procedures were not always built for biotech, and ICON team members were not well-versed in biotech. PRA’s customers began providing FE-14 with feedback that the work PRA was performing under ICON was inconsistent with its prior work as a freestanding company. He said that this led to legacy PRA customers leaving ICON “in droves” and not providing ICON with additional work.
  - c. FE-14 estimated that at least 30% of his biotech customers did not want to conduct business with ICON at all after the Merger. These customers told FE-14 that ICON’s biotech “solution” was not impressive.
  - d. As a result, it became increasingly difficult for FE-14 to develop business from his biotech customers, so he had to rely more on his large pharmaceutical customers to meet sales targets.



- iii. **ICON’s “Skeleton” Representations:** FE-14 believes that ICON executives sometimes publicly announced “partnerships” with large pharmaceutical companies to raise ICON’s share price by implying that ICON’s business with large pharmaceutical companies was bigger than it actually was. In reality, the contracts were low revenue, low dollar engagements, such as regulatory consulting work, which FE-14 called “skeleton” representations.

## 15. FE-15

485. FE-15 worked as a Regional Lead, Business Development from early 2023 to November 2024. FE-15 reported first to Perry Peck, Executive Director, Business Development, and then to Lloyd Harris, Sales Head, Business Development. FE-15’s unit covered the territory from the Mississippi to the Pacific Ocean and focused on driving meetings with companies that did not currently have relationships with ICON to land RFP opportunities. FE-15 managed a team of inside sales representatives, who were each assigned to two outside sales representatives (called directors of account development). FE-15’s group focused on biotech, or non-top 50, pharma companies and targeted companies with recent news about funding, new studies, or other “trigger events” to set up meetings and obtain RFPs. He noted that the average deal on his team was worth \$3.5 million. According to FE-15, based on personal knowledge:

- i. **The PRA Merger Led to Lost Business:** FE-15 reported that after the PRA Merger, smaller biotech companies that had previously worked with PRA were not getting the attention and resources they needed. FE-15 explained that ICON was simply buying a book of business through the Merger and did not know how to properly execute. According to FE-15, by 2024, ICON was experiencing PRA business loss.
  - a. FE-15 reported that the PRA Merger also caused issues with ICON’s large pharma customers because some of these companies had business with both PRA and ICON before the Merger and they “didn’t want to put all of their eggs in one basket.” FE-15 further explained that CROs need to be conscious not to take on all of the studies for a given indication because they might have trouble finding enough patients through their networks.
- ii. **ICON Terminated Employees as Business Slowed:** FE-15 observed terminations at ICON starting in 2022, with an effort to offshore various functions to reduce costs. He recalled that in 2023 and 2024, he began receiving calls from employees in other ICON units who were facing termination and inquiring about opportunities on the sales teams.

- iii. **ICON's Business Slowed Through 2023 and 2024:** FE-15 reported that in 2023 and 2024 he was hearing from both internal and external sales representatives that sponsors were shopping around their business and not reupping with ICON as much as in previous years. Further, while sponsors had generally gone to three to four CROs for RFPs, in 2024, they started going to as many as six to eight.
  - a. FE-15 stated that the narrative among teams at ICON in 2024 was that RFPs were not turning into awards at higher rates and customers were not ready to spend.
- iv. **Salesforce Tracked ICON's RFPs:** FE-15 reported that he and all managers had access to Salesforce. He recalled that Salesforce contained managers' dashboards that showed RFP wins and losses, the win/loss reasons, and a year-over-year report. FE-15 stated that Salesforce tracked both "outstanding" and "anticipated" RFPs.

### C. Defendants' Own Admissions Underscore Scienter

486. The Individual Defendants' own admissions confirm their prior knowledge of the decreasing demand from ICON's largest customers, ICON's failure to account for known risks, and ICON's inflated RFP flow.

487. As detailed above, in February 2024, Cutler internally admitted at a Company-wide town hall that ICON had lost the "Pfizer opportunity" and was no longer a preferred partner of Pfizer. Standing alone, this internal admission establishes Cutler's knowledge of the truth that his public statements misstated and concealed.

488. Moreover, an October 25, 2024 Truist report disclosed that ICON executives had known that its two largest customers were diversifying CRO providers away from ICON—management described this as "*not a new development*"—and that the overconcentration resulting from the PRA Merger "*was flagged internally at the pharma customers*" at the time of the Merger (*i.e.*, in 2021) and it was known within ICON that the customers wanted to "balance potential risk in how much work is being sent to one particular provider." Thus, competitors taking work from ICON admittedly "*did not come as a surprise to ICON.*"

489. In addition, Cutler admitted at the November 21, 2024 Jefferies London Healthcare Conference that one of the two large customers that contributed to ICON's disastrous 3Q24 results

*“had been falling over the last 12, 24 months,”* confirming Cutler’s knowledge of a deteriorating relationship for the last two years. And on ICON’s 3Q24 earnings call, Brennan admitted that *“we certainly anticipated a decline [in] revenues from a certain part of their business in terms of the full-service work”* for the two large customers.

490. During the same call, Cutler admitted that ICON had not accurately gauged the “risks and opportunities” in 3Q24, explaining that “going forward [we] will reformulate and relook at what those risks and opportunities are and *be able to be a little bit more accurate*, if that’s the right word in terms of in terms of how we I think the world is going to go and how it’s going to come in.” Cutler added that “we need to just look at ourselves a little bit more closely and *make sure that we are projecting and forecasting in a way that is reflective of those risks*,” tacitly admitting that Defendants had not done so before.

491. Further, the fact that many of ICON’s customer RFPs never resulted in awards was admittedly known to the Individual Defendants. On November 21, 2024, Cutler admitted that “around 20% to 30% of the RFP dollars that we put out don’t come to a decision. We call it close cancel. In other words, they’re canceled before they even get to a contracting point.” And on ICON’s May 1, 2025 earnings call, Defendant Balfe conceded that “the quality of that RFP flow isn’t always as strong as we might wish.”

**D. The Individual Defendants’ Access to Information Concerning RFPs and ICON’s Relationships with Large Pharmaceutical Customers**

492. Before and during the Class Period, the Individual Defendants received or had access to data and information concerning ICON’s revenue, contracts, and deteriorating relationships with large pharmaceutical customers, such as Pfizer, and worsening key business metrics—such as RFPs, win rates, and cancellations—that contradicted their public statements.

493. For example, ICON's Salesforce system tracked the status of Pfizer's backlog, awards, pipeline, all open RFPs, and ICON's chance of winning those RFPs. (FE-1.) Salesforce also tracked win rates, total awards and cancellations, and the status of individual awards—including whether they materialized into work and revenue or whether they were canceled—and generated automatic email notifications when cancellations or other changes were made to studies. (FE-1.)

494. These metrics from Salesforce were accessible to the Individual Defendants. During quarterly business development meetings, Defendants Brennan and Balfe saw ICON's decreasing biotech RFPs through 2023 and 2024. (FE-1.)

495. Further, during the quarterly business development meetings, Brennan and Balfe personally presented a company-wide dashboard in Salesforce that contained 10 or 15 datapoints—including cancellations, a “fixed piece” that was always presented—and showed “very high” and increasing biotech cancellations from mid-2023 onward, a trend that Brennan and Balfe complained was hurting ICON's numbers. (FE-1.) Cutler was also aware of ICON's increasing biotech cancellations because they were discussed at an annual sales meeting he attended in April 2024 in Tampa, Florida. (FE-1.)

496. Defendant Cutler was also aware that ICON's overall customer RFPs were declining in 2023 because he was consistently copied on quarterly internal emails stating that ICON's RFPs and awards were declining across the board. (FE-7.)

497. As detailed above, Cutler was aware of major developments with respect to Pfizer and other large customers. Before Christmas 2023, Cutler learned that Pfizer would award all of its Phase 1 business—and 85% of its Phase 2 and 3 business—to other CROs. (FE-2.)

498. By January 2024, Cutler knew that Pfizer had advised ICON that it was moving to FSP to reduce costs. Cutler headed a special Pfizer “liaison team” at ICON, reviewed and approved ICON’s internal email announcing the change, and participated extensively in working out the structure of the transition, including meeting with Pfizer regularly. (FE-2.)

499. In February 2024, during a Company-wide quarterly town hall, Cutler announced that ICON had lost its contract with Pfizer, lost the “Pfizer opportunity,” and was no longer a preferred partner of Pfizer. (FE-3.)

500. Cutler also approved requests from top 10 customers to reduce ICON’s project budgets, including approving a \$50 million budget cut for Pfizer in January 2024. The frequency of these emails increased towards the end of FE-2’s tenure in February 2024. And in 2Q24, ICON’s slowing business with large pharma drove Cutler to personally meet with the CEO of ICON’s tenth-largest customer and accept unfavorable terms. (FE-4.)

501. Further, Defendant Balfe, Defendant Cutler, and other ICON executives participated in Quarterly Business Review (QBR) meetings where senior leadership discussed business performance and risks, including issues with large contracts, in detail. (FE-11.) The structured, two-and-a-half-day QBR meetings focused on ICON’s FSP business and served as a barometer for the state of the business and its financial health.

502. The QBR meetings primarily focused on 7 to 8 key accounts, with ninety-minute presentations given on specific large pharma customers such as Pfizer and Novartis. The presentations—which were emailed to Balfe, Cutler and other attendees in advance—included detailed operational metrics for all key accounts, including:

- ICON’s actual performance, down to the gross profit per FTE, accounts payable and receivable, revenue, and margins (including actuals for the prior quarter and forecasts for the next two quarters);

- The status of customer contracts and renewals, including when the contract would expire;
- Risk factors to customer relationships, identified through red, yellow, and green indicators, such as contract termination and significant headcount reductions;
- Key performance indicators, also classified as red, yellow, and green; and
- Sales, including efforts to expand to new geographic regions.

503. As FE-11 confirmed, the prospect of a large customer significantly reducing headcount with ICON would be flagged in the QBR presentations months in advance. For example, FE-11 explained that Novartis reduced its headcount at ICON by about 200 people, or about 10% of the total. FE-11 started to discuss these possible reductions with Novartis in May and flagged the issue in at least two QBRs before Novartis implemented the reductions at year-end—*seven months* after FE-11 raised the issue at ICON.

504. In addition, Defendants Cutler, Brennan and Balfe attended monthly VP meetings (scheduled through a standing calendar invite) where they received and reviewed detailed presentations on studies' financial performance and problems, including revenue and margins, wins and losses, the studies' needs and problems, and upcoming deadlines and milestones. (FE-2.) In advance of the meetings, Cutler and the other executives received slide decks and reviewed the materials, since they came to the meetings with questions about specific studies. FE-2 knows this because Lachs sent FE-2 instant messages during the meetings with specific questions, such as "Steve [Cutler] wants to know what the problem is with study startup."

505. Cutler, Brennan, Balfe, McMillan and other senior executives also attended "end gate" meetings for underperforming studies, where they asked difficult questions about why the study numbers were not where they were supposed to be and whether more resources were required. (FE-2.) FE-2 personally presented at two "end gate" meetings around October and December 2023; Cutler attended the October 2023 meeting, which related to a study for Pfizer.

FE-2 emphasized that the attendees “would run you through the wringer about why you were not where you needed to be.”

506. The Individual Defendants also interacted directly with Pfizer executives. Defendant Cutler was assigned as Pfizer’s executive sponsor (FE-1) and personally led “Partner of Choice” Meetings where ICON invited senior executives from Pfizer, Novartis, and other large accounts to ICON’s headquarters in Blue Bell, Pennsylvania. (FE-11.) The goal of these meetings was to discuss challenges in the industry and issues related to ICON’s business—including Pfizer’s move from FSO to FSP, threatening ICON’s margins. (FE-11.) Defendant Balfe and other senior ICON executives were also intimately involved with the Pfizer relationship, which was their “baby.” (FE-11.)

507. Further, the Individual Defendants were aware of headcount changes at ICON. Specifically, as to Pfizer, after ICON made significant layoffs, including from the dedicated PSBU, Cutler and Brennan participated in periodic Zoom town halls where employees expressed concern about why ICON was laying off employees. (FE-8.) Notably, Cutler’s personal approval was required to add headcount or replace employees who departed (FE-13), so Cutler was necessarily aware that ICON’s declining PSBU headcount was not being replenished. And on the FSP side—where Pfizer shifted nearly 100% of its work at ICON—ICON’s standard contracts generally required 90 days advance notice for staffing changes (FE-1), confirming that ICON and the Individual Defendants were aware of Pfizer’s declining staffing needs well in advance.

508. ICON’s senior management was also directly involved with revenue opportunities tied to large customer relationships. For example, ICON senior leadership reviewed any revenue opportunity worth approximately \$30 million or more (often green-lighting discounts to get the work). (FE-14.) When such opportunities arose, Salesforce generated emails to ICON senior

leadership to alert them and trigger their involvement in the process. (FE-14.) And ICON executives personally reviewed target deals with large customers; for example, Cutler viewed target deals with Eli Lilly. (FE-14.)

509. ICON’s senior executives also closely tracked project margins. For example, at the March 13, 2025 Barclays Global Healthcare Conference, Cutler stated that “we track our margins, not just the margins that we operate on as we run the project, but what the theoretical margins are when we sell the business.”

510. Finally, underscoring Cutler’s access to information, Cutler—an Australian ex-rugby player—was a notorious bully and “micro-manager CEO” whose “approval was required for everything”; Cutler was personally involved in hiring decisions and personally approved even relatively small expenses above \$10,000 via email. (FE-9, FE-13.) For larger expenses, such as all laboratory equipment purchases over \$100,000, Cutler demanded detailed presentations and expense review meetings to justify the proposed purchases. (FE-13.) Cutler received and reviewed the materials in advance of the meetings, since he was ready with questions about the proposed purchases. (FE-13.) Cutler’s unusually detailed involvement in the minutiae of ICON’s operations confirms his knowledge and access to the true facts concerning issues worth hundreds of millions of dollars (or more), such as ICON’s contracts and relationships with large pharmaceutical customers; key business metrics, including RFPs and cancellations; and revenue recognition, internal controls over financial reporting, and disclosure controls and procedures.

**E. Defendants Repeatedly Discussed and Claimed to Have Specific Personal Knowledge and Insight into ICON’s Customer RFPs and Relationships with Large Pharma Customers**

511. During the Class Period, analysts focused intensely on ICON’s customer RFPs as a key leading indicator of demand for its services, as well as any issues with ICON’s relationships



with large pharma customers, such as Pfizer. In response, the Individual Defendants repeatedly spoke about these topics in detail and confirmed their personal knowledge of these issues. These statements support a strong inference that the Individual Defendants knew or had access to material facts that were misrepresented or concealed from investors, or that Defendants were reckless in failing to investigate the issues they repeatedly spoke about in detail to investors.

512. For example, Cutler repeatedly touted his knowledge of and personal involvement with ICON's large pharma customer relationships. On ICON's October 26, 2023 earnings call, Defendant Cutler explicitly rejected the idea that Pfizer's budget cuts would negatively affect ICON, emphasizing his "close contact" and personal role in "working closely" with Pfizer.

513. Similarly, on ICON's February 22, 2024 earnings call, Cutler specifically highlighted his "visibility" into ICON's large pharma relationships and involvement "in steering committee meetings" so "we're able to work out where we need to be as a partnership."

514. Cutler confirmed his direct involvement in large pharma relationships on ICON's July 25, 2024 earnings call, where he stated that "*you tend to get involved in some of these more strategic meetings. And I'm aware of some of the requests and the asks that our larger pharma partners are looking for*, particularly for these more strategic relationships." Cutler also stated that "I've been to one or two strategic partnership meetings recently."

515. At the November 21, 2024 Jefferies London Healthcare Conference, Cutler stated with respect to ICON's large customers that "*we talk to them on a regular basis*. We understand what their challenges are, and we're helping them to work through them."

516. The Individual Defendants also spoke extensively about ICON's RFPs. For example, during the October 26, 2023 earnings call, Cutler stated in his prepared remarks that "[o]verall, RFP activity continued to improve in quarter [three] with growth in the high single

digits . . . .” At the November 14, 2023 Jefferies London Healthcare Conference, Defendant Brennan claimed that ICON had seen “a significant kind of uptick [in RFPs] from our biotech customers.” On the February 22, 2024 earnings call, Cutler asserted that “we’ve probably seen the RFPs tick up and the environment sort of move up a notch. So overall, in terms of RFPs in the first quarter . . . we’re seeing sort of mid-teens growth on the RFP opportunity.”

517. Defendant Cutler also emphasized his personal involvement with ICON’s biotech customers. For example, during the April 25, 2024 earnings call, Cutler stated, “I’ve had a couple of discussions with [our biotech customers] myself, and they understand what we bring now to the biotech space, that dedicated resource and that financial stability and ability to bring innovation and creativity and agility to their projects.”

**F. Core Operations: Large Pharmaceutical Customers Comprised ICON’s Most Significant Client Base and Drove Revenues**

518. The strong inference of scienter is further supported by the fact that the alleged false and misleading statements concern the core of ICON’s business—its clinical trial services for large pharma and biotech customers. As discussed above (at ¶72), ICON derived *over 95% of its revenue* from such work.

519. Further, ICON’s business was dependent on a relatively small number of its largest customers. Indeed, ICON admitted that it “depend[s] on a limited number of customers” and that “[t]he loss of, or a significant decrease in, business from one or more of these key customers could have a material adverse impact on our results of operations and financial results.” ICON’s largest customers comprised a disproportionately large amount of revenue. For example, in fiscal year 2023, ICON earned approximately 41% of its revenues from its top ten customers.

520. ICON’s relationships with large pharmaceutical companies, such as Pfizer, Janssen, Roche, Merck, and Eli Lilly, were the “bread and butter” that kept revenue at ICON flowing.

(FE-14.) Cutler inserted himself into those financially significant relationships. For example, in late 2022, Cutler personally intervened to manipulate a pricing analysis for a large customer, Sanofi, to falsely show that ICON ISS and FSP pricing were similar. (FE-12.)

521. ICON's largest pharmaceutical customer, Pfizer, accounted for nearly 9% of its revenues. Defendant Cutler was formally assigned as the executive sponsor for Pfizer and certain other customers. (FE-1.) FE-11 corroborated that Cutler was central to the Pfizer relationship and managed it due to its prominence at ICON. And as detailed above, Cutler publicly praised "ICON's long-standing relationship with Pfizer" and "*close collaboration with Pfizer.*" In a September 2021 presentation with a Pfizer executive, Rob Goodwin (VP, Operations Center of Excellence, Global Product Development), Cutler stated that ICON and Pfizer have "shared history" and "a network of people and a network of relationships that *know each other very well.*"<sup>13</sup> Defendant Balfe was also intimately involved with the Pfizer account. (FE-11.)

522. The Individual Defendants also confirmed the significance of large pharmaceutical customers, such as Pfizer, in their statements during industry conferences and earnings calls. For example, during the November 14, 2023 call, Brennan stated that ICON has a "big embedded relationship[] with these large pharma companies." On January 10, 2024, at the J.P. Morgan Healthcare Conference, Cutler emphasized the strength of ICON's long-standing relationships with large pharma, as well as the Company's collective knowledge of this space, asserting that ICON has a "strong franchise in the large pharma space" because "we grew up with that, and it's an area we know well" based on ICON's work with these companies for "30 years."

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<sup>13</sup> <https://theconferenceforum.org/webinars/learnings-from-the-leadership-of-the-collaboration-that-delivered-a-covid-vaccine-in-record-time>

**G. Additional Indicia of Scienter**

523. The following facts further support a strong inference of Defendants' scienter.

524. Temporal Proximity Between Misstatements and Corrective Disclosure: On September 10, 2024, Cutler delivered positive statements, asserting that "the percentage of RFPs that are coming through, the dollar amounts that are coming through remain strong, remain good" and twice stating that there had been "***no material changes***" in ICON's business. Cutler further affirmed ICON's 2024 earnings guidance and assured that "we're seeing what we thought we'd see" and "***there's nothing that's fundamentally changed that we hadn't already thought about or included in our guidance.***"

525. Just over a month later, on October 23, 2024, ICON revealed a shocking "revenue shortfall" of \$100 million for the quarter and reduced its 2024 revenue guidance by \$220 million—despite claiming business as usual just a few weeks prior. Cutler cited "lower than anticipated revenue contribution from two of our largest customers," "slower than expected activity in our biotech segment," and "an outsized level of vaccine related cancellations [in] quarter three."

526. ICON's abrupt reversal in just six weeks underscores scienter, since none of these issues suddenly arose between September 10, 2024 and October 23, 2024. Instead, as detailed above, ICON's business with Pfizer and other large customers had declined for years; ICON's biotech customer RFPs had continuously decreased since late 2022, making clear to Defendants that ICON's biotech business was dying; and Pfizer's large COVID-flu vaccine trial had failed by early August 2024.

527. Defendants' Misleading Explanations: Further supporting scienter, Defendants offered misleading explanations for ICON's disastrous October 2024 disclosures. On November 21, 2024, Cutler blamed a "confluence of circumstances that hit us ***rather hard and rather late in quarter three*** [2024] leading to us reducing our guidance."

528. Again, that was not true. Cutler had known those “circumstances” for over a year.

529. FE-11 described the notion that Cutler only learned about Pfizer’s cuts in September 2024 as “**bullshit**.” FE-11 explained that a business reduction of that magnitude was known to Cutler and ICON’s other executives 12 to 18 months ahead of time, and they simply decided to delay public disclosure in an effort to generate other business to make up for the known loss. Indeed, Defendant Brennan admitted on November 29, 2023 that “80% of our business for next year or there or thereabouts is already decided by the time we get to the end of Q3,” meaning that the vast majority of ICON’s 2024 business was known over a year in advance.

530. Corroborating FE-11, FE-14 expressed skepticism about ICON’s claim that two large customers suddenly reduced their business in 3Q24, noting that as a large CRO, ICON’s management should be well entrenched with two large key customers and have executive steering committees and governance in place to make forecasts and ensure visibility of issues with the business.

531. As detailed above, they did: Cutler was intimately involved with ICON’s large customer relationships, personally led “Partner of Choice” Meetings with senior executives from Pfizer, Novartis, and other large customers, headed ICON’s Pfizer “liaison team,” and knew in 2023 and early 2024 that Pfizer and other large customers had materially reduced their business with ICON. Indeed, in February 2024, Cutler admitted during a town hall that ICON had lost the “Pfizer opportunity” and was no longer a preferred partner of Pfizer.

532. Analyst Commentary Supports Scienter: Analysts called out the surprising disparity between Defendants’ prior, consistently positive statements and ICON’s sudden earnings miss and guidance reduction in October 2024. For example, Deutsche Bank highlighted that “***the market was not expecting coincident (3%) / (8%) revisions to 2024 Revenue / EPS guidance,***

*especially after the company reiterated guidance at a September 10 conference.”* Truist reported that the revenue miss was a “*major surprise.*” J.P. Morgan reiterated that “*the magnitude of the miss was surprising.*” And William Blair noted the sudden reversal of Defendants’ prior representations, having previously “highlighted ICON as having one of the more favorable setups in the CRO space *based on what we considered to be decently healthy leading indicators . . . . Clearly this view was wrong.*” This analyst commentary highlights the sharp disparity between Defendants’ prior statements and the truth, further strengthening the inference of scienter.

533. Defendants’ GAAP Violations Support Scienter: ICON’s GAAP violations strengthen the inference of scienter as to Defendants Brennan and Cutler, since Brennan signed the Forms 6-K containing false and misleading statements certifying that ICON’s financial statements were prepared in accordance with GAAP, and both Brennan and Cutler signed SOX certifications stating that ICON’s financial statements “fairly present[ed], in all material respects, the financial conditions and operations of the Company,” yet they materially misstated the Company’s financial performance in violation of GAAP. The pervasive manipulation and inflation of ICON’s financial statements—including holding ICON’s reporting periods open, a basic failure for any public company—underscores the inference of scienter.

534. Defendants’ SOX Certifications Support Scienter: The fact that Cutler and Brennan signed SOX certifications during the Class Period strengthens the inference of scienter as to them, since the SOX certifications they signed establish that they are “responsible for establishing and maintaining disclosure controls and procedures . . . and internal control over financial reporting” for ICON and, in that capacity, require them to (a) design disclosure controls to ensure that material information is made known to them and so that they may “provide reasonable assurance” that the financial statements are reliable and GAAP-compliant; (b) evaluate the effectiveness of those

disclosure controls and procedures and disclose any deficiencies or changes that are reasonably likely to affect ICON's internal control over financial reporting; and (c) disclose all significant deficiencies and material weaknesses in internal controls, as well as any fraud, to ICON's auditors and the Audit Committee of ICON's Board of Directors.

535. Thus, Defendants Cutler and Brennan personally certified that they had designed, supervised, and assessed the effectiveness of ICON's internal control over financial reporting and disclosure controls and procedures—even as those materially deficient controls enabled the inflation of ICON's book-to-bill ratio and the manipulation of ICON's financial reporting, including the extension of ICON's reporting periods, the creation of fake invoices, and the omission of project costs to “hold the margins” and prematurely recognize additional revenue.

536. Cutler's Prior Fraudulent Practices Support Scier: Cutler also engaged in fraudulent practices prior to the Class Period. As detailed above, in early 2023, Cutler tried to mislead a large customer, Sanofi, by falsely indicating that ICON FSP and ISS had similar pricing, even though FSP was 25% more expensive. After Cutler directed that ICON portray the FSP and ISS pricing as “more even,” FE-12 warned that Cutler's request was “*essentially fraud*” and unethical, and his warning was forwarded to Cutler and Brennan. Nonetheless, shortly thereafter, ICON presented Sanofi with a misleading PowerPoint slide that “fudged” the pricing analysis to show that ISS's and FSP's pricing appeared to be within five percent of each other.

537. Executive Departures and Auditor Resignation Support Scier: The sudden resignation of Defendant Brennan in the middle of the Class Period, ICON's termination of its auditor KPMG (which had served since the Company's founding) at the end of 2024, and Cutler's abrupt departure in September 2025 strengthen the strong inference of scier.

538. On April 3, 2024, ICON abruptly announced Brennan's impending departure as CFO after twelve years in the position. At the same time, ICON announced that it would commence a search to find a new CFO, indicating that the resignation was not planned well in advance.

539. Brennan's resignation announcement—about a month after ICON reported 2023 financial results—was suspiciously timed in light of the extensive manipulation of ICON's financial statements, in violation of GAAP, under Brennan's tenure.

540. Notably, at the end of 2023, ICON had fallen significantly short of its targets, prompting a transfer of \$350 million to prop up ICON's failing biotech business (FE-9) and a “mad scramble” to find cash around Christmas 2023, with employees working 14- to 16-hour days and frantically creating fake invoices (marked with an asterisk) (FE-4). At the time, ICON's Finance Department personnel suspected that Brennan was probably about to leave ICON and wanted to “jack up” its share price. (FE-4.)

541. Brennan's resignation announcement also occurred when he knew about key metrics showing that ICON's business was in decline. For example, Brennan knew that ICON's biotech customer RFPs had consistently decreased through 2023; he had personally presented quarterly Salesforce dashboards showing that ICON's biotech cancellations had consistently increased since mid-2023 (FE-1); and he was aware from Zoom town halls that ICON was laying off employees by early 2024 (FE-8).

542. Additionally, during the Class Period, ICON ended its decades-long auditor-client relationship with KPMG. KPMG had served as ICON's auditor since the Company's founding in 1990. However, in 2024, ICON suddenly decided to terminate KPMG and appoint Ernst & Young as its principal accountant for the fiscal year 2025. Thus, the auditor-client relationship with



KPMG ceased following the completion of the audit of ICON's financial statements for the fiscal year 2024 as of December 31, 2024. KPMG's abrupt resignation at the end of 2024 supports scienter, particularly given the extensive and heightening manipulation of ICON's financial statements, in violation of GAAP, during 2023 and 2024.

543. Finally, on September 4, 2025, ICON announced that CEO Cutler will "retire" on October 1, 2025, to be replaced by Defendant Balfe as CEO. Cutler's sudden departure from ICON—with less than one month notice—strongly indicates that Cutler was forced to resign after the fraud's collapse.

544. Defendants' High-Level Positions Support Scienter: The Individual Defendants held high-level executive positions at ICON during the Class Period. As CEO, CFO, and President of Pharma Development Solutions (and current COO), respectively, Defendants Cutler, Brennan, and Balfe controlled ICON's daily operations, directly participated in the Company's management, and regularly received material nonpublic information about ICON's core operations, including demand for its clinical research offerings, RFP activity, and the status of its largest pharma customers, as detailed above.

545. Based on their roles as ICON's highest-ranking officers, the Individual Defendants controlled the contents of, drafted, reviewed, and/or disseminated the material misstatements alleged herein. Further, they were provided with, or had access to, the material misstatements prior to or upon their issuance, and they had the power and authority to prevent or correct the issuance of such misstatements. Accordingly, the Individual Defendants knew, or were deliberately reckless in not knowing, that the adverse facts alleged herein were being actively concealed from investors, and that Defendants' positive representations made to investors were materially false, misleading, and incomplete.

## **H. Corporate Scienter**

546. ICON possessed scienter because the Individual Defendants, who acted with scienter as set forth above, had binding authority over the Company. In addition, certain allegations herein establish ICON's corporate scienter based on (i) the state of mind of employees whose intent can be imputed to ICON, and/or on (ii) the knowledge of employees who approved the statements alleged herein despite knowing the statements' false and misleading nature.

547. It can be inferred that senior corporate executives at ICON possessed scienter such that their intent can be imputed to the Company. Given the significance of ICON's RFP flow, large pharma customers, and financial reporting, and the necessary involvement of numerous ICON departments and personnel—including sales and operations personnel who reviewed ICON's RFP data and key customer accounts, and accounting and finance personnel who approved the improper accounting—additional unknown executives sufficiently senior to impute their scienter to ICON were also aware of the materially misstated information and violations of GAAP.

548. As-yet-unidentified employees also approved the false statements despite knowing of their false and misleading nature. As alleged above, ICON executives were aware of ICON's inflated RFP flow, ICON's declining RFPs, ICON's collapsing relationships with Pfizer and other large customers, and ICON's aggressive revenue recognition practices, manipulation of project costs and margins, falsification of invoices, holding periods open to increase financial metrics, and other violations of GAAP. From this, it can be inferred that someone at ICON approved of the false and misleading statements in ICON's SEC filings concerning RFPs, large customers, financial performance, GAAP compliance, and internal controls, while knowing that these statements were materially false or misleading and violated applicable accounting standards and disclosure requirements.

## VIII. LOSS CAUSATION

549. Defendants' materially false and misleading statements and fraudulent scheme directly and proximately caused Plaintiffs and the Class to suffer substantial losses as a result of purchasing or otherwise acquiring ICON ordinary shares at artificially inflated prices during the Class Period.

550. Defendants' fraudulent statements and scheme artificially inflated and/or maintained the price of ICON ordinary shares and operated as a fraud or deceit on the Class. Relying on the integrity of the market price for ICON ordinary shares, Plaintiffs and other Class members purchased or acquired ICON ordinary shares at prices that incorporated and reflected Defendants' misstatements alleged herein.

551. However, Defendants' false and misleading statements concealed the truth, including about ICON's materially inflated key business metrics, ICON's declining business from biotech customers and large customers (including Pfizer), and ICON's materially inflated financial performance and violations of GAAP. It was foreseeable to Defendants that these concealed facts would negatively affect ICON's financial performance, reduce ICON's share price, and cause losses to Plaintiffs and the Class when revealed.

552. As the false and misleading nature of Defendants' misstatements became known to the market in piecemeal fashion through a series of partially corrective events, as alleged herein, the price of ICON ordinary shares fell precipitously. Specifically:

### A. July 24–25, 2024

553. On July 24, 2024, after market close, ICON reported relatively weak 2Q24 financial results, including 2Q24 revenue of \$2.12 billion (below analyst expectations of \$2.14 billion) and gross margins of 29.5% (32 basis points below analysts' expectations), along with cancellations of \$493 million (elevated from \$460 million in the prior quarter), and net business wins of \$2.579

billion (down \$75 million from the prior quarter). On ICON's July 25, 2024 earnings call, held before market open, Cutler also alluded to challenges and pricing pressure in the large pharma space (while denying that they had affected ICON). These negative disclosures were driven by and reflected the initial, partial unraveling of Defendants' fraud, including their accounting scheme and GAAP violations.

554. On this news, the price of ICON ordinary shares declined \$18.67 per share, or 5.6%, from \$331.77 per share on July 24, 2024 to \$313.10 per share on July 25, 2024.

**B. October 23–24, 2024**

555. On October 23, 2024, after market close, ICON reported 3Q24 financial results in a press release filed on Form 6-K with the SEC. In the press release, ICON revealed a surprise “revenue shortfall” of \$100 million for 3Q24 and reduced 2024 guidance from a range of \$8.45 billion to \$8.55 billion to a range of \$8.26 billion to \$8.3 billion, a \$220 million cut at the midpoint.

556. In the press release, ICON also revealed that leading indicators of underlying demand had significantly deteriorated. For instance, ICON's quarterly gross business wins were \$2.83 billion and cancellations were \$504 million, resulting in net new business wins of \$2.33 billion during the quarter, down from \$2.58 billion the previous quarter, and the Company's book-to-bill ratio declined to 1.15 from 1.22 the previous quarter.

557. Further, ICON's 3Q24 financial results were substantially below analysts' consensus, with a 4.9% (or \$104 million) revenue miss; a 9% (or \$51.5 million) Adjusted EBITDA miss; a 13% (or \$0.50) miss on Adjusted EPS; and a book-to-bill ratio 8% below consensus.

558. In the press release, Defendant Cutler acknowledged that “ICON's results for the third quarter did not meet the expectations we had previously provided,” citing “more material headwinds from two large customers” and “ongoing cautiousness from biotech customers resulting in award and study delays.” During ICON's October 24, 2024 earnings call, held before market

open, Defendant Cutler purported to explain the drivers of the poor financial results and reduced guidance, citing “lower-than-anticipated revenue contribution from two of our largest customers,” “slower than expected activity in our biotech segment,” and “an outsized level of vaccine related cancellations.”

559. ICON’s poor 3Q24 results and guidance cut were driven by the facts Defendants misstated and concealed, including with respect to ICON’s declining biotech business and declining business from Pfizer and other large customers. They also reflected the further collapse of Defendants’ accounting scheme and GAAP violations.

560. On this news, the price of ICON ordinary shares declined \$59.03 per share, or 21%, from \$280.76 per share on October 23, 2024, to \$221.73 per share on October 24, 2024.

561. After Defendants’ repeated assurances about the purported strength of ICON’s business—including affirming ICON’s guidance on September 10, 2024—analysts were shocked by ICON’s sudden disclosure of materially weaker financial results. For example, J.P. Morgan’s October 24, 2024 report stated that “*the magnitude of the miss was surprising*” and the “*incrementally new dynamic flagged in the quarter was the drop-off in spending from the two large pharma customers.*” UBS’s October 24, 2024 report added that ICON management admitted “that the [two large customers’] relative customer concentration and heightened magnitude of their decline had a *material, outsized impact* on ICON’s performance.” Analysts also significantly reduced their price targets. For example, J.P. Morgan and UBS lowered their price targets by 25.3% and 23.7%, respectively.

### C. January 14, 2025

562. Finally, on January 14, 2025, before market open, ICON issued financial guidance for 2025 in a press release filed on Form 6-K with the SEC. ICON announced revenue guidance for 2025 in the range of \$8.05 billion to \$8.65 billion, below analysts’ expectations.

563. In ICON's press release, Defendant Cutler stated that "trial activity has been impacted by cautious spending from biopharma customers, in both the biotech and large pharma businesses," and "[o]ur outlook for this year reflects an expected transition period which includes a headwind from our top two customers on a combined basis, coupled with an inconsistent recovery in biotech."

564. Also on January 14, 2025, ICON participated in an industry conference call hosted by J.P. Morgan. During the call, Cutler revealed, "we believe '25 will be a transition period" for ICON before "normal growth will be resumed." In response to analyst questions, Cutler admitted "softening of the backlog" and higher cancellations "on the biotech side," as well as an expectation of only "lower single digits [growth] outside of [its] top 2" customers.

565. On the January 14, 2025 news, the price of ICON ordinary shares declined \$17.75 per share, or 8.1%, from \$217.99 per share on January 13, 2025, to \$200.24 per share on January 14, 2025.

566. Again, analysts were disappointed. J.P. Morgan flagged ICON's lower-than-expected revenue and Adjusted EPS guidance, while TD Cowen wrote that ICON's 2025 outlook was "worse than expected."

## **IX. A PRESUMPTION OF RELIANCE APPLIES**

567. At all relevant times, the market for ICON's ordinary shares was an efficient market for the following reasons, among others:

- (a) The Company's shares met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;
- (b) As a regulated issuer, ICON filed periodic public reports with the SEC;
- (c) ICON regularly and publicly communicated with investors via established market communication mechanisms, including through regular

disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

- (d) ICON was followed by securities analysts employed by major brokerage firms who wrote reports that were published, distributed, and entered the public domain.

568. As a result of the foregoing, the market for ICON ordinary shares promptly digested current information regarding ICON from all publicly available sources and reflected such information in the market price. Under these circumstances, all purchasers of ICON ordinary shares during the Class Period suffered similar injury through their purchase of ICON ordinary shares at artificially inflated prices and the presumption of reliance applies.

569. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are grounded on Defendants' material omissions.

#### **X. THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE DO NOT APPLY**

570. The statutory safe harbor and the "bespeaks caution doctrine" applicable to forward-looking statements under certain circumstances does not apply to any of the materially false and/or misleading statements alleged herein. None of the statements complained of herein was a forward-looking statement. Instead, each challenged statement relates to then-existing facts and conditions. ICON's "Safe Harbor" warnings during the Class Period thus cannot shield the statements at issue from liability.

571. To the extent there were any forward-looking statements, they were not sufficiently identified as such at the time they were made, and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by ICON were not sufficient to insulate Defendants from liability for their materially false and/or misleading statements.

572. Defendants are also liable for any false or misleading forward-looking statements pleaded herein because, at the time each such statement was made, the speaker knew the statement was false or misleading and the statement was made by or authorized and/or approved by an executive officer of ICON who knew that the statement was false.

## **XI. CLASS ACTION ALLEGATIONS**

573. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a Class consisting of all persons and entities who or which purchased or otherwise acquired the publicly traded ordinary shares of ICON during the Class Period, and were damaged thereby.

574. Excluded from the Class are: (i) Defendants and any affiliates or subsidiaries thereof; (ii) members of the immediate family of any Individual Defendant; (iii) present and former officers, directors, and/or control persons of ICON, and their immediate family members (as defined in Item 404 of SEC Regulation S-K, 17 C.F.R. § 229.404, Instructions (1)(a)(iii) & (1)(b)(ii)); (iv) any firm, trust, corporation, or other entity in which any Defendant has or had a controlling interest; (v) Defendants' liability insurance carriers, and any affiliates or subsidiaries thereof; (vi) ICON's employee retirement and benefit plan(s) and their participants or beneficiaries, to the extent they made purchases through such plan(s); and (vii) the legal



representatives, affiliates, heirs, successors-in interest, or assigns of any person or entity in the preceding six categories, in their capacities as such.

575. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, ICON's ordinary shares were actively traded on the NASDAQ. As of December 31, 2024, there were more than 80 million ICON ordinary shares outstanding, owned by at least thousands of investors. Although the exact number of Class members is unknown to Plaintiffs at this time, Plaintiffs believe that there are at least thousands of members of the proposed Class. Members of the Class can be identified from records maintained by ICON or its transfer agent(s) and may be notified of the pendency of this action by publication using a form of notice similar to that customarily used in securities class actions.

576. Plaintiffs' claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law complained of herein.

577. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

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

- (a) Whether Defendants violated the Exchange Act;
- (b) Whether Defendants omitted and/or misrepresented material facts;

- (c) Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether Defendants knew or recklessly disregarded that their statements and/or omissions were false and/or misleading;
- (e) Whether the price of ICON's ordinary shares was artificially inflated;
- (f) Whether Defendants' conduct caused the members of the Class to sustain damages; and
- (g) The extent of damage sustained by Class members and the appropriate measure of damages.

579. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since the joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

## **XII. CAUSES OF ACTION**

### **COUNT I**

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

580. Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein. This Count is brought against Defendants ICON, Cutler, Brennan, and Balfe pursuant to Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, on behalf of Plaintiffs and all other members of the Class.

581. During the Class Period, Defendants made the false statements specified above, which they knew or recklessly disregarded were false or misleading in that the statements contained material misrepresentations and/or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

582. During the Class Period, Defendants carried out a plan, scheme, and course of conduct that was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and the Class; and (ii) cause Plaintiffs and the Class to purchase or otherwise acquire ICON ordinary shares at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants took the actions set forth herein.

583. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers or acquirers of ICON ordinary shares, each in violation of Section 10(b) of the Exchange Act and Rule 10b-5.

584. Defendants had actual knowledge of the false and misleading statements of material fact as set forth herein, or recklessly disregarded the true facts that were available to them.

585. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they purchased or otherwise acquired ICON ordinary shares at artificially inflated prices. Plaintiffs and the Class would not have purchased or otherwise acquired ICON ordinary shares at such prices, or at all, had they been aware that the market prices for ICON ordinary shares had been artificially inflated by Defendants' fraudulent statements and course of conduct.

586. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the Class suffered damages in connection with their purchases or acquisitions of ICON ordinary shares during the Class Period.

**COUNT II**  
**Violations of Section 20(a) of the Exchange Act**  
**Against Defendants Cutler and Brennan**

587. Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein. This Count is asserted against Defendants Cutler and Brennan pursuant to Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), on behalf of Plaintiffs and all other members of the Class.

588. Defendants Cutler and Brennan acted as controlling persons of ICON within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, and their ownership and contractual rights, participation in, and/or awareness of the Company's operations, and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, these Individual Defendants had the power to influence and control—and did influence and control, directly or indirectly—the decision-making of the Company, including the content and dissemination of the false and/or misleading statements alleged herein. These Individual Defendants were provided with or had unlimited access to copies of the Company's reports and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued or had the ability to prevent the issuance of the statements or cause the statements to be corrected.

589. In particular, each of these Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have

had the power to control or influence the activities giving rise to the securities violations as alleged herein, and exercised the same.

590. As described above, the Company and the Individual Defendants each violated Section 10(b) of the Exchange Act and Rule 10b-5 by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, Defendants Cutler and Brennan are also liable under Section 20(a) of the Exchange Act. As a direct and proximate result of this wrongful conduct, Plaintiffs and other Class members suffered damages in connection with their purchases or acquisitions of the Company's ordinary shares during the Class Period.

### **XIII. PRAYER FOR RELIEF**

591. **WHEREFORE**, Plaintiffs pray for judgment as follows:

- A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;
- B. Awarding damages in favor of Plaintiffs and other Class members against all Defendants, jointly and severally, in an amount to be proven at trial, including interest thereon;
- C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and
- D. Awarding such other further relief as the Court may deem just and proper.

### **XIV. JURY DEMAND**

592. Plaintiffs demand a jury trial.

Dated: September 12, 2025

**KESSLER TOPAZ  
MELTZER & CHECK, LLP**

/s/ Matthew L. Mustokoff  
Matthew L. Mustokoff  
Margaret E. Mazzeo\*  
Richard A. Russo\*

Respectfully submitted,

**BLEICHMAR FONTI & AULD LLP**

/s/ Joseph A. Fonti  
Joseph A. Fonti  
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*Additional Counsel for Plaintiff Police and  
Fire Retirement System of the City of Detroit*

**CERTIFICATION**

I, David Cetlinski, on behalf of Police & Fire Retirement System of the City of Detroit (“PFRSD”), as Executive Director of PFRSD, hereby certify as follows:

1. I am fully authorized to enter into and execute this Certification on behalf of PFRSD.

2. I have reviewed the Amended Complaint against ICON plc (“ICON”) and others alleging violations of the federal securities laws and have authorized its filing.

3. PFRSD did not purchase or sell securities of ICON at the direction of counsel, or in order to participate in any private action under the federal securities laws.

4. PFRSD is willing to serve as a representative party on behalf of the Class in this matter, including providing testimony at deposition and trial, if necessary.

5. PFRSD’s transactions in the ICON securities that are the subject of the Complaint during the class period specified therein of July 27, 2023 through January 13, 2025 are reflected in Schedule A, attached hereto.

6. For securities retained, PFRSD owns and holds legal title to the securities that are the subject of this litigation. For securities sold, PFRSD owned and held legal title to the securities that are the subject of this litigation at all relevant times.

7. PFRSD has sought to serve as a representative party in a class action filed under the federal securities laws during the last three years, in the following:



- *In re ASML Holding N.V. Securities Litigation*, No. 1:24-cv-08664 (S.D.N.Y.)
- *The Police & Fire Retirement System City of Detroit v. Argo Group International Holdings, Inc.*, No. 1:22-cv-08971 (S.D.N.Y.)
- *In Re F45 Training Holdings, Inc. Securities Litigation*, No. 1:22-cv-01291 (W.D. Tex.)

8. Beyond its *pro rata* share of any recovery, PFRSD will not accept payment for serving as a representative party on behalf of the Class, except the reimbursement of such reasonable costs and expenses including lost wages as ordered or approved by the Court.

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct.

Dated: 9-10-25



David Cetlinski  
Executive Director  
*Police & Fire Retirement System of the City of  
Detroit*



**SCHEDULE A**  
**TRANSACTIONS IN**  
**ICON PLC**

<b>Transaction Type</b>	<b>Trade Date</b>	<b>Shares</b>	<b>Price Per Share</b>	<b>Cost/Proceeds</b>
Purchase	09/15/2023	4.00	261.71	(\$1,046.84)
Sale	09/15/2023	-4.00	261.71	\$1,046.84
Purchase	01/18/2024	1,200.00	251.12	(\$301,338.60)
Purchase	03/13/2024	3,141.00	335.16	(\$1,052,731.91)
Sale	03/13/2024	-250.00	336.68	\$84,169.50
Sale	03/22/2024	-100.00	331.49	\$33,148.68
Purchase	04/15/2024	921.00	304.22	(\$280,183.76)
Purchase	04/19/2024	656.00	288.65	(\$189,353.35)
Purchase	04/26/2024	583.00	306.51	(\$178,695.85)
Sale	06/28/2024	-334.00	313.47	\$104,698.98
Sale	06/28/2024	-39.00	313.47	\$12,225.33
Purchase	09/11/2024	293.00	283.51	(\$83,068.34)
Purchase	09/13/2024	348.00	300.75	(\$104,661.00)
Purchase	09/18/2024	500.00	296.81	(\$148,404.30)
Purchase	09/27/2024	673.00	285.50	(\$192,141.70)
Purchase	09/30/2024	100.00	284.89	(\$28,489.21)
Purchase	10/24/2024	1,301.00	237.99	(\$309,624.60)
Sale	11/07/2024	-980.00	218.86	\$214,485.05
Sale	11/21/2024	-649.00	208.34	\$135,211.82
Purchase	12/03/2024	1,448.00	211.66	(\$306,483.68)
Sale	12/24/2024	-200.00	210.39	\$42,077.54
Sale	12/27/2024	-750.00	212.20	\$159,153.08

### CERTIFICATION

The Trustees of the Local 464A United Food & Commercial Workers' Union Welfare Service Benefit Fund and the Trustees of the Welfare and Pension Funds of Local 464A -- Pension Fund (collectively, "Local 464A") declare, as to the claims asserted under the federal securities laws, that:

1. Local 464A did not purchase the securities that are the subject of this action at the direction of counsel or in order to participate in any private action.
2. Local 464A has been serving and will continue to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.
3. Local 464A's Class Period purchase and sale transactions in the *ICON plc* securities that are the subject of this action are reflected in the attached Schedule A.
4. Local 464A has full power and authority to bring suit to recover for its investment losses.
5. Local 464A has reviewed the Amended Complaint for Violations of the Federal Securities Laws and authorizes its filing.
6. Local 464A intends to actively monitor and vigorously pursue this action for the benefit of the class.
7. Local 464A will endeavor to provide fair and adequate representation and work directly with class counsel to ensure that the largest recovery for the class consistent with good faith and meritorious judgment is obtained.
8. Local 464A is currently only serving as a representative party for a class action filed under the federal securities laws during the three years prior to the date of this Certification in this action, *In re ICON plc Securities Litigation*, No. 25-cv-00763 (E.D.N.Y.).
9. Local 464A sought to serve, but was not appointed, as a representative party for a

class action filed under the federal securities laws during the three years prior to the date of this Certification in *Trustees of the Welfare & Pension Funds of Local 464A – Pension Fund, et al. v. Medtronic plc, et al.*, No. 22-cv-02197 (D. Minn.) (filed initial complaint; not appointed as lead plaintiff). Additionally, the Trustees of the Welfare and Pension Funds of Local 464A – Pension Fund have sought to serve, but were not appointed as a representative party for a class action filed under the federal securities laws during the three years prior to the date of this Certification in *Trustees of the Welfare & Pension Funds of Local 464A – Pension Fund v. Enphase Energy, Inc.*, No. 24-cv-09038 (N.D. Cal.) (filed initial complaint; did not move for appointment as lead plaintiff).

10. Local 464A will not accept any payment for serving as a representative party on behalf of the class beyond Local 464A's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the Court.

11. I, Richard Whalen, as Secretary-Treasurer of the Local 464A United Food & Commercial Workers' Union Welfare Service Benefit Fund and the Welfare and Pension Funds of Local 464A – Pension Fund, am authorized to make legal decisions, and execute this certification, on behalf of Local 464A.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 9 day of September 2025.

By: 

Richard Whalen, Secretary-Treasurer of the Local 464A United Food & Commercial Workers' Union Welfare Service Benefit Fund and the Welfare and Pension Funds of Local 464A – Pension Fund

#### SCHEDULE A

**Local 464A United Food & Commercial Workers' Union Welfare Service Benefit Fund**

<u>Security</u>	<u>Buy/Sell</u>	<u>Date</u>	<u>Quantity</u>	<u>Price</u>
Ordinary Shares	Buy	6/10/2024	525	\$318.5255
Ordinary Shares	Buy	6/11/2024	1,156	\$317.1157
Ordinary Shares	Buy	6/12/2024	39	\$321.1700
Ordinary Shares	Buy	6/17/2024	801	\$316.4582
Ordinary Shares	Buy	6/28/2024	652	\$318.7332
Ordinary Shares	Buy	9/16/2024	95	\$294.9963
Ordinary Shares	Buy	9/17/2024	664	\$297.4255
Ordinary Shares	Buy	10/22/2024	113	\$289.1813
Ordinary Shares	Buy	11/15/2024	191	\$189.2200
Ordinary Shares	Sell	11/18/2024	4,236	\$185.9314

**Welfare and Pension Funds of Local 464A – Pension Fund**

<u>Security</u>	<u>Buy/Sell</u>	<u>Date</u>	<u>Quantity</u>	<u>Price</u>
Ordinary Shares	Buy	6/10/2024	860	\$318.5255
Ordinary Shares	Buy	6/11/2024	1,894	\$317.1157
Ordinary Shares	Buy	6/12/2024	63	\$321.1700
Ordinary Shares	Buy	6/17/2024	1,311	\$316.4582
Ordinary Shares	Buy	6/28/2024	1,068	\$318.7332
Ordinary Shares	Buy	9/16/2024	156	\$294.9963
Ordinary Shares	Buy	9/17/2024	1,087	\$297.4255
Ordinary Shares	Buy	10/22/2024	190	\$286.0097
Ordinary Shares	Sell	11/18/2024	6,629	\$185.9314