

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

PLAINTIFF, Individually and on Behalf  
of All Others Similarly Situated,

Plaintiff,

v.

ICON PLC, STEPHEN CUTLER, and  
BRENDAN BRENNAN,

Defendants.

Case No.

CLASS ACTION

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

**JURY TRIAL DEMANDED**

Plaintiff, by and through its counsel, alleges the following upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Plaintiff's information and belief are based on, among other things, the independent investigation of counsel. This investigation includes, but is not limited to, a review and analysis of: (i) public filings by ICON plc ("ICON" or the "Company") with the Securities and Exchange Commission ("SEC"); (ii) transcripts of ICON conferences with investors and analysts; (iii) press releases and media reports issued and disseminated by the Company; (iv) analyst reports concerning ICON; and (v) other public information and data regarding the Company.

**NATURE OF THE ACTION AND OVERVIEW**

1. This is a class action on behalf of all persons and entities who purchased or acquired ICON ordinary shares between July 27, 2023 and January 13, 2025 (the "Class Period"). Plaintiff asserts claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and Rule 10b-5 promulgated thereunder, against: (i) ICON; (ii) the Company's

Chief Executive Officer (“CEO”) Stephen Cutler (“Cutler”); and (iii) the Company’s former Chief Financial Officer (“CFO”) Brendan Brennan (“Brennan”).

2. ICON conducts clinical trials for companies developing new drugs and medical devices.

3. This case concerns Defendants’ misrepresentations that ICON was benefitting from a significant industry-wide downturn during which the Company’s current and prospective customers scaled back their outsourcing of clinical trial work to cut costs. Specifically, throughout the Class Period, Defendants assured investors that ICON was “well positioned” to win business during the downturn due to the “depth and breadth of our capabilities,” that the Company’s “competitive position has never been better in being able to address our customer needs,” that “we’re taking market share” due to “our strong operational delivery,” and that ICON was seeing “healthy,” “stable,” and “strong” demand, while touting a purportedly high volume of RFPs for clinical trial work from prospective customers as a sign that demand was strong.

4. Defendants also specifically asserted that ICON’s largest customer Pfizer’s efforts to cut \$4 billion in annual costs presented an “opportunity” for ICON as Pfizer was “happy to further consolidate their spending” with the Company.

5. The truth was far different. Rather than benefiting from the industry downturn, ICON experienced a significant decline in demand. Additionally, its two largest customers, including Pfizer, warned ICON for years that they intended to diversify their business away from the Company. Moreover, the “RFP flow” that Defendants touted as a sign of strong demand did not indicate anything of the sort. Instead, ICON executives knew that a significant portion of those RFPs only sought to gauge prevailing industry prices for clinical trial services and were never intended to lead to actual clinical trial work.

6. The truth began to emerge on October 23, 2024, when ICON announced its 3Q24 financial results. On that day, the Company revealed a surprise “revenue shortfall” of \$100 million for the quarter and reduced full-year fiscal 2024 revenue guidance by \$220 million at the midpoint, despite reiterating 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,” that “we expect . . . to continue into quarter four.”

7. On October 25, 2024, Truist Securities (“Truist”) published a report summarizing a conversation Truist analysts had with ICON management which included new details about the reasons for the poor 3Q 24 financial results and reduced guidance. According to Truist, Defendants knew that its two largest customers intended to diversify business away from ICON and that contracted clinical work from the two customers was scheduled to end in the summer of 2024. ICON management described the situation to Truist as “not a new development,” and said that it “did not come as a surprise” that the customers moved business to ICON’s competitors.

8. Truist further revealed that after ICON merged with a large competitor named PRA Health Sciences, Inc. (“PRA”) in 2021, customers that previously had business with both companies were left with an unwanted overconcentration of business with ICON. According to Truist, the overconcentration “was flagged internally at the pharma customers” at the time of the merger 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.”

9. On these disclosures, the price of ICON ordinary shares declined \$60.29 per share, or more than 21%, from \$280.76 per share on October 23, 2024, to \$220.47 per share on October 25, 2024.

10. Next, on November 21, 2024, during an investor conference call, Defendant Cutler admitted that ICON knew that “20% to 30%” of the RFPs ICON responded to only sought to gauge prevailing industry prices for clinical trial services and were never intended to lead to actual clinical trial work.

11. 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.” Defendants also revealed that 2025 will be a “transition period” for ICON, indicating that the Company would not return to normal growth for some time.

12. The news of the disappointing guidance and expected “transition period” due to industry headwinds caused the price of ICON ordinary shares to decline \$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.

#### **JURISDICTION AND VENUE**

13. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. §78aa).

15. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b) because Defendants conducted substantial economic activity in the District, including through ICON subsidiary ICON Central Laboratories, which has its headquarters in Farmingdale, New York.

16. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

### **PARTIES**

17. Plaintiff purchased ICON ordinary shares during the Class Period, as detailed in the Certification attached hereto and incorporated herein, and has been damaged thereby.

18. Defendant ICON is a clinical research organization incorporated in Ireland. The Company's headquarters are located in Dublin, Ireland. ICON's ordinary shares trade on the NASDAQ under the ticker symbol "ICLR."

19. Defendant Cutler is, and was at all relevant times, ICON's CEO.

20. Defendant Brennan served as ICON's CFO during the Class Period until October 2024.

21. Defendants Cutler and Brennan are collectively referred to herein as the "Individual Defendants." The Individual Defendants, because of their positions with ICON, 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.

22. The Individual Defendants 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 and omissions specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations and omissions which were being made were then materially false and/or misleading.

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

23. ICON is a clinical research organization (“CRO”) that provides development and commercialization services, including conducting clinical trials, to companies developing new drugs and medical devices.

24. In 2021, ICON acquired rival CRO PRA for approximately \$12 billion. Upon the merger with PRA, ICON became the second largest CRO in the world.

25. The Company serves two main customer segments: (1) large pharmaceutical companies; and (2) biotechnology companies. ICON earns the majority of its revenue from its largest pharmaceutical customers.

26. ICON provides its clinical trial services across several operating models, including most prominently Full-Service Outsourcing (“FSO”) and Functional Service Provision (“FSP”). Under FSO arrangements, the Company conducts all aspects of a clinical trial, from site selection to post-approval monitoring. Under FSP arrangements, ICON’s customers outsource certain aspects of a clinical trial, such as site monitoring or data management, which allows customers to retain greater control over their costs.

27. ICON’s financial performance and growth prospects depend on a steady flow of new business. The Company secures new business contracts largely based on its response to requests for proposals (“RFPs”) that ICON receives from existing and prospective customers.

28. Before and during the Class Period, many of ICON's current and prospective customers sought to reduce their R&D expenditure due to an industry-wide tightening of available capital and a higher-interest rate environment. Many of ICON's large pharmaceutical customers implemented significant cost reduction programs designed to cut billions of dollars in annual R&D costs. For example, Pfizer announced a "cost realignment program" in 2024 to cut \$4 billion in annual costs, with 70% of the total proposed reduction targeted at its R&D costs.

29. One way that large pharmaceutical companies sought to cut costs was by moving away from costly FSO arrangements in favor of so-called "hybrid" models that incorporated elements of both FSO and FSP solutions.

30. ICON's smaller customers, which are largely dependent on funding from outside investors like private equity firms, were also mired in an unfavorable funding environment, which limited their ability to engage CROs like ICON for clinical trial work.

#### **Materially False and Misleading Statements Issued During the Class Period**

31. The Class Period begins on July 27, 2023. 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 2Q 23 financial results. For 2Q 23, ICON generated \$2.02 billion in quarterly revenue, representing a 4.4% increase year-over-year. ICON further stated that the Company's adjusted EBITDA grew 16.9% year-over-year to \$414 million. ICON also stated in the press release that its gross business wins during the quarter were \$2.86 billion while cancellations were \$441 million, resulting in net new business awards of \$2.42 billion and a book-to-bill ratio of 1.2. Also in the press release, ICON quoted Defendant Cutler as stating the Company was "encouraged by the positive customer demand trends across our business."

32. The next day, July 27, 2023, ICON held a conference call with investment analysts to discuss the Company's 2Q 23 financial results. During the call, Barclays Bank PLC analyst Luke England Sergott asked, "as you guys are thinking about the industry growth as it is now and talking about seeing green shoots and funding, . . . what are the conversations you're hearing from your larger customers on the large pharma side[?]" In response, Defendant Cutler asserted that ICON works with its large customers to help them spend "effectively and efficiently" so when the large customers reduce their spending, it presents "an opportunity" for ICON. Specifically, he stated:

The conversations we have are really around how they're spending their money effectively and efficiently and how we can help them get their drugs to market. So . . . even when R&D budgets are going up or they're spending more, we clearly have an opportunity. But even when they're not and even going down or staying flat, we have an opportunity. In fact, sometimes it's more of an opportunity for organizations like ours when budgets are flat because they – the pharma companies look at how they're spending and try to optimize their spend.

33. Defendant Cutler also touted RFP flow and insisted ICON was seeing "broad-based" business opportunities. Specifically, he stated:

The opportunities that we're seeing in the business are not just in the biotech, they're really fairly broad-based across the business. . . . I think we reported last quarter an increase in RFP 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.

34. Also during the call, Deutsche Bank analyst Justin Bowers asked, "on the improving demand environment, is that across all customer segments[?]" In response Cutler stated, "Yes . . . the RFP opportunities are really across the segments of the business. I mean our large pharma group, in our biotech group and in the more lab services, preclinical early phase as well. So it's, from that point of view, a consistent function as well. So I'm pleased with the way that that's, as I say, broad-based."

35. On October 25, 2023, ICON filed a press release on Form 6-K with the SEC reporting the Company's 3Q 23 financial results. For 3Q 23, ICON reported that quarterly revenue grew 5.8% year-over-year to \$2.06 billion. The press release further stated that ICON's adjusted EBITDA in the quarter grew 13.9% year-over-year to \$433 million. The press release also stated that ICON's gross business wins during the quarter were \$3.06 billion and that cancellations were \$474 million, resulting in net new business wins of \$2.58 billion and a book-to-bill ratio of 1.26.

In the press release, ICON quoted Defendant Cutler as stating:

Our net book to bill improved to 1.26x in the quarter, reflective of the healthy demand for our market-leading offering across the customer segments we serve. We remain well positioned as a critical partner with new and existing customers to play a long-term role in accelerating their development portfolios.

36. The next day, October 26, 2023, ICON held a conference call with investment analysts to discuss the Company's 3Q 23 financial results. During the call, Defendant Cutler touted the "scale" and "breadth" of ICON's services and represented that its competitive position had "never been better." Specifically, he stated:

Given the scale of the company and the range of our customer base, we are well diversified and embedded from a customer and service segment perspective, ensuring that the impact of any market changes can be managed effectively. To that end, we are seeing a significant level of demand with customers seeking novel solutions to customize a development model that is built on flexibility and efficient delivery of services. As we've noted before, this often takes the shape of a blended model of development, incorporating elements of full service and functional solutions. Our competitive position has never been better in being able to address our customer needs in this regard. The experience, depth and breadth of our capabilities across full service and functional solutions is unmatched in the industry.

37. Defendant Cutler also asserted that ICON continued to see "healthy" demand and touted "RFP activity." Specifically, he stated:

The industry demand environment in clinical development remains healthy with a solid level of opportunities present across all customer segments. Overall, RFP activity continued to improve in quarter 3 with growth in the high single digits on a trailing 12-month basis. . . . We are encouraged by the positive trends we are

seeing across our business that have continued into the beginning of quarter 4, and we remain cautiously optimistic that this trend will continue as we close out this year.

38. Also during the call, Evercore ISI analyst Elizabeth Hammel Anderson asked about the demand environment. In relevant part, she asked:

I think obviously investors have been a bit nervous because of sort of what's happening on tools and maybe on the early development side, which I understand, obviously, you don't play in. But how do we think about like from your conversations with pharma [companies], like where are they prioritizing the spending, and I guess I'm just sort of like a back way of trying to figure out like how are you guys continuing to sort of outperform what we've seen in the sort of worst results on some of the earlier stuff.

39. In response, Defendant Cutler assured investors that the Company experienced a "very solid" and "broad-based positive" demand environment:

We've seen a very solid environment, RFP-wise worldwide, right across the segments, be it large pharma, the biotech, and more in the sort of ancillary services that we do. . . . So, it's been fairly broad-based. I would say, I think we've called it out before, there's been a little bit of a move towards FSP and hybrid solutions in the large pharma market. That's, that's been certainly a feature. And we feel well placed to be able to accommodate that and to put in place solutions that are more hybrid, I suppose, in terms of adding technology and adding opportunity to push on with margins in that space.

But overall, again, [I'd] say, a broad-based positive environment, biotech funding, of course, remains something of an overhang, but even that seems to be, to us, stabilizing. And I think the last month or 2, there's some green shoots there. So again, we're finding good signs getting funded.

40. Later during the call, JP Morgan Chase & Co analyst Casey Rene Woodring asked about the RFP growth ICON was purportedly seeing and about the demand environment from small and mid-sized ("SMID") companies. In response, Defendant Cutler discussed the "uptick" and "broad-based" opportunities from RFPs:

[W]e've talked about RFP growth being greater in the last 2 quarters. So Q3 and Q2. I think that's what we've talked about some nice uptick on the RFP. . . . In terms of the opportunity across the sort of large or SMID, I mean it's been -- I keep saying it's been pretty broad-based. SMID biotech, large pharma, again, in the last 2 quarters in that sort of high single-digit range, and those opportunities have been

solid. And we've seen decisions being made within a reasonable time frame, et cetera, so. So it is what it is. The market seems pretty constructive to us across the different segments.

41. Woodring then asked about "cost-cutting" measures from customers:

Given where we are in the year, how have those conversations trended in terms of large customer cost cuts . . . it doesn't sound like those cost cuts will necessarily hit R&D spending at the moment. But just is there any indication that if macro doesn't improve here soon that R&D spend could be the next kind of cost-cutting measure from those customers? Or are those kind of more insulated?

42. In response, Defendant Cutler stated that cost-cutting is "not always bad news" because customers "consolidat[e] some of their spend" and "we come out of it fairly positively":

Our experience with specific customers is similar, one or two, of course, as you well know, we've got some specific challenges in the very short term. But we're their partners. As I said, we believe we can provide some solutions for them. And we can help them to reduce some of their costs, but also not necessarily reduce our revenues because they can help us by consolidating some of their spend.

So, as I say, when these sort of things come out, it's not always bad news. In fact, it's often we come out of it fairly positively. So I'm optimistic that as we go into the budgeting season that we'll be able to maintain or even improve our share of wallet within some of our larger customers and be an even better partner to them in terms of helping them to be more efficient, irrespective of the model that they're prosecuting or the spend that they have to provide.

43. Deutsche Bank analyst Justin Bowers also asked about the demand environment compared to a year earlier, specifically, "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? Just trying to get a sense of how the environments evolved." In response, Defendant Cutler pointed to ICON's "positive RFP numbers" as an indicator of a "constructive solid positive environment":

[W]e've seen pretty constructive positive RFP numbers for -- certainly for the last 2 quarters over all the segments across biotech, large pharma, . . . et cetera, and obviously, FSP as well. . . . So overall, we see a very constructive, a very positive sort of business environment. Obviously, there are some challenges out there in the macroeconomic environment. We're very aware of that. But I think we talked about cautiously optimistic as being our sort of watch words for this present time.

And there's nothing that we've seen, certainly from an RFP point of view or from an awards point of view that would, that would change that. It's a constructive solid positive environment. We feel we're well placed to benefit from it.

44. Finally, on the call, William Blair & Company analyst Christine Rains asked about the "impact [of] Pfizer's recently announced cost cuts . . . was this baked into your outlook? Or were they unexpected?" In response, Defendant Cutler stated that the cuts were "expected," and they presented an "opportunity" for ICON because Pfizer was "happy to further consolidate their spending" with ICON:

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.

45. Then, on November 14, 2023, Defendant Brennan participated in an investor conference call hosted by Jefferies analyst David Howard Windley. During the call, Windley said, "just want to start at the demand environment . . . and talk about the RFP flow acceleration that both you and Steve Cutler have talked about . . . So open with that, please." In response, Defendant Brennan asserted that demand was "solid," and that ICON was seeing a sustained "uptick" in RFPs:

[I]t'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.

46. Two weeks later, Defendant Brennan participated in an investor conference call hosted by Evercore ISI analyst Elizabeth Hammell Anderson. During the call, Anderson asked,

“any sort of changes in RFP flow as we’re thinking about 4Q?” In response, Brennan stated: “No, at this stage, it remains solid. And we talked about [it] 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 . . . 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. So that’s good.”

47. On January 9, 2024, ICON filed a press release on Form 6-K with the SEC announcing its financial guidance for 2024. The press release stated that ICON was on track to achieve revenue in 2024 in a range of \$8.4 billion to \$8.8 billion, or 3.2% to 8.1% growth over the Company’s 2023 revenue. ICON also represented that it was on track to achieve adjusted EPS in the range of \$14.50 per share to \$15.30 per share, representing growth of 13.5% to nearly 20% over ICON’s 2023 adjusted EPS. The press release also quoted Defendant Cutler as stating: “Our outlook for 2024 indicates a positive demand environment across our segments, notwithstanding continuing macroeconomic pressures faced by our customers[.]”

48. The following day, January 10, 2024, Defendant Cutler participated in an investor conference call hosted by JP Morgan Chase & Co analyst Casey Rene Woodring. During the call, Defendant Cutler discussed the industry downturn. He stated:

[I]t’s a relatively challenging environment. You’re all aware there are 1 or 2 of the large pharma customers who are looking to reduce costs, and that’s playing through a little bit with us. But on the other hand, there are some opportunities for us. As they recognize they need to spend more effectively and more efficiently, they consolidate spend. And we’re in a position, as a scale player in the industry, to benefit from that consolidation. We can do it all. We have the ability -- it’s not as though there’s only some things we can do. There are things -- there’s nothing really we can’t take on, . . . and that helps us to provide them with more aggressive, I suppose, pricing and it helps them to save some money, but also helps us to improve our revenues.

49. Next, on February 21, 2024, ICON filed a press release on Form 6-K with the SEC reporting the Company’s 4Q and full year 2023 financial results. For 4Q 23, ICON reported that

its revenue grew 5.3% year-over-year to \$2.07 billion. ICON further reported that its adjusted EBITDA in the quarter grew 10.7% year-over-year to \$448 million. The press release also stated that ICON's gross business wins in the quarter were \$2.99 billion and that cancellations were \$461 million, resulting in net new business wins of \$2.53 billion and a book-to-bill ratio of 1.22. The press release quoted Defendant Cutler as stating: "We remain encouraged by the positive demand environment as we enter this year, and as such, reaffirm our previously issued financial guidance for the full year 2024[.]"

50. The next day, February 22, 2024, ICON held a conference call with investment analysts to discuss the financial results. During the call, Nephron Research analyst Jack Meehan asked, "how should we think about the durability of growth here?" Defendant Cutler responded that business with most of its top customers was growing and that customers cutting costs were consolidating their spending with ICON:

We feel we're in a good place with our top 10, top 20 customers. They're all apart from 1 or 2 [] they're growing. And the ones that aren't growing, it's more a mix shift change rather than anything else. And even so we're seeing more of the business that they're wanting to go into, albeit it's at a different revenue flow.

So overall, we feel good. I've said it a number of times. We've made progress on the strategic front with a couple of customers and even others in the large pharma space, where we haven't necessarily become a strategic partner with them. We're talking to them about some significant opportunities. Some of them are having some challenges, as we all know. And that has led to probably more strategic discussions around what we can do and how we can help them to get through some of the short or medium-term pain that they have to endure.

So I know we often think about when customers are having a hard time sort of financially that they necessarily cut costs or cut spending[,] they can spend in different ways in my experience. And sometimes that can be a significant benefit for us in terms of what they do versus when they're running and growing and their revenues are going up as well. So hard times produce opportunity for us. And that's certainly proving the case in 1 or 2 areas on the significant large pharma space.

51. Also on the call, Evercore ISI analyst Elizabeth Hammell Anderson asked, “one thing people continue to be worried about is like the overall sort of pharma spending environment . . . 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 you help give people a little bit more confidence in the trajectory there?” In response, Defendant Cutler said ICON saw “more opportunity” as its customers were allocating more of their R&D spending to ICON:

[A]s their budgets become perhaps a little bit more constrained or they watch where they’re spending their dollars, they do appear to becoming more open to outsourcing and outsourcing even more than they’re doing at the moment. So as I said, I can’t add much in terms of where the budgets are and whether it’s an increase or decrease. We see and we read the same data you do in terms of modest increases in R&D spending over the medium to long term. But it’s how that money is allocated is really what’s important for us. And if anything, I think we’re seeing more opportunity in terms of the dollars that are outsourced and the opportunity to penetrate further that market.

52. Roughly two weeks later, on March 5, 2024, Defendant Brennan participated in an investor conference call hosted by TD Cowen analyst Charles Rhyee. During the call, Rhyee asked Brennan to “reconcile” a purported “uptick in sort of activity, good RFP flow . . . for the start of ‘24 here and continued strength in the large pharma segment” with “the news of pharma kind of retrenching cost-cutting and concerns with the large customers.” In response, Brennan asserted that large pharmaceutical companies would increase their spending in 2024 after “getting their structure[s] right” in 2023:

[P]harma really took 2023 to get their ducks in a row. And I think what we feel now in 2024 is a bit more traction. 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 a nadir point and they want to continue to increase R&D spend as they go forward. So I do think we see

good traction there. And I think it was really about them getting their structure right, with an idea to be able to really jump off and have a better '24.

53. On April 24, 2024, ICON filed a press release on Form 6-K with the SEC reporting its 1Q 24 financial results. The press release stated that ICON's quarterly revenue grew 5.7% year-over-year to \$2.09 billion. The press release also stated that the Company's adjusted EBITDA grew 11.3% year-over-year to \$444 million. The press release further stated that ICON's gross business wins for the quarter were \$3.11 billion and that cancellations were \$460 million, resulting in net new business wins of \$2.65 billion and a book-to-bill ratio of 1.27. The press release also quoted Defendant Cutler as stating: "Our performance is reflective of the current favorable demand trends across our industry, as well as the further development of strategic customer partnerships."

54. The next day, ICON held an earnings conference call with investment analysts to discuss the Company's 1Q 24 financial results. During the call, Defendant Cutler asserted that demand was "incrementally more positive" and touted an increase in RFP volume to support his assertion:

Underlying demand drivers are incrementally more positive through quarter 1, with biotech funding increasing over 50% on a year-over-year basis in quarter 1, . . . and large pharma R&D spend figures indicating low single-digit growth for the full year, in line with previous expectations. Proposal volumes are at healthy levels, with overall RFP volume increasing low double digits on a trailing 12-month basis.

55. Defendant Cutler further touted ICON's RFP flow during the call. He stated:

[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. We're seeing some -- plenty of good opportunities in the biotech space. We've been successful. Our win rate in that biotech space has gone up over the last quarter or so. So we feel good about the solutions and the propositions we're putting in front of customers and their receptivity to those. But as I say, overall,

the very solid, very constructive environment on the RFP front and we feel good about where the market is heading overall.

56. Also during the call, BofA Securities analyst Michael Leonidovich Ryskin asked about “news this morning of Bristol [Myers] announcing job cuts, 2,200 layoffs . . . So just curious how those conversations have evolved year-to-date and sort of [what is the] upside/downside risk for the rest of the year?” In response, Defendant Cutler discussed the “strong demand” ICON experienced:

[W]e’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. And as I think I talked about sort of 3% to 4%, but we believe we’re taking market share in that space. And a good part of our growth is due to our strong operational delivery in that space.

57. On May 30, 2024, ICON hosted its 2024 Investor Day conference call. During the call, Citi analyst Patrick Donnelly asked about “market growth rate.” Specifically, he asked: “It seems like your confidence has been building this year. . . . Today, to have the confidence that you have, is it just based on what you’re seeing on the RFP flow, the bookings still? Are you still feeling good about that 1.25-plus [book-to-bill] trend here in the near term?” In response, Defendant Cutler said ICON’s confidence was based on strong RFP flow and improved biotech funding:

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. We came out of last year with a little caution given where the biotech funding was. But as we’ve seen the first quarter come through and that being constructive – very positive, constructive environment, certainly, it looks like things are moving in the right direction. That’s given us additional confidence as well.

58. ICON reported its 2Q 24 financial results in a press release that the Company filed on Form 6-K with the SEC on July 24, 2024. For 2Q 24, ICON reported that quarterly revenue grew 4.9% year-over-year to \$2.12 billion. The press release further stated that ICON's adjusted EBITDA for the quarter increased 8.7% year-over-year to \$450 million. ICON also reported that its gross business wins in the quarter were \$3.07 billion and that cancellations were \$493 million, resulting in net new business wins of \$2.58 billion and a book-to-bill ratio of 1.22. The press release also quoted Defendant Cutler as stating: "We are updating our full-year financial revenue guidance range for 2024 to account for the impact of the strengthening US dollar, as well as delayed trial starts related to next-generation COVID vaccine work. We now expect full year revenue to be in the range of \$8,450 - \$8,550 million[.]" The new guidance was a narrowing of the guidance the Company provided in January 2024, when it represented that it was on track to achieve revenue in 2024 in a range of \$8.4 billion to \$8.8 billion.

59. The next day, July 25, 2024, ICON held an earnings conference call with investment analysts to discuss the 2Q 24 financial results. During the call, Defendant Cutler once again touted ICON's "RFP flow" and represented that demand was "increasing." Specifically, he stated:

[O]ur leading scaled offering continues to resonate with our customers, uniquely positioning ICON to meet increasing demand for innovative and flexible solutions in clinical development. 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. Importantly, customer sentiment appears to be improving, and we remain optimistic around the contribution to midterm growth, this important customer segment represents.

60. Defendant Cutler further explained that ICON was seeing fewer RFP cancellations which demonstrated that demand in ICON's biotechnology business had improved:

I think year to date, we see a very positive constructive progress in that biotech funding area. In terms of the activity, we're still seeing opportunities, something like 50% to 60% of the opportunities that we have in the pending pipeline. I'm talking about significantly to the top 25 are in the biotech space. And these are very substantial opportunities. So we feel there's plenty of opportunity and the [sic] plenty of projects coming through. 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. And as I said, of the top 25 opportunities, about half of them are in the biotech segment. So it really shows that the biotech are coming through. They're serious about offering us opportunities, and they are substantial opportunities.

61. Also during the call, Deutsche Bank analyst Justin Bowers asked, “[i]n terms of what you're seeing with large pharma, what inning are we in in terms of some of the announcements that we've seen, let's say, over the last six months[?].” In response, Defendant Cutler asserted that ICON was “optimistic about large pharma growth” based on “what we see in our RFP numbers” and that the Company benefits from large customers cutting costs and consolidating their spending. Specifically, he stated:

I suspect we're into the middle [innings]. I'm thinking four, fifth, even sixth. I think we've seen a number of companies make fairly public announcement[s]. Certainly, some of our top customers have been in that cohort. And so, I think -- but I think we're seeing that starting to get through. And we're pretty optimistic about large pharma growth in terms of R&D spend. And in terms of outsourcing growth going forward, that's what we see in our RFP numbers. Certainly, on the trailing 12-month basis from large pharma, we're in the low-double-digits, even pushing up a little bit higher than that. And so, we're pretty optimistic around where large pharma is going. Sometimes, as I think I've said before on these calls, the cost cuts and the budgets, while they do have an immediate impact, long-term they think more about how they spend their money. And we can benefit from that.

62. On September 10, 2024, Defendant Cutler participated in an investor conference call hosted by Robert W. Baird & Co. analyst Eric Codwell. During the call, Cutler said ICON

was “reiterating guidance” for 2024, adding “[w]e feel good about the guidance for this year, and there’s no change to that.”

63. Also on the call, Cutler again discussed the RFP flow and demand, and downplayed the impact of large customers cutting costs. Specifically, he stated:

[T]he 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. And that’s, of course, having some impact on our business. That’s a headwind for us in the very short term. We feel we have a bit more visibility about that now, about the amount and about the timing of it. And we feel that will play out really over the next couple of quarters. And as we get into next year, we’ll feel that that will become much more neutral. And so we wanted to be honest and transparent about that.

64. The above statements identified in ¶¶31-63 were materially false and/or misleading. In truth, rather than benefiting from the industry downturn, ICON was experiencing a significant decline in demand. Further, its largest customers, including Pfizer, had warned the Company for years that they intended to diversify business away from ICON. Moreover, the “RFP flow” Defendants touted as a sign of strong demand did not indicate anything of the sort. Indeed, ICON executives knew that a significant portion of those RFPs only sought to gauge prevailing industry prices for clinical trial services and were not intended to lead to actual clinical trial work.

### **The Truth Begins To Be Revealed**

65. On October 23, 2024, ICON reported 3Q 24 financial results in a press release that it filed on Form 6-K with the SEC. In the press release, ICON revealed a surprise “revenue shortfall” of \$100 million for 3Q 24 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, a \$220 million cut at the midpoint.

66. ICON quoted Defendant Cutler as attributing the shortfall to “budget cuts” and “cautiousness from biotech customers”:

ICON’s results for the third quarter did not meet the expectations we had previously provided due to specific customer and division-level impacts. Our revenue shortfall was attributable to more material headwinds from two large customers undergoing budget cuts and changes in their development model . . . and ongoing cautiousness from biotech customers resulting in award and study delays.

67. 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.

68. However, ICON still concealed the full extent of the impact of the industry downturn on the Company. For instance, Defendant Cutler indicated in the press release that the headwinds would be short lived, stating, “[w]e expect these impacts to continue into quarter four,” while insisting the “fundamentals of our business remain strong” and touting “further success in the quarter with a new top 10 pharma strategic partnership win, which has already started contributing to our pipeline of awards.”

69. During ICON’s earnings conference call the following day, October 24, 2024, Defendant Cutler again discussed the drivers of the poor financial results and reduced guidance. First, he noted that ICON experienced, “lower than anticipated revenue contribution from two of our largest customers, that are undergoing development model transitions, which we have been supporting them with -- since the start of the year.” He further revealed that, “[h]eightened focus on portfolio prioritizations, leading to tighter development spending mode through the quarter 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.”

70. Second, Cutler revealed that “slower than expected activity in our biotech segment . . . impacted our total level of new awards as well as in operation prioritization decisions, which resulted in negative study modifications and delays in study startup that occurred in the quarter.”

71. Also during the call, Nephron Research analyst Jack Meehan asked, “do you think any of this relates to customers assessing their concentration of work with ICON” after the PRA merger in 2021. Meehan further suggested that “maybe ICON is seeing some disproportionate pressure because [] the concentration went up with PRA, even though you are a few years in[to] the deal.” In response, Cutler admitted, “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.” However, ICON did not disclose that the “one or two” customers were its two largest and did not correct the false statements addressing the transient nature of the downturn as communicated in the October 23 press release discussed above.

72. Then, on October 25, 2024, Truist published a report that summarized a discussion Truist analysts had with ICON’s management about the 3Q 24 financial results that revealed new details about what caused the poor results and reduced guidance. According to Truist, ICON knew for some time that two large customers were planning to diversify their business away from the Company. Specifically, ICON’s management described the situation as “not a new development” and explained that it “is actually a result of [ICON] merging with PRA.” Management further explained to Truist that “ICON became a significant provider” for the two customers after ICON

acquired PRA. The consolidation of providers caused by the merger “was flagged internally at the pharma customers” and it was known within ICON that these customers wanted to “balance potential risk in how much work is being sent to one particular provider. Thus, additional competitors coming in [and taking work from the Company] did not come as a surprise to ICON.” Truist also revealed that ICON “knew it had some studies finishing off over the course of the summer in its long-term contract base[.]”

73. On the news from October 23, 2024 to October 25, 2024, the price of ICON ordinary shares declined \$60.29 per share, or more than 21%, from \$280.76 per share on October 23, 2024, to \$220.47 per share on October 25, 2024.

74. Roughly one month later, during a November 21, 2024 investor conference call hosted by Jefferies analyst David Windley, Defendant Cutler admitted that a material portion of the RFPs ICON received and responded to were only issued so that those companies could assess prevailing market prices for clinical trial services and would never reach contract. Specifically, Windley said, “we talk about RFP flows, delays in decision making, et cetera” and “[w]e obviously care a lot about top line and what [the RFP flow] signals for top line” but, “we hear that [it] is a problem that there’s more RFPs floating around out there, one that biotechs are fishing for more price and so they’re issuing to more CROs to try to get a better price. And then in some cases, the award just never goes to decision.” Windley then asked, “[h]ow big of an issue is that right now?” In response, Defendant Cutler admitted “that is an issue . . . [W]e’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.”

75. Finally, on January 14, 2025, ICON issued financial guidance for 2025 in a press release that the Company 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."

76. Also on January 14, 2025, ICON participated in an industry conference call hosted by JP 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. So think of '25, as I say, as a transition period moving into the longer term, medium term, '26, '27, where we do believe normal growth will be resumed."

77. The news of the disappointing guidance and expected "transition period" due to industry headwinds caused the price of ICON ordinary shares to decline \$17.75 per share, or more than 8%, from \$217.99 per share on January 13, 2025, to \$200.24 per share on January 14, 2025.

### **LOSS CAUSATION**

78. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and omissions, and engaged in a scheme to deceive the market. This artificially inflated the price of ICON ordinary shares and operated as a fraud or deceit on the Class. Later, when Defendants' prior misrepresentations and fraudulent conduct were disclosed to the market on October 23, 2024, October 24, 2024, October 25, 2024, and January 14, 2025 as

alleged herein, the price of ICON ordinary shares fell precipitously, as the prior artificial inflation came out of the price. As a result of their purchases of ICON ordinary shares during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

### **SCIENTER ALLEGATIONS**

79. As alleged herein, Defendants acted with scienter because Defendants knew that the public statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements as primary violations of the federal securities laws. As set forth elsewhere herein, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding ICON, their control over allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning ICON, participated in the fraudulent scheme alleged herein.

### **CLASS ACTION ALLEGATIONS**

80. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired ICON ordinary shares during the Class Period and were damaged thereby (the “Class”). Excluded from the Class are Defendants and their families, directors, and officers of ICON and their families and affiliates.

81. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. As of December 31, 2024, there were more than 82 million ICON ordinary shares outstanding, owned by at least thousands of investors.

82. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- A. Whether Defendants violated the Exchange Act;
- B. Whether Defendants omitted and/or misrepresented material facts;
- C. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- D. Whether Defendants knew or recklessly disregarded that their statements and/or omissions were false and 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.

83. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct.

84. Plaintiff will adequately protect the interests of the Class and has retained counsel experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

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

## **INAPPLICABILITY OF STATUTORY SAFE HARBOR**

86. ICON's "Safe Harbor" warnings accompanying its forward-looking statements issued during the Class Period were ineffective and inapplicable and cannot shield the statements at issue from liability. The statements alleged to be false and misleading above relate to then-existing facts and conditions.

87. 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.

88. 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.

## **PRESUMPTION OF RELIANCE**

89. 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 which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

90. 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 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.

91. 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.

## **COUNT I**

### **For Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants**

92. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

93. During the Class Period, Defendants carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase ICON ordinary shares at artificially inflated prices.

94. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state 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 of the Company's ordinary shares in an effort to maintain artificially high market prices for ICON ordinary shares in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

95. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about ICON's business, as specified herein.

96. During the Class Period, Defendants made the false statements specified above which they knew or recklessly disregarded to be false or misleading in that they contained misrepresentations and 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.

97. Defendants had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or recklessly disregarded the true facts that were available to them. Defendants engaged in this misconduct to conceal the truth about the demand for the Company's services and the loss of business from its two largest customers, as specified herein, from the investing public and to support the artificially inflated prices of ICON's ordinary shares.

98. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for ICON's ordinary shares. Plaintiff and the Class would not have purchased the Company's ordinary shares at the prices they paid, or at all, had they

been aware that the market prices had been artificially inflated by Defendants' fraudulent course of conduct.

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

100. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

## **COUNT II**

### **For Violation of Section 20(a) of the Exchange Act Against The Individual Defendants**

101. Plaintiff repeats, incorporates, and re-alleges each and every allegation set forth above as if fully set forth herein.

102. The Individual Defendants acted as controlling persons of ICON within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, participation in and/or awareness of the Company's operations, direct involvement in the day-to-day operations of the Company, and/or intimate knowledge of the Company's actual performance, and their power to control public statements about ICON, the Individual Defendants had the power and ability to control the actions of ICON and its employees. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

## **PRAYER FOR RELIEF**

103. **WHEREFORE**, Plaintiff prays 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 compensatory damages in favor of Plaintiff and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and
- D. Awarding such equitable/injunctive or other further relief as the Court may deem just and proper.

**JURY DEMAND**

104. Plaintiff demands a jury trial.