

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

ELECTRICAL WORKERS PENSION FUND,
LOCAL 103, I.B.E.W., Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

v.

BAXTER INTERNATIONAL, INC., JOSÉ E.
ALMEIDA, JOEL T. GRADE, HEATHER
KNIGHT, JAMES SACCARO, and CLARE
TRACHTMAN,

Defendants.

Case No. 1:25-cv-12672

Honorable Steven C. Seeger

CLASS ACTION

AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

I.	PRELIMINARY STATEMENT	2
II.	JURISDICTION & VENUE.....	5
III.	THE PARTIES.....	6
A.	Lead Plaintiffs.....	6
B.	Defendants	7
IV.	OVERVIEW OF THE FRAUD.....	8
A.	Baxter Announces its “Novum” Infusion Pump Platform.....	8
B.	The Novum Was Critical To Baxter’s Class Period Growth And Success	10
C.	Before The Class Period Began, Baxter Launched The Novum In Canada	12
D.	During The Class Period, Defendants Repeatedly Represented That The Novum Was A Safe, Reliable Device Critical To Baxter’s Revenue And Market Share Growth.....	14
1.	Defendants Misrepresented The Novum’s Launch And Market Performance In Canada.....	15
a.	Defendants Falsely Touted The Canadian Launch As A “Resounding Success”	15
b.	In Reality, As Known Internally At Baxter, The Novum Suffered From Serious Product Defects And Was Launched In Canada Well Before It Was Ready To Function	17
2.	Defendants Misrepresented That Baxter Had Successfully Resolved Issues And Concerns With The Pumps And Touted The U.S. Launch	25
a.	Defendants Falsely Touted Their Resolution of All “Bugs And Kinks” With The LVP And “Successful” Launch In The U.S.	25
b.	In Reality, And Known At Baxter, The Novum Remained Defective, Suffered From Myriad Software And Infusion Inaccuracy Problems, Impairing The Success Of The Launch	30
E.	Defendants Continued To Reassure Investors And Customers About The Novum As Safety Problems Publicly Surface	36

F.	Baxter’s Executives Were Kept Apprised Of The Novum’s Defects	38
G.	Information Regarding The Novum’s Impact On Baxter Financial Performance Emerges And Causes Significant Harm To Investors	40
1.	Baxter Announces A Hold On Shipping And Installation Of All Novum LVP Pumps	41
2.	Baxter Announces The Shipping And Installation Hold On The Novum LVP Will Continue “Beyond 2025”	44
3.	Baxter Discloses The Ship Hold Will Continue Through 2026, Causing Further Financial Harm To The Company	48
V.	ADDITIONAL INDICIA OF SCIENTER	53
A.	Repeated Regulatory And Safety Events Before And During The Class Period Placed Defendants On Notice Of Serious Defects In The Novum Platform And Related Software	54
B.	Former Employees Confirm That Defects With The Novum LVP Were Pervasive And Widely Known Inside Of Baxter, Including To The Executive Defendants	55
C.	The Executive Defendants Were Financially Motivated To Mislead Investors By Their Compensation Plan	56
1.	Defendants Received Substantial Annual Cash Bonuses Tied To Safety And Quality	57
2.	Defendants Received Substantial PSU Awards	60
D.	Departures Of Baxter’s Executives Involved With The Novum Support Scienter	63
E.	Defendants’ Statements Concerned Matters Critical To Baxter’s Success And Demonstrated Their Knowledge And Familiarity With The Topics Of Their False Statements	64
VI.	DEFENDANTS’ MATERIALLY FALSE AND MISLEADING STATEMENTS	67
A.	Defendants Misrepresented The Novum’s Launch And Market Performance In Canada	68
B.	Defendants Misrepresented The Superiority Of The Novum’s Specific Product Features, That Baxter Had Successfully Resolved Issues And Concerns With The Pumps, And The Success Of The U.S. Launch	71

C.	Defendants Continued To Mislead Investors, Even As Negative Information Was Revealed	79
VII.	PRESUMPTION OF RELIANCE	81
VIII.	CLASS ACTION ALLEGATIONS	82
IX.	CLAIMS FOR RELIEF	84
	COUNT I	84
	COUNT II	85
X.	PRAYER FOR RELIEF	86
XI.	JURY DEMAND	86

GLOSSARY

Term	Description
Baxter or the Company	Defendant Baxter International, Inc.
Class Period	February 23, 2022 through February 12, 2026, inclusive
Defendant Almeida	Defendant José E. Almeida, former CEO of Baxter
Defendant Grade	Defendant Joel T. Grade, former CFO of Baxter
Defendant Knight	Defendant Heather Knight, former EVP of MPT Segment and COO of Baxter
Defendant Saccaro	Defendant James Saccaro, former CFO of Baxter
Defendant Trachtman	Defendant Clare Trachtman, former VP of Investor Relations at Baxter
Defendants	Defendants Baxter, Almeida, Grade, Knight, Saccaro and Trachtman
Dose IQ Safety Software or Dose IQ	Software system used in Baxter’s Spectrum and Novum infusion pumps
Exchange Act	Securities Exchange Act of 1934
Executive Defendants	Defendants Almeida, Grade, Knight, Saccaro, and Trachtman
FDA	U.S. Food & Drug Administration, tasked with regulation of medical devices, software and related products
Health Canada	Canadian regulator of medical devices, software and related products
ITT	Baxter’s Infusion Therapies and Technologies business unit, which sold infusion pumps and related products
Lead Plaintiffs	Nebraska Investment Council, National Elevator Industry Pension Plan, and Louisiana Sheriffs’ Pension & Relief Fund
LVP or Novum LVP	Large volume pump on the Novum Platform
MPT Segment	Medical Products and Therapies segment of Baxter, which contained the Infusion Therapies and Technologies business that sold infusion pumps and related products
Novum Platform or Novum Products	Baxter’s “next generation” infusion pump system consisting of the LVP, Syringe and Dose IQ Safety Software
SEC	U.S. Securities and Exchange Commission
Spectrum Pump or Spectrum	Baxter’s Spectrum infusion pump system
Syringe or Novum Syringe	Small volume pump on the Novum Platform

1. Lead Plaintiffs Nebraska Investment Council, National Elevator Industry Pension Plan, and Louisiana Sheriffs' Pension & Relief Fund (collectively, "Lead Plaintiffs"), by the undersigned counsel, bring this action for violations of §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§78j(b) and 78t(a), and Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. §240.10b-5, against Defendants Baxter International, Inc. ("Baxter" or the "Company"), the Company's former CEO José E. Almeida, former CFO Joel T. Grade, former CFO James Saccaro, former COO Heather Knight, and former VP of Investor Relations Clare Trachtman (collectively, "Defendants"). Lead Plaintiffs bring these claims on behalf of a class of investors who purchased Baxter common stock from February 23, 2022 through February 12, 2026, inclusive (the "Class Period") and were damaged thereby.

2. Lead Plaintiffs allege the following upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters. Lead Plaintiffs' information and belief as to allegations concerning matters other than themselves and their own acts are based upon the investigation of Lead Plaintiffs and their counsel, including (a) review and analysis of documents filed publicly by Baxter with the U.S. Securities and Exchange Commission; (b) review and analysis of Baxter's press releases, presentations, and other public statements; (c) review and analysis of transcripts of Baxter's investor conference calls; (d) review and analysis of research reports by financial analysts and news reports concerning Baxter; (e) information from percipient witnesses described below; and (f) other publicly available sources as described below. Lead Plaintiffs' investigation into the factual allegations contained in this Complaint is continuing, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control. Lead Plaintiffs believe that substantial additional evidentiary support will exist for the allegations in this complaint after a reasonable opportunity for further investigation or discovery.

I. PRELIMINARY STATEMENT

3. This securities fraud action arises from materially false and misleading statements Defendants made to investors about Baxter’s Novum infusion pump platform—a line of medical devices and software that was critical to the Company’s performance and growth. Defendants publicly referred to the Novum as the “centerpiece” of Baxter’s growth strategy and promised it would deliver “greater than market growth” and “\$400 million in new product revenue by 2023.” But the Novum was fundamentally defective from the start, plagued by over-infusion and under-infusion problems, which meant the device could not accurately deliver medications to patients. Defendants knew or recklessly disregarded this. Yet throughout the Class Period, they told investors that the Novum was a safe, reliable device generating substantial sales for Baxter and delivering on the promised market share growth. But in 2025, after Baxter’s CEO José Almeida departed the Company abruptly, Baxter admitted to significant defects in the Novum devices—defects so severe that they forced the Company to halt all shipments of the Novum altogether, acknowledge it had no viable long-term solution to the device’s defects, and seek regulatory re-approval only after it fixed the severe defects.

4. The Novum was Baxter’s flagship infusion pump platform—a medical device hospitals use to deliver the correct amount of drugs to patients. In May 2018, Baxter announced the Novum line, a suite of products featuring a large volume pump or “LVP” and a smaller “Syringe” pump, both operated by Baxter’s Dose IQ Safety Software.

5. Baxter first launched the Novum in Canada in November 2020. Because Canada was the first jurisdiction to approve the Novum—and the FDA delayed Baxter’s launch of the platform due to “cybersecurity” concerns—the Canadian launch served as both a critical testing ground and a launch pad for the U.S. market. Defendants led investors to believe the Canadian launch was a resounding success, stating the Novum was *“doing very well in Canada,”* that

“customer satisfaction, right now, is very high,” and that the Canadian experience proved the device was *“absolutely what it needs to go into the US market.”* In reality, as multiple former Baxter employees confirmed, the Novum was *“a huge disappointment”* plagued by serious defects from the start. One former employee reported that Baxter launched the device in Canada before it was ready—for example, a September 2020 product demonstration revealed the product was “not ready to be launched,” yet Baxter pushed forward with a November 2020 launch anyway. As a result, the Novum was plagued with defects and customers were canceling orders and demanding refunds, including large health care systems that reported serious problems with the pumps.

6. When the FDA finally cleared the Novum for U.S. sale in April 2024, the stakes could not have been higher. Defendants characterized the U.S. launch as a *“resounding success”* and *“a really smooth and impactful rollout,”* claiming the Canadian launch had enabled Baxter to resolve *“bugs or some tweaks”* before introducing the product to U.S. customers. As late as January 2025, Defendants claimed, *“[W]e don’t see any issues with infusion pumps.”* In truth, the problems had never been resolved. Indeed, former employees reported that Baxter maintained an internal list of *hundreds* of known software bugs, with a whistleblower describing the Company’s response to defects as “Band-Aid solutions.” Multiple former employees confirmed that the LVP suffered from over-infusion and under-infusion problems—meaning the device did not accurately deliver medications to patients. One former employee stated the Company was aware of “over- and under-infusion problems” as early as 2022 and that “there was a problem with Novum involving a major partner in the U.S. from 2024 to 2025.” Another confirmed that by early 2025, a major customer reported life-threatening problems with the LVP that were so severe that Baxter pulled the product from its planned European launch entirely.

7. Notwithstanding these major undisclosed problems, Defendants knowingly or recklessly misrepresented the Novum's contributions to Baxter's financial success. Defendants claimed the Novum drove Baxter's pump business to achieve ***"50% growth in 2024 with significant potential for growth in 2025,"*** that Baxter had ***"doubled"*** its market share gains, and that Baxter had ***"converted some really large and important accounts from the competition."*** In truth, by early 2025, several large institutional customers had reported significant defects causing them to return or cancel their contracts.

8. Defendants knew or recklessly disregarded that their statements were false and misleading. As Defendants publicly touted the Novum's ***"resounding success," "advanced safety features,"*** and ***"very high" "customer satisfaction,"*** the Novum's defects were the subject of repeated regulatory events and safety signals during the Class Period, including Class I recalls—which were known to Defendants. Customer complaints were tracked through internal reporting systems, and investigations were escalated to the C-suite. Defendant Almeida, who was "very hands-on" with product technology, personally tracked complaints and participated in quarterly reviews where problems with the Novum were discussed.

9. Under escalating regulatory scrutiny following steady customer complaints, Defendant CEO Almeida suddenly and without explanation left the Company in February 2025. On July 31, 2025, Baxter shocked investors by announcing a "pause" on all shipments and installations of the Novum LVP, sending the stock price down 22.42% in a single day. When analysts asked whether the issues were ***"transient,"*** Defendants reassured them the problems affected only ***"a very small subset of clinical use cases."*** That reassurance proved false. On October 30, 2025, Baxter revealed the shipping hold would continue "beyond 2025" and that third-quarter sales had "declined 4%" due to the hold—causing the stock price to fall an additional

14.54%, and a further 3.6% the following day. Analysts noted that customers had “started seeking alternatives” and the hold was “leading to competitive losses.”

10. Finally, on February 12, 2026, Baxter disclosed that the hold would continue for the full year 2026, the Company had recorded approximately \$105 million in reserves for customer returns and remediation costs, and—seven months after the first ship-hold announcement—Baxter had still not “identif[ied] the longer-term solution set” for the defects. Baxter further disclosed that whatever fix it might develop “may require regulatory clearance or approval”—an admission that the Company would need to go back to the FDA before it could resume selling the Novum. As of the date of this Complaint, Baxter still has not resolved the underlying problems with the Novum.

11. Collectively, these corrective disclosures wiped out billions of dollars in shareholder value, resulting in Baxter’s stock price declining over 33% during the Class Period. Plaintiffs bring this action on behalf of all persons and entities who purchased or otherwise acquired Baxter common stock during the Class Period and were damaged thereby.

II. JURISDICTION & VENUE

12. Lead Plaintiffs bring this action, on behalf of themselves and other similarly situated investors, to recover losses sustained in connection with Defendants’ fraud.

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 Judicial District pursuant to 28 U.S.C. § 1391(b), Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Baxter’s common stock is and was listed and traded on the New York Stock Exchange during the Class Period, and many of the acts and transactions

alleged herein, including the dissemination of materially false and misleading statements, occurred in substantial part in this District.

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 United States mail, interstate telephone communications and the facilities of the national securities exchanges.

III. THE PARTIES

A. Lead Plaintiffs

17. Lead Plaintiff Louisiana Sheriffs' Pension & Relief Fund is based in Baton Rouge, Louisiana, and is a public pension fund that provides pension and other benefits for sheriffs, deputy sheriffs, and tax collectors in the State of Louisiana. Louisiana Sheriffs' Pension & Relief Fund is responsible for the retirement income of these employees and their beneficiaries. Louisiana Sheriffs' Pension & Relief Fund manages approximately \$5.6 billion in assets for the benefit of its approximately 22,000 active and retired sheriffs and deputy sheriffs.

18. Lead Plaintiff National Elevator Industry Pension Plan is based in Newtown Square, Pennsylvania, and is a multiemployer defined benefit pension plan established to provide retirement benefits to participants and beneficiaries in the elevator industry. The National Elevator Industry Pension Plan manages approximately \$11.3 billion in assets for the benefit of approximately 54,200 covered participants and beneficiaries, including active participants, retirees and beneficiaries receiving benefits, and participants and beneficiaries entitled to future benefits.

19. Lead Plaintiff Nebraska Investment Council is based in Lincoln, Nebraska, and is a centralized state investment agency that oversees and manages investments for the State's retirement plans and other trusts and endowments. The Nebraska Investment Council manages approximately \$45.5 billion in assets across 32 investment programs, including defined benefit

pension plans, other retirement plans, public endowments, college savings plans, state trusts, and other state investment programs, for the benefit of plan participants, state agencies, and the owners of the entrusted funds.

B. Defendants

20. Defendant Baxter is a Delaware corporation with its principal place of business located in Deerfield, Illinois. Baxter's common stock trades on the NYSE under the ticker symbol "BAX."

21. Defendant José E. Almeida served as Baxter's Chief Executive Officer, President, and Chair of the Board of Directors until February 2025, when he retired from his role effective immediately. Throughout the Class Period, Defendant Almeida repeatedly touted the Novum Products to investors and assured investors that the Novum LVP was a "great product." During the Class Period, Defendant Almeida received more than \$7 million in incentive payments tied to Novum performance and Baxter's stock price.

22. Defendant Joel T. Grade served as Baxter's Chief Financial Officer from October 2023. Defendant Grade repeatedly promoted the Novum Products and the LVP specifically, touting the rollout of the LVP as "really smooth and impactful" and going "really well." During the Class Period, Defendant Grade received more than \$2.5 million in incentive payments tied to Novum performance and Baxter's stock price.

23. Defendant Heather Knight served as Baxter's Chief Operating Officer from February 2025 through October 29, 2025. Throughout the Class Period, Defendant Knight regularly touted the Novum Platform's "safety software" and that the Novum IQ was designed to be "95% field serviceable," while also promoting the Novum rollout, claiming Baxter was "getting great feedback" on the products. During the Class Period, Defendant Knight received more than \$1 million in incentive payments tied to Novum performance and Baxter's stock price.

24. Defendant James Saccaro served as Baxter’s Chief Financial Officer from July 2014 through May 2023. During the Class Period, Defendant Saccaro promoted the Novum Products and the LVP, specifically touting qualities that “differentiate it” including the “medication safety provisions,” “drug safety library,” and “simple and easy user interface.” During the Class Period, Defendant Saccaro received more than \$260,000 in incentive payments and stock awards worth more than \$1.5 million (though later forfeited) tied to Novum performance and Baxter’s stock price.

25. Defendant Clare Trachtman was Baxter’s Vice President of Investor Relations at all relevant times. During the Class Period, Defendant Trachtman also touted the “advanced safety features” and “95%” remote serviceability of the Novum products. Baxter did not disclose details of Trachtman’s incentive compensation during the Class Period.

IV. OVERVIEW OF THE FRAUD

26. Baxter is a medical technology and healthcare products company that supplies hospitals and other healthcare providers with products used in day-to-day patient care. Baxter produces and sells a variety of medical device products including intravenous drug delivery products, infusion pumps and medication-delivery systems, surgical products and patient-monitoring and diagnostic equipment. Baxter’s primary customers are hospitals, ambulatory surgery centers, and nursing and rehabilitation facilities.

A. Baxter Announces its “Novum” Infusion Pump Platform

27. In May 2018, Baxter announced its development of a new medical device—the Novum infusion pump system. The Novum was a suite of infusion pump products that delivered infusions of medication and fluids to patients in hospitals and healthcare settings for a variety of purposes, including chemotherapy, pain management, and providing stabilizing therapies during and after surgeries. The Novum Platform featured pumps in two different sizes, the LVP used to

deliver high-volume infusions, and the Syringe pump for infusing lower volumes.

28. The Novum Platform also included Baxter's "Dose IQ Safety Software"—a new software system that would be used to operate the Novum pumps. This software served two critical, related functions: controlling the amount and rate of the infusion delivered to the patient, and connecting the devices to hospital networks. Unlike earlier generations of infusion pumps with software embedded on the pumps, the Novum's "next generation" software purportedly operated remotely through a "cloud-based" system hosted by Baxter.

29. Baxter executives hailed the Novum as a "landmark" new product with "*the most advanced safety features*" and software that was "*95% field serviceable*," enabling Baxter to deliver any critical updates "remotely" without taking pumps off "the nursing floor for manual software and firmware updates." Based on these "game changer" features, Defendants told investors the Novum would "deliver greater than market growth" for the Company. They touted the Novum as a "key element" of the Company's overall growth strategy, helping Baxter to achieve "5% to 6% revenue growth" and "\$400 million in new product revenue by 2023."

30. The Novum was a key topic of analyst and investor interest starting from the moment Defendants announced the new platform in May 2018. For example, on May 21, 2018, in response to Baxter's announcement of the Novum, analysts asked about "the key points of differentiation" of the product. Defendants responded that the LVP would add "the auto-programming feature" and be "the best pump in the market." In a January 2019 report on Baxter, Wells Fargo analysts wrote that the Novum was a "key" subject for investors: "[i]n Infusion Systems, development of the next-generation pump platform is on track for 2020 launch . . . BAX holds <25% share in the pump market and targets 100bps share gain a year," and "we expect increased investor focus on the company's pipeline and new product launch opportunities."

31. Baxter executives also claimed that the Novum’s supposed safety and reliability gave the pumps a competitive edge over other pump manufacturers. For example, during a July 25, 2019 investor conference, analysts asked Baxter executives how the Novum would fare given other pumps in the market having recall “issues with their pump and infusion sets.” In response, Defendant Almeida stated “there’s always opportunity when there is a problem with a competitor,” and the “guts of [Baxter’s] new pump all are different, are more modern, and will be a horizontal pump. . . . you have a new product with phenomenal operability.”

B. The Novum Was Critical To Baxter’s Class Period Growth And Success

32. The Novum Platform was central to Baxter’s Class Period financial performance and success. The Novum was sold within Baxter’s Infusion Therapies and Technologies (“ITT”) business, the central driver of Baxter’s largest segment, the Medical Products and Therapies segment (“MPT Segment”). In announcing the Platform, Baxter told investors that Novum was “a platform that will deliver greater than market growth” and was a “key element” of Baxter’s growth strategy. Both before and during the Class Period, Defendants repeatedly represented to investors that the Novum Platform would “deliver greater than market growth” for Baxter, making it a “centerpiece” of Baxter’s growth strategy. In support of these claims, Defendants represented that Novum would generate substantial sustained sales based on its positive performance in the market. Because of its centrality to Baxter’s largest and most closely watched segment, the success or failure of the Novum Platform carried outsized significance for the Company’s overall results.

33. During the Class Period, Defendants also repeatedly raised Baxter’s earnings guidance based on the Novum’s supposed “outperformance” in the market and contributions to growth. For example, when speaking to investors in December 2022, Baxter executives stated that Novum sales were “an important variable for 2023” behind Baxter raising its guidance to “4% to 5% compounded annual sales growth.” During the Class Period in May 2024, Baxter raised full-

year sales growth guidance and adjusted EPS guidance, attributing the increase to upcoming Novum sales.

34. Similarly, in November 2024, as the U.S. launch of the Novum LVP was underway, Defendants told investors that the MPT Segment, which contained Baxter's infusion pump business, led "all segments with 7% growth" due to "strong uptake" of Novum. Defendants stated that the Novum caused Baxter's infusion pump business to experience "50% growth in 2024 with significant potential for growth in 2025." Defendants continued to reassure investors of the Novum's contributions to Baxter's growth and earnings in 2025. For example, in February 2025, Defendants reaffirmed its 5% growth targets for the MPT Segment based on "continued momentum" from the Novum LVP launch. In May 2025, Baxter reported that sales of its infusion pump business were "\$994 million," an increase of "6%" which Defendants credited to sales from the U.S. Novum rollout.

35. Investors and analysts credited these pronouncements from Defendants, quickly homing in on Novum as the key to the Company's future success. Both before and during the Class Period, analysts described Novum as an "important new multi-year growth driver," positioning the Company to "increase[] its overall LVP pump share . . . by 100bps a year," potentially even "capturing up to 40% share of new pumps (vs. 25% now)." One analyst noted that the addition of Novum to the MPT Segment could generate "above market growth for the next couple years." In short, as analysts noted, Novum alone "improv[ed] the company's competitive position," presented a "meaningful" opportunity for growth, and "potential upside" for several years.

36. As these public statements and analyst commentary show, the Company's success—and failure—depended significantly on the market success of the Novum. As discussed

below, Baxter repeatedly kept analysts and investors apprised of their efforts to obtain regulatory clearance to sell the Novum.

C. Before The Class Period Began, Baxter Launched The Novum In Canada

37. Baxter promoted the Novum as the Company's first "global" infusion pump platform, planning to first launch the product in North America before expanding it to markets worldwide.

38. Leading up to the Class Period, Baxter applied for regulatory clearance of the Novum Platform from the FDA and Health Canada (the Canadian equivalent to the FDA) to sell the devices in the U.S. and Canada, respectively. Baxter's applications to these regulators were for the same devices—the LVP, the Syringe, and the Dose IQ software used in these devices.

39. In Canada, Baxter sought (and received) approval through Health Canada's Class 3 Medical Device Licence process, which limits regulatory review because the product is purportedly highly similar to existing previously approved predicate devices. By applying through this avenue, Baxter avoided having to provide the rigorous clinical testing and scientific evidence of safety and efficacy that these regulators apply to new devices, such as factory inspections and studies with human subjects. Notably, at the time of Baxter's Canadian application, Health Canada did not have a developed regulatory regime in place for reviewing medical device software like Baxter's Dose IQ. Indeed, Canada only finished creating and promulgated its software device regulations on December 18, 2019—over two months after Baxter submitted its application for the Novum to Canadian regulators.

40. Just months after submitting its application, Baxter obtained clearance for the Novum Platform in Canada. Health Canada cleared these products based on Baxter's representation that the Novum was "closely based on the previously licenced device Spectrum IQ infusion pump"—Baxter's existing line of infusion pumps. Based on Baxter's asserted similarity

of the devices, Health Canada determined that “[d]evice specific clinical studies were not required because the device technology is well established for the indicated use.”

41. In November 2020, Baxter launched the Novum in the Canadian market. As Baxter launched the devices in Canada, it continued to stoke investor anticipation for the upcoming U.S. launch, promoting the Novum as “a global platform” with Canada being “the first regulatory clearance in a series of planned submissions globally.” Crediting Baxter’s representations, analysts lauded that “[t]he new pump platform represents a multi-year growth driver” and “we are bullish about the infusion pump opportunity for BAX over the next few years,” explaining that “Baxter was poised to take market share.”

42. Baxter also pursued FDA approval of the Novum Platform on the basis that the devices were purportedly highly similar to an approved device. Baxter submitted a 510(k) application, through which Baxter claimed the device was the “substantial equivalent” to a previously approved device—the Spectrum Pump. As a result, the FDA did not request—nor did Baxter provide—any “clinical testing [to be] performed” for clearance of the Novum. Thus, Baxter avoided having to undergo a pre-clearance facility inspection by the FDA to confirm compliance with quality system regulations prior to marketing its devices, nor was Baxter required to submit the detailed manufacturing information, environmental assessments, or comprehensive published literature reviews that accompany an application for approval of new medical devices.

43. In January 2022, Baxter told analysts and investors that the FDA had requested “additional data on cybersecurity” regarding its Novum application. On October 27, 2022, during the Company’s third-quarter 2022 earnings call, Defendant Almeida told investors the FDA’s request had been “successfully resolved” and Baxter would “submit data” to the FDA showing its “successful resolution of the issue” in a forthcoming submission.

44. The FDA's hold on Baxter's 510(k) application was significant. In 2022, the delay forced Baxter to eliminate \$100 million in anticipated Novum sales from its annual forecast, and the company would not receive final FDA clearance until April 2024—nearly three years after its initial submission. Because the Novum LVP remained unavailable in the lucrative U.S. market during this extended regulatory limbo, analysts closely monitored the Canadian rollout as the primary indicator of the device's commercial viability and Baxter's ability to capture market share once FDA approval was obtained.

D. During The Class Period, Defendants Repeatedly Represented That The Novum Was A Safe, Reliable Device Critical To Baxter's Revenue And Market Share Growth

45. During the Class Period, Defendants consistently touted the Novum LVP's success in their public statements to investors. In these statements, Defendants touted the Novum's supposedly successful launch and market performance in Canada; Baxter's purported successful resolution of any performance and regulatory concerns and subsequent launch in the United States; and the central role of Novum sales and market share growth to Baxter's ongoing and future growth.

46. Unbeknownst to investors, however, the Novum suffered from undisclosed defects that jeopardized patients and undermined its commercial viability. Throughout the Class Period, Defendants never disclosed to investors the severity of these defects or the fundamental nature of the design and software problems plaguing the Novum Platform. As explained below, these problems were known to Defendants and contradicted their statements to investors, rendering them false and misleading when made.

1. Defendants Misrepresented The Novum's Launch And Market Performance In Canada

a. Defendants Falsely Touted The Canadian Launch As A "Resounding Success"

47. Throughout the Class Period, Defendants falsely assured investors about the Novum's *"resounding success"* in the Canadian market. They told investors that the product was *"doing very well in Canada,"* customer satisfaction was *"very high,"* and customer reception was *"outstanding."* These reassurances were critical to investors. Given the staggered approvals of Novum Products, success in the Canadian rollout would effectively serve as proof of concept for investors that Baxter's eventual launch in the United States (to a much larger market) would also be a success.

48. Joining the other Defendants in touting the Canadian rollout, Defendant Knight spoke at the Company's 2022 Investor Conference on May 25, 2022. There, Defendant Knight assured investors that the Company was receiving positive feedback from Canadian customers, stating *"I remain very, very confident in this platform, because of the feedback we've gotten from our customers, because of the feedback our customers have given us into design of this platform . . . our customers in Canada are already enjoying this platform today, and we're getting great feedback."* Similarly, on February 9, 2023, Baxter held its Q4 and year-end 2022 earnings call. During the call, when Defendants were asked by analysts about highlights in 2023 fiscal year, Defendant Almeida pointed to the success of the Novum LVP, stating the product was *"doing very well in Canada"* and U.S. markets were *"very anxiously waiting for our [Novum LVP] pump."* At a September 6, 2023 investor conference, Defendant Almeida continued to stoke investor interest in the U.S. launch by pointing to the Novum's success in Canada, stating *the LVP was "working on the market today"* and *"this product is absolutely what it needs to go into the US market."*

49. In their public statements, Defendants described characteristics of the device that purportedly led to the Company's success. For example, on February 23, 2022, at the start of the Class Period, when analysts questioned Defendant Saccaro about the Novum Products at an analyst conference, he claimed, "the pump is exciting [because] *it really leverages all of the best things that we have with our pump, including . . . the medication safety provisions that we have with respect to it, simple and easy user interface and then now adds to it a whole platform.*" Similarly, at another analyst conference that spring, Defendant Saccaro claimed that *"the Novum pump incorporates all of our learnings from being in the large volume pump business for perhaps the last 20 years into this next generation pump. Things like a drug safety library, things like simple and easy to use interface."* Defendant Knight also touted the Novum's "Dose IQ Safety Software" and *"dose error reduction system, and it enhances infusion safety by creating one of the highest drug library compliances in the industry."*

50. Analysts relied on Defendants' claims about the success of the Canadian rollout. Indeed, even before the Class Period began, analysts treated the Canadian rollout as validation of the device's viability and as reassurance when FDA delays occurred. For example, in early 2021 UBS analysts relied on the Canadian approval and success when evaluating the FDA delays due to cybersecurity concerns, explaining "BAX does have the product approved in Canada . . . At the end of the day, we do think the pump platform will likely be approved." Similarly, Raymond James analysts as far back as 2020 contextualized delays in the U.S. approval by relying on Canadian success and approval as a counterweight, noting "Baxter 'remains confident in the fundamentals' of its new pump platform and noted that the product(s) are cleared for marketing in Canada." Likewise, during the Class Period, on September 10, 2023, analysts from Wells Fargo noted that

“some of the hardware/software updates in the US filing are based on learnings from Novum IQ launch in Canada.”

51. As investors waited for eventual FDA approval—and the massive revenue growth anticipated to follow—Defendants’ false and misleading statements about Baxter’s Canadian experience buoyed investor expectations and helped calm any concerns over the delayed FDA approval process. The truth behind the scenes, however, was far different.

b. In Reality, As Known Internally At Baxter, The Novum Suffered From Serious Product Defects And Was Launched In Canada Well Before It Was Ready To Function

52. Unbeknownst to investors, Baxter launched the device in Canada before it was ready for market, resulting in a defective and unreliable device sold to Canadian customers. This is confirmed by the accounts of multiple former Baxter employees.

53. Contrary to Defendant Almeida’s claims that the LVP was “*working on the market [in Canada] today,*” multiple former employees confirmed that the LVP encountered significant problems when it was launched to Canadian customers. For example, FE-1 reported that when the LVP was launched in Canada, problems came up in the initial deployment to Canadian customers.¹ He described the Novum LVP as a huge disappointment for the Company. FE-1 recalled that the LVP both under- and over-performed, which was a significant problem because the whole purpose of the pump was to deliver medications precisely. He compared the defects in the device to a car that does not drive. Similarly, FE-2 confirmed that, by no later than 2022, Baxter was aware of

¹ FE-1 was the Principal ID/UX Designer at Baxter from September 2022 through February 2026. He handled the support software, inventory control, location, and performance metrics. In order to standardize and preserve the anonymity of former employees who provided the accounts in this Complaint, “he/him/his” pronouns are used throughout.

infusion inaccuracy problems.² FE-2's role was to prepare for the European launch of the Novum platform. However, due to the internally known concerns regarding Novum's software, as well as over- and under-infusion problems with the LVP, Baxter ultimately did not launch the Novum platform in the European market.

54. Customers repeatedly reported these major problems to Baxter. For example, FE-3 stated that Baxter received complaints due to issues with the Novum LVP during the product launch in Canada.³ FE-3 reported that the complaints included problems with the LVP not infusing patients properly. For example, he recounted that when nurses entered a certain dose, the LVP would not deliver the infusion correctly, or deliver the infusion with a delay, resulting in issues for the patient. FE-3 further explained that in Canada, Baxter had to replace "a whole bunch of machines" and that "there were a lot of replacements."

55. FE-3 also recalled that a significant customer of Baxter's, Alberta Health Services (which operates over 100 facilities and provides services to more than 5 million people across Alberta), complained to Baxter about issues with the Novum. FE-3 explained that Alberta Health Services expressed that it felt like the Company was not doing anything about their complaints.

56. In spite of these customer complaints, Baxter was unable to correct the technical issues that caused the infusion inaccuracy. For example, FE-4 reported infusion issues with the

² FE-2 was a Marketing Manager for Western Europe Infusion at Baxter from November 2019 to April 2026. In his role, he was involved in European infusion pump strategies for Baxter. He reported to a Global Marketing Director who reported to Andy Goldney, the Vice President Western Europe, Infusion Therapy, Medical Devices and Pharmaceuticals, who in turn reported to Group President Cecilia Soriano.

³ FE-3 was a Quality Specialist from November 2017 through October 2024, and handled regulatory complaints for Baxter's products, including Novum in Canada. He was responsible for reviewing complaints that Baxter received and determining whether the complaints were reportable to Health Canada.

LVP in 2023—and that the Company was unable to solve them.⁴ FE-4 stated that, in his role working on the LVP software, he was responsible for working on applications that pushed the prescriptions to the Novum pump, which included critical information such as the dosage and type of medication that the patient needed to receive. FE-4 stated that he was sent to Canada because Baxter did not have enough personnel in Canada to address the many problems customers faced with the pumps, so he was sent with six to seven other U.S. software engineers. According to FE-4, when these problems arose, he worked on altering the pumps' software and firmware. FE-4 explained that firmware was what made the mechanical system run, whereas software was what was used to receive and translate information then sent to the firmware. These trips occurred in winter 2023 and February 2024.

57. FE-4 described specific malfunctions he observed during these trips to address Novum malfunctions. For example, FE-4 described connectivity problems with the LVP. As FE-4 explained, for the pumps to work properly, the servers operating on the back-end needed to transmit information back and forth to the pumps via the hospital's wireless networks, but the pumps were malfunctioning due to a wireless connectivity defect in the devices. Since the on-the-ground team was unable to address the problem at the hospitals, Baxter's development team, a team separate from FE-4's and based in Baxter's corporate office, had to work on the issue.

58. FE-4 also described a problem with the LVP in which the device would simply present a blank screen while he and his team were trying to perform updates on the devices. When this issue occurred, FE-4 stated that, rather than having an effective solution to prevent this issue

⁴ FE-4 served as a Principal Software Engineer for Global Healthcare Digital Products Technical Services from September 2022 through July 2024. In this role, he was responsible for working on applications that pushed the prescriptions to the Novum pump.

from occurring, he and his team were told to just reboot the system and hope the error would not occur again.

59. FE-4 further noted that by late 2023, within the Company, his team was being scapegoated for the many accuracy problems with the infusion issues, yet in reality the problems were not with the back-end applications that FE-4's team serviced but rather the front-end, due to problems with the device itself. FE-4 explained that applications were working properly on other devices, which meant the infusion issues must have been from the device itself, rather than back-end software that serviced multiple different devices.

60. Indeed, former Baxter employees reported that the problems with the Novum were known even before it was launched to the Canadian market. FE-5, was responsible for educating clinicians and staff at hospitals on the wireless connectivity of Baxter pumps.⁵ According to FE-5, Baxter held a product demonstration for the Novum in September 2020 that revealed the product was not ready to be launched. FE-5 explained that infusion pumps operate by connecting to hospital wireless networks and transmitting data back and forth between the devices and the central monitoring system application. The central monitoring system was used by nurses and clinicians to identify the medication type and volume to be administered. They were responsible for updating the drug library, and then a firmware update would ensure the pumps had that information. The application was primarily used to update the drug library.

61. FE-5 stated that it was critical to patient safety for the Novum to properly interface with the central monitoring system in hospitals. For example, for the pumps to operate safely,

⁵ FE-5 was a Wireless Technical Specialist at Baxter from June 2020 to February 2022. FE-5's role involved going on site to hospitals, conducting surveys, customer training on pumps, and connecting pumps to the network. He reported to Brian Guild, Senior Manager of Technical Integration, and Mark Simms, Director of Technical Implementation Services. Simms in turn reported Donny Patel, then VP of Digital Transformation.

Baxter needed to clearly identify and document: (a) how the pump communicated wirelessly with hospital networks; (b) for critical medication doses, how to prevent two types of medication from being mixed; and (c) how to adjust drug deliveries if the pump was not receiving an update or connected to a wireless infrastructure. When FE-5 was shown the demonstration, Baxter personnel were unable to explain how the device software could reliably perform any of these functions. The software was simply not completed at the time of the demonstration. According to FE-5, there was no way Baxter had time to test it and validate the software before the November 2020 release.

62. FE-5 explained that hospitals generally operated large fleets of pumps, ranging from hundreds to thousands, and the central monitoring system was necessary to deliver critical safety updates to the pumps without having to install them manually. Yet based on his first-hand observations of the device, the software could not perform these basic functions. In other words, the connectivity problems with the Novum were a particular problem for large hospital systems buying the pumps.

63. FE-5 confirmed that, when he saw the demonstration in September 2020, he raised numerous concerns to Baxter's leadership, including then VP Donny Patel, and that no one at Baxter had adequate answers. For example, he specifically told Patel that the Novum was not ready for the November 2020 launch. FE-5 stated that Patel listened to his concerns about the device but did not provide any response. FE-5 also recounted that, in November 2020, Baxter held a Company-wide meeting to address that salespeople were improperly promoting the Novum to U.S. customers, despite having a lack of FDA clearance. The meeting included anyone that had a customer facing role, including sales, presales, trainers, support roles and nurses, as well as VPs in the Company segments dealing with the Novum. FE-5 stated that Baxter's salespeople promoting the functionality of the Novum to customers was improper because Baxter did not have

a functional product at the time. FE-5 confirmed that despite these unresolved problems with the Novum, Baxter was under intense pressure to sell the product.

64. FE-5 stated that part of Baxter's motivation for developing the Novum was to save money. FE-5 confirmed that with the Spectrum Pump, Baxter contracted the software work to outside engineers, who charged Baxter fees to maintain the software. Baxter attempted to develop the software for the Novum on their own with in-house software engineers. However, FE-5 stated that the Baxter team tasked with developing the software did not seem to have experience or skill necessary to properly develop the device.

65. As evidenced by customer reports, the same problems—and others—that these former employees observed continued throughout the Canadian launch. Under Canadian law, mandatory incident reports must be investigated by the device manufacturer and internally reported to the company's leadership, including senior and executive management. In total, from the time Baxter first launched the Novum LVP in Canada to when it was launched in the United States in April 2024, nearly 300 incident reports were lodged with Health Canada regarding the Novum LVP, often describing (though in fragmentary form) "flow" issues, "software problem[s]," and infusion problems. Though these mandatory incident reports appear to the public in barebones form—listing only the date, product, and issue category—the sheer consistency and volume of these reports, considered alongside the previously undisclosed detailed accounts of former employees, reveal a pattern of systemic defects that were far more serious than what the public disclosures alone conveyed.

66. As these issues persisted, on September 15, 2022, Baxter quietly initiated the first of several voluntary recalls of the LVP in Canada, made without any contemporaneous public announcement. In a private letter to its customers, Baxter explained that internal testing had

identified “isolated incidents” where the pump delivered slightly more medication than intended (over-infusion) under very specific circumstances. The letter recommended using an alternative device when delivering certain high-alert medications to vulnerable patient populations, such as newborns, at the lowest flow rates for extended periods.

67. Baxter quietly initiated a second recall of the LVP in Canada on October 20, 2022. That day, in a letter privately issued to Baxter customers (and without any contemporaneous public announcement), Baxter characterized the recall in muted terms as “related to two different software issues that occur during use,” presenting the issues as isolated without disclosing the full volume of mounting problems or explaining the connection between the issues and the underlying defects. Both “software issues,” however, again related to infusion inaccuracy, including problems with under-infusion. The first software defect impacted the LVP’s ability to handle “bolus delivery”—i.e., the rapid administration of a specific, pre-programmed volume of medication over a short, designated period, causing the device to miscalculate remaining volume to be administered and “result[ing] in insufficient or excessive therapy.” The consequences varied, depending on the remaining medication, but could result in rapid administration of drugs meant for a slower, baseline rate and vice versa.

68. This software issue also compromised the LVP’s ability to properly administer “loading dose[s].” As with the negative impact on bolus delivery, this issue similarly caused secondary infusion to be “delivered at the primary rate”—i.e., rapid administration of drugs meant for baseline rates and vice versa. The October 20, 2022 customer letter stated that Baxter had multiple customer complaints associated with the issue, but did not provide specifics or address the underlying defects in the device.

69. Rather than fully disclosing the severity of the issues, the October 20, 2022 letter instead instructed customers to simply work around the defects rather than removing the devices from use. The letter instructed operators to “[m]onitor the patient during bolus delivery to completion or minimally at completion to ensure appropriate return to the maintenance rate.”

70. In February 2023, Baxter issued an Urgent Medical Device Correction letter, again sent privately to customers without any public announcement, in which Baxter stated that the infusion inaccuracy problems behind its September 15, 2022 recall had not been resolved. Contrary to Defendants’ repeated public assurances to investors regarding the safety and quality of the LVP, Baxter privately acknowledged to its customers that it had failed to fully resolve the defects referenced in the September 15, 2022 customer letter. The February 6, 2023 letter conceded that the LVP was incompatible with Baxter’s standard issue primary IV administration set (the “1W5000”). Baxter warned customers to “immediately discontinue the use of the 1W5000 product code when using the Novum IQ LVP.”

71. Notwithstanding the widespread issues with the Novum LVP in Canada, Defendants disclaimed any such issues, continuing to tout the rollout and “success” of the Canadian launch. As noted above, despite the issues highlighted by the former employees’ accounts, the quiet recalls of the device, and the growing number of incident reports, Defendants relentlessly boasted to investors that the LVP was “doing very well in Canada,” receiving “great feedback” from Canadian customers and the pump was “working on the market today” in Canada. In doing so, Defendants misrepresented the severity of the Novum’s defects and misled investors about the fundamental nature of the design and software flaws that plagued the device from its inception. These were systemic problems that rendered the Novum incapable of performing its

core function of delivering accurate infusions to patients—undermining the product’s commercial viability in Canada, the U.S., and beyond.

2. Defendants Misrepresented That Baxter Had Successfully Resolved Issues And Concerns With The Pumps And Touted The U.S. Launch

a. Defendants Falsely Touted Their Resolution of All “Bugs And Kinks” With The LVP And “Successful” Launch In The U.S.

72. Leading into the important launch of the Novum in the U.S., Defendants repeatedly assured investors that Baxter had identified and resolved any possible issues with the Novum—while insisting that any such problems with the Canada rollout had been minor. For example, between February 2023 and September 2024, Defendants claimed the Canadian rollout allowed Baxter to resolve *“some bugs or some tweaks,”* that software changes were *“finished,”* that the product was *“doing very well in Canada,”* that the product was *“absolutely what it needs to go into the US market,”* and Baxter had *“nothing else [] to do”* to ensure the safety and regulatory compliance of the pumps.

73. These reassurances were particularly important to analysts, because Baxter’s competitors were suffering significant public safety issues with their products. By early 2023, multiple competing pump manufacturers experienced serious recalls due to defects with their infusion-pump products. For example, in March 2023, ICU Medical—one of Baxter’s competitors—experienced a Class I recall of its Plum infusion system, which included large volume pumps like the Novum LVP, due to manufacturing defects and under-infusion risks that could cause “serious injuries or death.” Similarly, competitor Becton Dickinson’s Alaris large volume pump remained under Class I recall and was the subject of an FDA consent decree that had been in place since 2007 due to longstanding safety and compliance issues. By early 2023, the Alaris system had already been linked to at least 55 injuries and one death, with recalls affecting more than 2.4 million devices—issues that ultimately resulted in BD paying \$175 million to the

SEC in 2024 for misleading investors about regulatory compliance risks and an \$85 million class action settlement.

74. By contrast, Defendants minimized any issues Baxter may have experienced in the Canadian launch as routine “bugs” and “tweaks” that had been “finished,” giving investors the impression that Baxter had avoided the serious safety problems plaguing its competitors. For example, during Baxter’s April 27, 2023 earnings call, analysts asked Defendants about the “potential for share gains” over Baxter’s “other competitor” pumps. In response, Defendant Almeida drew explicit contrasts between the LVP and other “pumps on recall at the moment.” He stated that ***Baxter had “significant opportunities to gain market share once Novum is approved” when “facing competitors who have consent decree and recalls.”***

75. Indeed, Defendants repeatedly told investors that the Novum was a “differentiated” product with superior safety and technical features relative to “competitors who have consent decree and recalls.” Throughout the Class Period, Defendants pointed to the Novum LVP’s supposed ***“good precision”*** with infusion accuracy, ***“very good interface with the rest of hospital systems,”*** ***“95% field serviceability”*** through “over the air firmware updates,” and seamless “EMR” (or “electronic medical records”) integration with hospital record-keeping systems. Defendants also pointed to certain ***“advanced safety features”*** such as the “Dose IQ Safety Software” and ***“dose error reduction system.”*** These features were important to both customers and investors to evaluate the safety and viability of the Novum Platform. For hospitals considering a multi-million dollar purchase of infusion pumps, features like precision, connectivity, and remote serviceability are requirements that determine whether those hospitals enter into a contract with Baxter or with one of its competitors.

76. These features were critically important to investors evaluating Baxter's opportunity for growth. For example, as Jefferies noted in a March 2026 report on ICU Medical, "[o]nly ~15-20% of US infusion pumps are bi-directionally integrated" with electronic medical records, "positioning interoperability as a key differentiator and driver of stickiness." In other words, only a small fraction of infusion pumps on the market—including, supposedly, Baxter—could communicate in real-time with hospital record systems. If Baxter could successfully implement this capability, it would be able to lock in long-term relationships with key hospital system customers.

77. On April 1, 2024, Baxter announced that it had received the FDA's clearance of the Novum LVP for U.S. sale. On May 7, 2024, Defendants touted the LVP's deployment "into hospitals, with the integration into EMRs"—i.e., Electronic Medical Record systems, used by hospitals to transmit information between medical devices and hospital networks—which Defendants stated gave Novum customers "access [to] a world-class drug library" and "safer delivery of medication to the patient." As Defendants stated to investors on June 5, 2024, ***Baxter's U.S. launch of the device was off to "a great start."***

78. As Baxter introduced the Novum LVP to U.S. customers, Defendants continued to tout the supposed success and positive reception of the device by customers. On August 6, 2024, on the Company's Q2 2024 earnings call, Defendant Almeida stated, ***"[c]ustomer interest is high for the Novum platform," the "pumps are already live and in use at multiple sites,*** making a difference for caregivers and the patients they serve." Similarly, on September 5, 2024, during an analyst conference, Defendant Grade told investors that because the Novum had "launched in Canada for a couple of years," ***Baxter was able to resolve "bugs or some tweaks that we had to do within that product."*** Defendant Grade represented that these ***"bugs or some tweaks" were***

“taken care of by the time we actually launched it in the US.” That same day, Defendant Grade told investors that *the U.S. “launch itself has gone well”* and Baxter was *“in a really good place from a product availability perspective.”* At a November 20, 2024 analyst conference, Defendant Grade also claimed that Baxter’s Canadian rollout allowed the Company *“to just work out any last minute kind of bugs and kinks,”* resulting in *“a really smooth and impactful rollout of Novum here in the US.”* Thus, Defendants’ representations reassured investors that any issues arising with the Novum pumps and Dose IQ software—which they minimized—had been successfully resolved prior to launching the product in the U.S.

79. Defendants claimed that the U.S. launch was a massive success. On a February 20, 2025 earnings call, Defendant Knight, Baxter’s head of the MPT Segment who “spearheaded” the Novum’s U.S. launch, told investors that Baxter had made “a pretty big bet” on Novum—and investors were “seeing it pay off.” Defendant Knight stated that *“customer satisfaction, right now, is very high, both on the implementation of the pump as well as the EMR integration with the new platform.”* Similarly, Defendant Grade claimed on March 3, 2025, that since the Novum launch “[t]he demand has been outstanding,” and that “[t]he performance of the product itself has been outstanding.” Similar to Defendants’ earlier comments differentiating the Novum from competing pumps under recall, Defendant Grade further stated that *Novum was “a very competitive product” with “lots of areas that are differentiated,”* and that *Baxter had “continued to increase [its] share by competitive wins as well as replacements.”* Defendant Grade stated, *“the launch itself went extremely well,”* and the Canadian rollout enabled Baxter *“to work out any kinks and tweaks.”*

80. Defendants continued touting the supposed success of the rollout of the device—and that that purportedly successful launch set Baxter up for global growth. At a November 20,

2024 analyst conference, Defendant Grade stated that the *Novum* had *“a feature set that’s been really well-received”* and *“a rollout process that’s actually gone really well.”* On January 13, 2025, Defendant Almeida stated that *the LVP was “a world-class product that has tremendous acceptance.”* He emphatically reassured investors, *“right now we don’t see any issues with infusion pumps.”* On March 5, 2025, Defendant Trachtman told investors that the Novum Platform’s design and software allowed Baxter to “leverage these digital capabilities across the portfolio.” Defendant Trachtman stated that this was “the promise” that had been “unlocked really with the Novum gateway.” Defendant Trachtman claimed that the U.S. and Canadian launches had been so successful that Baxter was now considering “markets outside the US and Canada”—“we’ll further expand, so looking at targeted geographic expansion for the Novum platform, going forward.”

81. During the Class Period, Defendants also repeatedly—and misleadingly—credited the Novum as a driver of Baxter’s financial performance. For example, they claimed that the Novum drove Baxter’s MPT Segment to experience “50% growth in 2024 with significant potential for growth in 2025,” that Baxter had “doubled” its market share gains to multiple “points of share a year,” and that Novum sales supported raising MPT Segment growth guidance to “approximately 5%.”

82. Specifically, on August 6, 2024, on the Company’s Q2 2024 earnings call, Defendant Almeida stated that based on the Novum’s successful launch in the U.S. market, the Novum created “a healthy funnel of opportunities,” and the Company would experience *“continued strong, steady uptake from Novum across the balance of 2024 and beyond.”* Similarly, on September 5, 2024, at the Wells Fargo Healthcare Conference, Defendant Grade told investors that the Novum would “continue to be a growth driver in MPT” and Baxter was *“ahead*

of schedule” achieving the Company’s initial projections of \$25 million in Novum sales for the year. These claims—which misrepresented the Novum’s critical commercial risks due to its widespread product defects—further misled investors.

83. Defendants’ claims about the Novum and the purported success of the U.S. launch were of paramount importance to Baxter investors for multiple reasons. The United States represents the single largest market for infusion pumps globally, accounting for approximately 40% of worldwide infusion pump sales and generating over \$7 billion in annual revenue. Baxter had invested years of research and development capital into the Novum Platform, positioning it as the “centerpiece” of the Company’s growth strategy and projecting it would deliver “\$400 million in new product revenue.” Investors who had been told the Novum would generate “greater than market growth” reasonably expected the U.S. launch to validate Baxter’s significant investment and produce substantial returns. The U.S. launch represented Baxter’s opportunity to capture market share from competitors whose products were under FDA recall or consent decree, a competitive advantage Defendants repeatedly emphasized to investors. Finally, Baxter’s ability to execute a successful U.S. launch served as a proxy for the overall quality of the Novum Platform—if the devices performed as Defendants represented, investors could expect sustained revenue growth. If they did not, Baxter faced not only lost sales but also regulatory scrutiny and potential liability exposure that could materially impair the Company’s financial condition.

b. In Reality, And Known At Baxter, The Novum Remained Defective, Suffered From Myriad Software And Infusion Inaccuracy Problems, Impairing The Success Of The Launch

84. In truth, the Novum suffered from serious defects by the time it launched in the U.S., and Baxter had no viable means to resolve them, undermining any claim that the U.S. launch was successful. The evidence supporting this conclusion includes contemporaneous accounts from former Baxter employees, customer complaints, and Baxter’s own later admissions. As discussed

below, within 15 months of the Novum's release, Baxter acknowledged that the product was not fit for customer use and imposed an indefinite hold on Novum shipments.

85. Contrary to Defendants' claims that Baxter had resolved all "last minute" issues with the Novum LVP prior to launching in the U.S., former Baxter employees reported that the opposite was true. For example, FE-6,⁶ who personally participated in writing Baxter's regulatory submissions for the LVP, stated that Baxter had a slow rollout in Canada due to the immediate lack of buyers, and encountered quality problems with the Novum pumps in Canada in 2022.

86. Other former employees similarly reported facts directly contradicting Defendants' claims that the LVP was "*absolutely what it needs to go into the US market*" and they did not "*see any issues with infusion pumps,*" nor "*any issues with hospitals ordering things that we sell.*"

87. For example, FE-7 stated that the problems with the LVP were known in advance of releasing the product into the U.S. market.⁷ FE-7 worked on the side of the business concerning connected care products that Baxter sought to market with the Novum pumps. According to FE-7, the Company was exploring adding Novum pumps to the connected care products, but they never got added because the product had so many problems. Despite knowing the LVP was not going to perform properly, Baxter sold the pumps into the U.S. market anyway. FE-7 said that, once products are sold to customers, the pump life cycle meant it was possible to not see the customer

⁶ FE-6 was a Regulatory Affairs Manager at Baxter from September 2018 through April 2022. In his role, FE-6 supported pre-market products. He reported to Donna Haraden, Director of Global Regulatory Affairs, who reported to Senior Director, Kathy O'Neill, and then to VP Lynn Pawelski. Pawelski in turn reported to Tobi Karchmer, Baxter's Chief Medical Officer.

⁷ FE-7 was the General Manager of Care Communications & Collaboration at Baxter from September 2023 through February 2025. In this role, he worked on Baxter's efforts to add Novum pumps to the connected care products. He reported to Julie Brewer, who served as President, and later reported to Connected Care executive Donny Patel at the end of FE-7's tenure. Brewer reported to EVP and Group President, Reaz Rasul, who in turn reported to Defendant Almeida.

again for another ten years. Baxter was under pressure to get customers to purchase multiple connectivity products in order to drive revenue.

88. FE-7 stated that Donny Patel, President of Connected Care, was involved in actively up-marketing the popularity of the Novum pumps, even though they were defective. FE-7 stated that Baxter targeted the biggest hospital systems for contracts worth millions to hundreds of millions of dollars. FE-7 stated that in late 2024, FE-7 personally attended sales meetings with Baxter clients where the Company attempted to sell major hospital and health systems on switching their entire infusion pump fleets to the Novum Platform. For example, FE-7 recounted such meetings with Ascension, a major U.S. hospital operator with approximately 80 hospitals in multiple states, and HCA Healthcare, which had over 100 hospitals in its network. During these presentations, Patel pitched Novum pumps and connectivity features to customers. FE-7 stated that the connectivity features of Novum that Patel was promoting did not provide any real value. He further stated that Patel was notorious at Baxter for selling things that did not work.

89. FE-7 stated that Baxter executives who developed the Novum put big career investments into the pumps getting to market, even though it was widely known throughout the Company that the devices were defective. Thus, Patel was actively selling and promoting a product that was not ready for market. As FE-7 explained, Baxter was promoting the pumps on the bet Baxter was going to fix the product.

90. Unsurprisingly, given the ongoing defects in the product, former employees also reported facts contrary to Defendants' claims that, during the U.S. rollout, the Novum gave Baxter significant "competitive wins as well as replacements."

91. For example, FE-2 said that Baxter customers had problems with their Novum LVP devices from 2024 to 2025, including a problem with a "major partner" in the U.S. Moreover,

because of the infusion problems with the product, according to FE-2, the Novum was pulled *two weeks* prior to its planned release in the European market. As a result, he had to mitigate planning because Novum did not get released in Europe, even though he had already recruited clinical and sales teams across the region. Similar information contradicting Defendants' claims was reported by FE-1, who stated that in early 2025, Baxter learned that a major customer was experiencing life-threatening problems with the LVP device. As a result, Baxter lost significant business from the LVP defects. FE-1 stated that Baxter was desperate to solve these problems.

92. Further, contrary to Defendants' claims touting the Novum LVP's "good precision" and infusion accuracy, the devices suffered from design flaws and infusion inaccuracy problems from the very outset. For example, FE-8 reported that the Novum had design flaws that caused under-infusion problems with the pump.⁸ FE-8 stated that these infusion inaccuracy problems with the LVP were known by the time FE-8 started at the Company in June 2022 and persisted through the end of his tenure in May 2024. According to FE-8, the LVP suffered from problems that stemmed from flaws in the design of the device. These problems were known before the Novum launched in the U.S. in April 2024. FE-8 stated these flow rate issues could be significant with the LVP, resulting in the amount of medication being delivered incorrectly to patients while using the device. Confirming this defect in the pump, FE-8 reported that the tubing used with the LVP had to be very specific, since they knew it had under-flow-rate issues due to the design of the pump. As FE-8 explained, the flow rate issue with the tubing occurred because the Novum pump is horizontal while other infusion machines are typically vertical. The Company knew about this issue by no later than 2024, as it prepared its re-submission of the LVP to the FDA.

⁸ FE-8 was a former Research and Development Engineer at Baxter from June 2022 through May 2024. FE-8 worked on IV administration sets, including related to Novum.

93. According to FE-8, the Novum LVP also had issues with tolerance, i.e., the limit on how much infusion fluid can safely remain behind when the infusion is supposedly complete. FE-8 explained that if you have a 500ml bag and you want to make sure to deliver 100% of the medication, you have to account for a small amount of volume that may not be fully delivered. FE-8 reported that the LVP's flow rate accuracy tolerance was potentially more than 10%, which stood out to FE-8. As Baxter only later admitted in April 2025, this "10% variability"—which FE-8 stated was known within Baxter during his tenure, or before the U.S. launch—presented serious patient safety risks "of dehydration, inadequate drug therapy and nutrition, as well as insufficient blood infusion, leading to increased risk of morbidity and mortality."

94. Other former employees similarly confirmed these infusion inaccuracy problems with the LVP. For example, FE-2 stated that there were high volumes that the Novum LVP could not accurately deliver at infusion rates of 1,200 milligrams per hour, which the devices were supposed to be capable of handling. FE-2 explained that this was a serious problem. Over-infusion could have been catastrophic for an infusion pump; even a 1% deviation in infusion rates meant the device did not meet safety and quality standards.

95. Facts reported by former Baxter employees also confirm that, at the time of Defendants' statements touting the Novum's connectivity and "very good interface with the rest of hospital systems," the LVP could not reliably function with hospital networks. As noted above, FE-4 personally observed that the Novum had problems with wireless connectivity with hospital networks—a critical function for the device.

96. Consistent with these internal employee accounts and the Health Canada records discussed above, FDA records also reflected widespread problems and customer complaints that, in combination with the former employee accounts, provided Defendants with continued notice of

widespread and significant defects in the device. The FDA requires device manufacturers such as Baxter to “[s]ubmit reports of individual adverse events no later than 30 calendar days after the day that [the manufacturer] become[s] aware of a reportable death, serious injury, or malfunction.” 21 C.F.R. § 803.10(c)(1). The FDA relies on these reports to identify safety issues and allocate investigative and enforcement resources. The FDA collects the reports it receives from manufacturers, patients, and healthcare providers in its Manufacturer and User Facility Device Experience (“MAUDE”) database. Like their Canadian counterparts, these MAUDE reports are often minimal in details and individually can appear episodic and isolated. For Defendants, however, the pervasiveness, consistency, and volume of the MAUDE reports—along with the internal reporting and issues identified by Baxter’s former employees—put Defendants on ample notice of the problems with the Novum Platform, in particular with infusion-related problems and malfunctions. Indeed, as Baxter would later admit in a letter privately sent to customers in July 2025, “[f]rom June 2023 through May 2025, Baxter has received 79 reports of serious injury, and two reports of death potentially related to overinfusion or underinfusion.”

97. Between the date the FDA approved the Novum LVP in the United States on April 1, 2024 and July 2025, the MAUDE database shows nearly 1000 reports, sometimes resulting in serious patient injuries and patient deaths. Indeed, reports began funneling into the MAUDE database almost immediately after Baxter began distributing the product in the United States. Starting in June 2024, the MAUDE database received 41 different reports of problems with the LVP. This number skyrocketed in 2025 to over 900 such reports, including over 100 reports of serious patient injury.

98. Notwithstanding these persistent—even if barebones—MAUDE reports and internal knowledge about significant defects in the devices, Defendants and the Company

continued to disclaim any such problems with the device, claiming to not see “*any issues*” with infusion pumps and touting the device’s “*advanced safety features*,” “*good precision*,” and the success of the U.S. launch.

E. Defendants Continued To Reassure Investors And Customers About The Novum As Safety Problems Publicly Surface

99. In 2025, as Baxter continued to market and sell the LVP to customers in the U.S. and Canada and Defendants publicly touted its purported success in those markets, whistleblower and media reports began to surface, revealing problems with the device’s ability to deliver safe and accurate infusions. Yet even as these incidents arose, Defendants reassured investors and customers that the LVP remained a safe, reliable product and denied any systemic problems with the device.

100. On April 7, 2025, a Missouri news outlet reported that a whistleblower at BJC Health System, a major hospital system based in St. Louis, had raised serious safety concerns about inaccurate infusion rates with the LVP. The whistleblower reported that, within days of starting to use the LVP devices, hospital staff began observing and reporting major malfunctions, and warned that “patients should not be being treated with these pumps” because “[t]hese pumps are not safe.” The whistleblower provided documentation of a March 3, 2025 email to hospital staff reflecting that Baxter had been notified of the issues and claimed to be “providing additional in-servicing and problem solving.” However, consistent with former employees’ recollections that Baxter lacked permanent solutions to remediate the Novum issues, the whistleblower further stated that Baxter’s attempted fixes had not resolved the safety issues, characterizing them as “Band-Aid solutions.” In response to the reporters’ inquiries about Baxter’s defects with the LVP, an FDA spokesperson stated: “As a general matter, the FDA does not disclose internal discussions it may be having with any particular firm.” A follow-up report issued by the same news outlet on April

8, 2025 stated that the St. Louis hospital system first received the LVP “in late October [2024], and within days, staff started reporting problems.” The reporting also stated that BJC responded by removing all Novum LVPs from service.

101. Several weeks later, in late April 2025, Baxter issued a letter to U.S. and Canadian customers regarding under-infusion problems with the LVP. As Baxter wrote to customers, the LVP had the “potential for underinfusion” when using the pump’s “standby mode” feature—a routine function that allowed clinicians to temporarily pause and resume an infusion. Baxter told customers that its “testing” of the product revealed that infusion volumes could deviate “more than 10%” after keeping the device in standby mode for 2 hours and 30 minutes. As noted above, FE-8 reported that this flow rate tolerance problem with the LVP was known within Baxter during his tenure; this was well before Baxter purported to reveal this issue to customers and regulators. Yet Baxter reassured customers that, “customers can continue to use the [] LVP” provided that they did not use standby mode for more than “2 hours and 30 minutes,” and “[m]onitor[ed] patients frequently to ensure that the appropriate infusion is being delivered.” Baxter also reassured customers that “Baxter is developing a software update . . . to resolve the issue and will contact customers once the software update is available.”

102. As Baxter falsely reassured customers and the FDA that the LVP remained safe and reliable, Baxter also falsely reassured investors that the Novum remained commercially viable, providing a sustainable source of growth for the Company. For example, on May 13, 2025, Defendant Grade stated that “*continuous demand for Novum[] continues to remain strong.*” Similarly, on June 10, 2025, Defendant Grade told investors that Baxter had “*certainly continued progress from Novum*” and claimed that *Novum sales “continue[] to be a driver” of the “positive*

trends” for Baxter’s growth. Defendant Grade also told investors that the Novum “*product is performing really well.*”

103. On July 14, 2025, Baxter issued another letter to customers regarding the LVP, in which Baxter blamed potential user error for underinfusion issues with the Novum—issues the Company had been observing for years. In this communication, Baxter stated that the LVP had a “potential for underinfusion” when customers used it to perform routine functions that involved “transitioning from a lower to a higher flow rate.” The July 2025 letter further stated that, “[f]rom June 2023 through May 2025, Baxter has received 79 reports of serious injury, and two reports of death potentially related to overinfusion or underinfusion.” But Baxter claimed that the LVP reports of “over or underinfusion” “may be due to set misloading”—i.e., customers improperly connecting the device.

104. Baxter assured customers that the issue was fixable and did not prevent their continued use of the LVP. In the July 2025 letter, Baxter reassured customers it was “working to identify software and/or hardware corrections to address the issue.” Baxter further told customers that, as Baxter implemented these solutions, “[c]ustomers may continue to use the [] LVP.”

105. Yet contrary to Defendants’ repeated assurances to customers, the FDA and Health Canada, and investors, as discussed below, the LVP’s defects were so severe and systemic that they had no viable solution, and ultimately required a complete ship-hold on distribution and installation of all LVP devices worldwide.

F. Baxter’s Executives Were Kept Apprised Of The Novum’s Defects

106. Multiple former Baxter employees have confirmed that the Novum LVP’s defects were pervasive and widely known inside of Baxter, including by the Executive Defendants. These former employees reported facts showing that Defendants received specific information—through

multiple internal reporting channels—that directly contradicted the public statements they were making to investors about the Novum Platform’s safety, reliability, and market success.

107. For example, Baxter held quarterly management reviews at which Defendants Almeida, Knight, and Grade were regularly informed about the problems with the Novum LVP. According to FE-7, the C-suite was “informed about the problems with the LVP from regular meetings and quality reporting at Baxter.” FE-7 stated that Baxter held quarterly reviews in which Defendant Almeida, Defendant Knight, and the CFO attended, and “updates on Baxter’s regulatory applications for the Novum were consistently discussed.” FE-7 personally attended these reviews.

108. Beyond quarterly reviews, former employees confirmed that Baxter maintained internal quality reporting systems that ensured the Executive Defendants were regularly informed of the Novum’s defects and safety issues. According to FE-7, customer complaints and remediation issues “were tightly controlled and monitored within the organization.” Every customer complaint was monitored, such that issues with Novum pumps during a quality control process were catalogued. FE-7 stated that if issues arose with the Novum pumps, they would have been “color-coded for severity and presented to Almeida.” He explained that Defendant Almeida was “very hands-on” and “got into the trenches on the technical matters with the Novum pumps.” FE-7 explained that Almeida “fancied himself as being deeply into product technology” and, as “an engineer by education,” “dug in deeply into the technology, including testing mechanisms, quality control and tolerance levels for device errors.”

109. In addition to the internal reporting mechanisms described above, former employees confirmed that specific issues with the Novum LVP were known to Baxter’s executive leadership. FE-9 reported that Baxter maintained an internal list of hundreds of known software

bugs that posed quality issues.⁹ According to FE-9, C-suite members were aware of this internal bug list, including Defendant Almeida. In other words, rather than resolving these software bugs, Baxter’s leadership chose to release products with hundreds of known defects that remained on an internal tracking list. This contradicted Defendants’ repeated public assurances, such as Defendant Grade’s November 20, 2024 claim that Baxter’s Canadian rollout allowed the Company “to just work out any last minute kind of bugs and kinks,” resulting in “a really smooth and impactful rollout of Novum here in the US.”

110. Similarly, FE-8, who worked on an IV administration set for the LVP, noted tolerance problems with the LVP’s infusion capabilities during his tenure from 2022 to 2024. He stated that this tolerance problem was known during his tenure with Baxter. As FE-7 explained, Defendant Almeida would have been informed of these tolerance issues through Baxter’s internal quality reporting systems. He stated that, if such issues arose, they would have been “color-coded for severity and presented to Almeida.”

G. Information Regarding The Novum’s Impact On Baxter Financial Performance Emerges And Causes Significant Harm To Investors

111. On three separate occasions—July 31, 2025, October 30, 2025, and February 12, 2026—new information came to light that contradicted Defendants’ previous statements and revealed to the market that the Novum’s defects were significant enough to affect the Company’s financial performance. Each disclosure revealed only part of the picture, so the stock price did not fully correct until (at least) the final disclosure on February 12, 2026—the last day of the Class Period.

⁹ FE-9 was a Software Quality Assurance Tester from April 2021 to October 2025. In that role, he was involved in testing products at Baxter. In particular, his department was the last group to give a “stamp of approval” for a product, after it went through engineers and production processes.

1. Baxter Announces A Hold On Shipping And Installation Of All Novum LVP Pumps

112. On July 31, 2025—a mere fifteen months after the FDA cleared the Novum LVP for sale in the United States—Baxter shocked analysts and investors by revealing that, “a couple of weeks ago,” and in order “[t]o address feedback that has been identified through our ongoing quality procedures,” Baxter “decided to voluntarily and temporarily pause shipments and planned installations of the Novum LVP.”

113. In explaining the ship-hold, Defendant Knight drew a direct connection between the safety issues and defects of the device and the ship-hold, claiming that “with patient safety and quality really at the forefront of everything that we do as a company, this decision aligns with our mission focus as an organization.” In response to analyst questioning, Defendant Knight further explained “our decision to voluntarily institute the ship and implementation hold was really because we’re working transparently with our customers”—the very customers who were canceling orders and reporting significant problems, injuries, and even deaths—“[a]nd we wanted to stop and pause and take their feedback and make sure that we’re working through the interim mitigations with them.”

114. Baxter’s July 31, 2025 disclosures revealed the negative impact of the ship-hold on Baxter’s earnings. Only one quarter earlier, on May 1, 2025, Baxter issued EPS guidance of \$2.47 – \$2.55 per share, and sales growth guidance of 4%-5%, based on “double-digit growth for our U.S. infusion systems portfolio as the rollout of Novum IQ pump platform continues.” In announcing the ship-hold, however, Baxter lowered this guidance significantly, reducing its EPS guidance to \$2.42 – \$2.52 per share and its sales growth guidance to 3%-4%. In the earnings press release filed on July 31, 2025, Baxter attributed its guidance reduction to “downside risks

associated with factors primarily impacting the company's Medical Products & Therapies segment"—i.e., its segment containing the infusion pump business.

115. Analysts and investors were surprised by these disclosures given Defendants' repeated false and misleading statements touting the success of Novum and downplaying the product defects. For example, on July 31, 2025, the day Baxter announced the ship-hold, a Wells Fargo analyst report stated plainly that the "Novum IQ . . . sales pause came as a surprise." Indeed, underscoring the shocking nature of Baxter's ship-hold announcement, the LVP was launched in the U.S. only 15 months earlier. This compressed timeline from FDA clearance to ship-hold stands in stark contrast to industry norms, where post-market safety issues typically emerge gradually over years of commercial use—not within the first year of launch. Indeed, the rapidity with which the Novum's defects manifested to the extent that Baxter had to stop shipping the product underscores that these were the foreseeable consequences of pre-existing problems that Defendants knew or should have known before obtaining FDA clearance.

116. A day later, on August 1, 2025, Raymond James analysts similarly described the announcement as a "[s]urprise [s]lowdown." The Raymond James analysts also expressed their disappointment, noting that "BAX highlighted [the device] as a key growth driver." JP Morgan analysts also expressed their disappointment, stating "[i]t's disappointing to see Baxter taking two steps back" and "it's hard not to be disappointed" since the Novum LVP was "framed by management as [a] key growth opportunit[y]."

117. Analysts also drew a direct connection between the ship-hold announcement and the truth about defects with the product. Citigroup analysts noted that "during this pause management is working to incorporate customer feedback into the product [as well as an FDA Alert on Novum," later pointing out "it is unclear how much of the pause is in response to the alert

versus patient feedback, or both.” Raymond James analysts similarly explained “FDA notices identified issues for some users, but these issues have now escalated to the point where BAX has put the product on a voluntary ship/implementation hold.” Likewise, Wells Fargo analysts drew a direct connection between the “voluntarily paused sales” in order “to incorporate feedback from customers and fix under-infusion issue.” In other words, the very issues that former employees reported dogged the product for years and resulted in numerous incident reports was now causing the ship-hold. Other analysts from Jefferies and UBS similarly connected the pause to “quality procedures,” “customer insights,” and “customer quality checks.”

118. In response to these disclosures, the price of Baxter common stock declined \$6.29 per share, or 22.42%, from a closing price of \$28.05 per share on July 30, 2025, to a closing price of \$21.76 per share on July 31, 2025.

119. Despite revealing this negative information, Defendants continued to misrepresent and conceal the full truth through misrepresentations that downplayed the scope and severity of the issues behind the recall and hold. For example, during the July 31, 2025 earnings call, Defendant Knight repeatedly assured investors that the issues behind the ship-hold were “*transient in nature*,” involved “*a very small subset of clinical use cases*,” and were “*very different than maybe what you’ve seen historically with competitors*”—i.e., competitors like BD, whose lengthy, costly recalls of similar pump products exposed those companies to negative financial and legal repercussions, including for alleged securities fraud.

120. Along with continuing to tout LVP, Defendants misrepresented the true breadth of the problems with the device. Defendants’ July 31, 2025 statements were themselves false or half-truths for multiple reasons. First, Defendants characterized the issues as “transient” and affecting only a “very small subset of clinical use cases” when, as former employees confirmed, the defects

stemmed from fundamental design flaws that had plagued the device since before its Canadian launch and affected core infusion-accuracy functions across all use cases. Second, Defendants claimed they had “signed a number of new contracts” and that “customer receptivity” was “positive,” when in fact customers were canceling contracts and demanding refunds. Third, Defendants stated they “remain confident” in the platform and expected to resume shipments “as soon as possible this year,” when they knew or recklessly disregarded that the underlying design and software defects had not been resolved. In truth, as Baxter would only later publicly report in February 2026, the problems behind the ship-hold were so severe that they rendered the LVP out of compliance with regulatory requirements, such that they would require “regulatory clearance or approval” before Baxter could sell the device again.

121. Analysts continued to credit the Company’s representations about the Novum Products. For example, Citigroup analysts quoted management verbatim, stating that “while [Baxter] is not committing to an exact timing goal it is working to resume shipments ‘as soon as possible,’ believing it is transient in nature.” Based on Defendants’ statements, Jefferies analysts similarly identified the ship hold as “temporary” and “with a goal to resume shipments as soon as possible this year.” These analysts also listed the “Novum LVP pump returning to market” as a going forward “catalyst” for the company. Wells Fargo analysts put it succinctly, “[o]ur sense is that the company has a handle on the issue.”

122. The full truth concerning the severity of the Novum Products defects and the resulting financial impact remained hidden from investors and only emerged through subsequent disclosures.

2. Baxter Announces The Shipping And Installation Hold On The Novum LVP Will Continue “Beyond 2025”

123. On October 30, 2025, Baxter revealed additional “disappoint[ing]” news “related to the pause . . . on deliveries and installations of the Novum IQ Large Volume Pump.” During the October 30, 2025 earnings call, Baxter’s then CEO Andrew Hider disclosed that Baxter missed its guidance, stating “[o]ur third quarter top line performance came in lower than our previously issued guidance.” Hider revealed that Baxter’s poor performance “reflect[ed] challenges” within “the Infusion Therapies & Technologies division” containing Baxter’s Novum LVP pump business.

124. As Hider disclosed, these “challenges” “hampered [Baxter’s] growth and consistent execution” during the quarter. Turning specifically to the “critical area” of the Novum recall and hold, Hider disclosed, “we’re disappointed that we expect the current hold to remain in place beyond year-end.” When asked by analysts why the shipping hold was “taking longer” to lift, Defendant Grade stated, “we’re unable to commit to specific timing around the ship and install for Novum LVP. We do anticipate this still being in place beyond 2025.” During the call, Baxter revealed that it had not even identified a way to fix the defects, let alone implement one. As Hider stated, “We are working tirelessly to evaluate and test potential corrections to fully resolve the flow rate issues.”

125. During the earnings call, Defendant Grade disclosed additional information concerning the disastrous financial impact of the Novum recall and hold. Defendant Grade revealed that third quarter sales in the ITT division “declined 4%, primarily reflecting lower infusion pump sales due to the previously discussed ship and installation hold of Novum LVP.” In other words, contrary to Defendants’ repeated public claims that the Novum LVP would unlock significant additional revenue, the Novum LVP dramatically reduced sales by 4% in a single quarter because of the safety problems with the Novum, which as explained above, Defendants

were aware of throughout the Class Period. Defendant Grade further disclosed that the “[s]ales decline in Infusion Systems” caused by the recall and hold included both “lost sales” and “Novum LVP customer returns.”

126. Defendant Grade also revealed that the Company’s disastrous rollout of the Novum LVP cost the Company significant market share. Contrary to Defendants’ repeated claims to investors that the Novum LVP would unlock 2% per year market share gains, Defendant Grade disclosed that “the timing and nature of the resolution of the Novum LVP hold is leading some customers to evaluate alternative solutions.”

127. Defendants also slashed Baxter’s sales guidance based on “the Novum situation.” For example, during the October 30, 2025 call, Defendant Grade disclosed that, “[f]or MPT, we now expect sales to be flat to 1%, reflecting the uncertainty around the Novum situation as discussed previously.” That was in sharp contrast to the 4%-5% sales growth Defendants had repeatedly told investors that Baxter would achieve as a result of the Novum LVP, and the reduced guidance Baxter had issued only one quarter earlier.

128. Analysts and investors were surprised by these disclosures. Wells Fargo analysts stated plainly that the “[m]agnitude of BAX’s 2025 guide reduction was unexpected implying limited line of sight into the recovery time frame in LVP.” Analysts at JP Morgan lamented that “following the voluntary pause on Novum shipments and planned installations, the company now expects the hold to remain in place beyond year-end, which is a longer timeline than expected relative to prior commentary from last quarter.”

129. Analysts were also disappointed by the lack of clarity from the Company. As analysts from Barclays bluntly put it, “Disappointing results and limited 2026 visibility have sank the stock.” The Barclays analysts further explained “[i]t is clear to us that there is some confusion

among investors and the Street regarding the voluntary pump ship-hold announced in July.” JP Morgan analysts similarly noted that “[i]t’s become painfully clear that business trends have yet to stabilize at Baxter as challenges to major growth drivers like Novum . . . are set to linger into 2026.” Wells Fargo analysts also elaborated that while the “new CEO sounded hopeful that sales can grow next year . . . it appears uncertain w/ headwinds from Novum IQ . . . expected to continue into 2026 . . . timing of Novum IQ return is uncertain.”

130. Other analysts also noted the competitive impact the now continued shipping hold was having on Baxter. Citigroup analysts noted that “Novum pump continues to be on hold, next steps unclear . . . Management continues to work with customers [but] some are leaving for other solutions.” Deutsche Bank analysts similarly noted that “the ship-hold is now leading to competitive losses for pump placements.” Likewise, UBS analysts explained that “BAX noting that some customers have ‘started seeking alternatives.’”

131. In response to these disclosures, the price of Baxter common stock declined \$3.26 per share, or 14.54%, from a closing price of \$22.42 per share on October 29, 2025, to a closing price of \$19.16 per share on October 30, 2025. Baxter’s stock price continued to decline the following day, falling an additional \$0.69 or 3.6% to a closing price of \$18.47 per share on October 31, 2025.

132. However, Defendants failed to reveal the full truth and continued to mislead investors. During the October 30, 2025 earnings call, Defendant Grade responded to a question about the Novum hold by stating “the thing I’d like to reinforce as much as anything is we remain confident in our Novum Spectrum Infusion platforms.” This confidence evidently calmed investors enough, as one analyst noted, their “base” scenario “expect[ed] Novum IQ sales to resume in 26” with upside for “Novum IQ sales to resume in 1H26.” Defendants continued to

mislead through the end of 2025. For example, on December 2, 2025, Defendant Grade reassured investors that “[*there are*] a number of customers that are able to safely use our pump, and [*there are*] certain protocols that we’ve put out in order to do that.” Thus, Defendants continued to assure investors that the Novum did not suffer from defects so severe they rendered the product unfit for sale and customer use.

133. Analysts continued to credit the Company’s representations about the Novum Platform. Indeed, the same Barclays analysts who lamented that the announcements “sank the stock” also cautiously explained that “[f]or pumps, the company remains committed to resolve the ship-hold on Novum pumps.”

3. Baxter Discloses The Ship Hold Will Continue Through 2026, Causing Further Financial Harm To The Company

134. Finally, on February 12, 2026, Baxter revealed that the ship-hold would continue through at least the end of the year due to the LVP’s continued unmarketability due to unresolved defects. In particular, Baxter revealed that it had yet to finish “developing additional corrections related to these recalls,” and indicated that the changes it was contemplating were so significant that they “may require regulatory clearance or approval.”

135. In reporting Baxter’s fourth-quarter and full-year 2025 results, Baxter disclosed that the MPT Segment suffered from “reduced sales in infusion systems due to the previously disclosed shipment and installation hold of the Novum IQ LVP.” With respect to Baxter’s ITT business unit in particular, Baxter disclosed that “Infusion Therapies & Technologies net sales were flat for the year ended December 31, 2025, as compared to the prior year period. Sales performance in 2025 was primarily driven by lower sales as a result of the ship and installation hold on Novum LVP.”

136. During the earnings call that day, February 12, 2026, Defendants disclosed additional negative information. In his prepared remarks, Defendant Grade disclosed that “[i]n infusion systems, results in the quarter reflected the net impact of lost sales due to the ongoing shipment and installation hold of the Novum LVP, customer returns, and transitions to Spectrum.” Defendant Grade also revealed that customers were still “waiting for additional clarity on the nature and timing of additional corrections that we will look to deploy and of the release of the ship and installation hold.” As Hider elaborated during the call, “our customers are a bit of a wait-and-see mode still, and therefore, as we referenced last quarter, there’s an ongoing risk for customer responses there”—i.e., additional returns of the Novum Products, resulting in costly refunds and continued market share losses as customers switched to Baxter’s competitors. Hider further disclosed that “uncertainty around customer . . . really carries into this year.”

137. In explaining Baxter’s guidance for the fiscal year 2026 on the earnings call, Defendant Grade stated that the shipping and installation hold on the Novum would continue for the full year: “This reflects the continued uncertainty around the Novum situation, including the potential impact from various customer responses. It also reflects the assumption that the ship and installation hold will remain in place for the full year.”

138. In the 2025 Form 10-K filed on February 12, 2026, Baxter revealed that, “[w]e have recorded estimates for sales reductions, for returns or exchanges of Novum LVP, and certain other charges, including estimates of reserves for remediation costs and inventory and contract asset write-downs associated with these Novum LVP corrections of approximately \$105 million in the aggregate in 2025.” The 2025 Form 10-K further disclosed, “[t]he timing of the release of the ship and installation hold remains uncertain. As a result, we expect no meaningful sales of Novum LVP while these holds are in effect.” The Form 10-K also stated that, despite Baxter having purportedly

“implemented certain corrections related to the recalls,” Baxter had yet to finish “developing additional corrections related to these recalls, some of which may require regulatory clearance or approval.” As Hider further disclosed in response to analyst questions during the earnings call that day, Baxter had yet to “identify[] the longer-term solution set” for the defects that sidelined the Novum LVP.

139. These disclosures were contrary to Defendants’ prior assurances to investors. For example, in announcing the ship-hold in July 2025, Defendants represented the issue with the LVP was “*transient*” and affected only “*a very small subset of clinical use cases.*” Further, in December 2025, Defendant Grade had reassured investors that, despite the ship-hold, customers were “*able to safely use our pump,*” *due to Baxter’s safety “protocols that we’ve put out” for the device.*” Yet in contrast to these assurances, Baxter’s February 2026 disclosures now revealed that the Company had no viable long-term solutions to render the product safe for sale—and the only solutions it was exploring would “require regulatory clearance or approval,” thus exposing the Company to indefinite loss of sales and market share Defendants had represented the Novum would generate.

140. In response to Baxter’s February 2026 disclosures, Citigroup analysts also framed the 2026 guidance as disappointing, noting that “2026 guidance fell short of expectations weighing on shares.” Wells Fargo reported dismay for investors that Baxter’s disclosures “alluded to potentially more customer returns” and noted that Baxter’s announcement of the continued ship-hold “could prompt more returns” as customers grew increasingly worried about the safety of the pumps.

141. In response to these disclosures, the price of Baxter common stock declined \$3.56 per share, or 15.99%, from a closing price of \$22.27 per share on February 11, 2026, to a closing price of \$18.71 per share on February 12, 2026.

* * *

142. When the information detailed above was disclosed to investors, the share price of Baxter’s common stock fell significantly. As a result of these disclosures, Baxter’s stock price decreased *\$9.34 per share*, representing a *33.29% decline*, from a closing price of \$28.05 on July 30, 2025, to a close of \$18.71 on February 12, 2026. Each disclosure revealed information that had been concealed from investors and that directly contradicted specific prior misstatements: (1) the July 31, 2025 disclosure revealed that the defects were severe enough to require halting all shipments—contradicting Defendants’ prior statements that the Novum was a “resounding success” and that any issues had been “worked out”; (2) the October 30, 2025 disclosure revealed that Defendants had not even identified a solution to the defects and the hold would extend beyond year-end—contradicting their July 2025 assurances that the problems were “transient” and affected only a “very small subset of clinical use cases”; and (3) the February 12, 2026 disclosure revealed that Baxter had still not identified a “longer-term solution,” would require new regulatory approval, and had recorded \$105 million in reserves for returns or exchanges—contradicting Defendants’ repeated assurances of confidence in the platform and that customers could “safely use” the pump. Each time this information reached the market, Baxter’s stock price dropped sharply on heavy trading volume. Collectively, these corrective disclosures wiped out billions of dollars in shareholder value.¹⁰

¹⁰ A “corrective disclosure,” as used in the caselaw and this Complaint, is information that “corrects” the issuer’s stock price by removing “artificial inflation” in the stock price that had been

143. Because of Defendants’ alleged misstatements and half-truths, Baxter’s stock traded at prices higher than it would have if investors had known the truth. Lead Plaintiffs and other Class members bought Baxter stock at these inflated prices, trusting that the market price reflected accurate public information about the Company. When the corrective information came out and the stock price fell, Lead Plaintiffs and other Class members who had purchased at inflated prices suffered losses.

144. The disclosures that partially corrected the market price of Baxter’s common stock and reduced the artificial inflation caused by Defendants’ materially false and misleading statements and half-truths are summarized below:

Date*	Disclosure Summary	Closing Stock Price	Common Stock Price Change
July 31, 2025 (July 31, 2025)	Baxter shocked analysts and investors by revealing that Baxter had “decided to voluntarily and temporarily pause shipments and planned installations of the Novum LVP.” Baxter also lowered its full-year 2025 guidance, attributing the reduction to “downside risks associated with factors primarily impacting the company’s Medical Products & Therapies segment.”**	\$21.76	-\$6.29 (-22.42%)
October 30, 2025 (October 30-31, 2025)	Baxter revealed that the shipping and installation hold on the Novum LVP would continue “beyond 2025.” Defendants disclosed that Baxter had not yet identified a way to fix the defects, that third quarter sales in the ITT division “declined 4%” due to the hold, and that the Company was losing customers as “some customers” were starting to “evaluate alternative solutions.”	\$18.47	-\$3.95 (-17.62%)

created by Defendants’ misstatements or half-truths and thereby proximately causes investors’ losses.

Date*	Disclosure Summary	Closing Stock Price	Common Stock Price Change
February 12, 2026 (February 12, 2026)	Baxter disclosed that the shipping and installation hold on the Novum LVP would continue for the full year 2026. Defendants also revealed that Baxter had yet to “identify[] the longer-term solution set” for the defects. Baxter disclosed reserves of approximately \$105 million for sales reductions, returns, remediation costs, and inventory write-downs associated with the Novum LVP.	\$18.71	-\$3.56 (-15.99%)
<i>*Date of stock price drop is in parentheses.</i> <i>**Reflects disclosure made before market open.</i>			

145. It was entirely foreseeable to Defendants that their materially misleading statements regarding the key drivers of Baxter’s revenue and profitability would artificially inflate the price of Baxter’s common stock. It was foreseeable to Defendants that the price of the Company’s securities would fall as the artificial inflation caused by Defendants’ misstatements and half-truths were removed. Thus, the economic losses (*i.e.*, damages suffered by Lead Plaintiffs and other members of the Class) were a direct, proximate, and foreseeable result of Defendants’ materially false and misleading statements, which artificially inflated or maintained the price of the Company’s common stock, and the subsequent significant decline in the value of the Company’s common stock when the relevant truth was revealed.

V. ADDITIONAL INDICIA OF SCIENTER

146. The facts detailed above and summarized below, when viewed holistically and together with all the other allegations in this Complaint, establish a strong inference that each of the Defendants knew or were severely reckless in not knowing that each of the misrepresentations and half-truths alleged herein would be, and were, misleading to investors at the time they were made.

147. Defendants' scienter is supported by, among other things: (i) repeated regulatory and safety events before and during the Class Period that placed Defendants on notice of serious defects in the Novum Platform and related software; (ii) former Baxter employees' accounts confirming that the Novum's defects and FDA issues were pervasive, internally discussed, and escalated to senior leadership; (iii) Defendants' compensation incentives tied to sales, growth, and financial performance; (iv) Defendants' repeated, specific statements in response to direct analyst questions about the very topics on which they were misleading investors; (v) the wave of senior executive departures during and after the unraveling of the Novum LVP launch; and (vi) the fact that Novum concerned a core, mission-critical product line for Baxter.

A. Repeated Regulatory And Safety Events Before And During The Class Period Placed Defendants On Notice Of Serious Defects In The Novum Platform And Related Software

148. Defendants knew—or were severely reckless in not knowing—that their statements about the Novum Platform's safety and reliability were false and misleading. Throughout the Class Period, Defendants were confronted with repeated regulatory events and safety signals that placed them on direct notice of serious defects in the Novum LVP and its associated software. These regulatory events were addressed directly to Baxter, demanded responses from senior executives, and required formal corrective actions. The accumulation of these events during the Class Period—including multiple Class I recalls, formal device corrections, and mounting adverse event reports tied to patient injuries and deaths—created a pattern of regulatory red flags that executives with direct oversight of the Novum Platform could not have ignored.

149. The publicly available information revealed only a fraction of the facts available to Defendants. Ordinary investors, reviewing a recall notice or media report, would have no way of knowing the internal deliberations, early warning signals, regulatory correspondence, and escalation processes that brought those events to senior leadership's attention long before they

became public. As detailed below, the regulatory events that ultimately reached the public domain were the visible manifestations of far deeper institutional knowledge that Defendants possessed and concealed.

150. Under FDA regulations and industry practice, recalls are the product of extensive, senior-level deliberation within the Company. When quality problems arise, manufacturers are required to implement Corrective and Preventive Action (CAPA) procedures that include investigating the cause of nonconformities, identifying corrective actions, and “submit[ting] relevant information on identified quality problems, as well as corrective and preventive actions, for management review.” 21 C.F.R. § 820.100(a)(7). In other words, by the time a company like Baxter initiates a recall, issues a device correction letter, or reports adverse events to the FDA, the underlying quality problem has already been identified, escalated through the organization’s quality management hierarchy, reviewed by senior leadership, and approved for corrective action.

B. Former Employees Confirm That Defects With The Novum LVP Were Pervasive And Widely Known Inside Of Baxter, Including To The Executive Defendants

151. Baxter experienced numerous safety incidents, customer complaints, and recalls during the Class Period. As multiple former employees confirmed, these developments and facts were internally reported and known to Defendants throughout the Class Period.

152. For example, according to FE-7, the problems with the LVP were known to the Company’s executive leadership, including Baxter’s CEO Almeida. He explained that Defendant Almeida was very hands-on in the lab and got into the trenches on the technical matters with the Novum pumps. For example, Almeida fancied himself as being deeply into product technology. Almeida was an engineer by education and dug deeply into the technology, including testing mechanisms, quality control and tolerance levels for device errors. FE-7 stated that Almeida and the rest of the C-suite were informed about the problems with the LVP from regular meetings and

quality reporting at Baxter. For example, Baxter held quarterly reviews, in which Defendant Almeida, Defendant Knight, and the CFO attended, and updates on Baxter's regulatory applications for the Novum were consistently discussed. FE-7 personally attended these reviews.

153. Almeida was also aware of problems with the Novum pumps from Baxter's internal quality reporting systems. According to FE-7, customer complaints and remediation issues were tightly controlled and monitored within the organization. Every customer complaint was monitored, such that issues with Novum pumps during a quality control process were catalogued. FE-7 stated that, if issues with the LVP arose, they would have been "color-coded for severity and presented to Almeida."

154. Similarly, FE-6 confirmed that when there were negative developments, his direct supervisors Haraden and Adalpe, and VP Pawelski were in charge of breaking the bad news to senior leadership and the CEO about the Novum.

155. These former employee accounts establish that the Executive Defendants were regularly informed about problems with the Novum LVP through multiple internal reporting channels, including quarterly management reviews, monitoring through complaint tracking systems, and direct escalation of field actions and corrective actions to the C-suite. Despite this knowledge, Defendants continued to make false and misleading statements touting the Novum Products to investors.

C. The Executive Defendants Were Financially Motivated To Mislead Investors By Their Compensation Plan

156. Under Baxter's compensation plan, the Executive Defendants were compensated through three elements: base salary, a variable annual cash incentive, and long-term equity incentives, consisting of performance share units ("PSUs"), stock options, and restricted stock units.

157. During the Class Period, on average, more than 80% of each Executive Defendant's pay was determined by achieving certain performance metrics and stock-price performance. This pay-for-performance design incentivized the Executive Defendants to misrepresent and conceal the problems experienced by Novum. As detailed below, the Executive Defendants reaped substantial financial benefits in the form of cash bonuses and stock units by achieving several performance metrics tied to Novum's safety and the Company's sales growth, which was propped up by Defendants' misstatements and half-truths concerning problems with Novum and its rollout.

1. Defendants Received Substantial Annual Cash Bonuses Tied To Safety And Quality

158. During the Class Period, the Executive Defendants earned millions of dollars in annual cash bonuses that were funded, in part, by the achievement of performance and qualitative metrics tied to Defendants' misstatements and/or half-truths concerning Novum.

159. Each Executive Defendant's annual cash incentive was determined by a fixed formula with two performance multipliers applied to the Executive Defendants' target bonus—Financial Performance (0%-200%) and Individual Performance Assessment (0%-125%). The financial performance multiplier is measured through three metrics—Adjusted Net Sales (weighted 50%), Adjusted EPS (weighted 25%), and Free Cash Flow (weighted 25%), with Baxter placing “greater emphasis on Adjusted Net Sales” to “recognize the criticality of continuing organic sales growth.” The individual performance assessment multiplier is measured against several strategic-priority categories, the largest of which was “Patient Safety and Quality.” In 2021, Patient Safety and Quality carried a 50% weighting within the individual performance assessment. For 2022, 2023, and 2024, Patient Safety and Quality was weighted at 40%, the largest of the three categories, with Best Place to Work and Growth Through Innovation each weighted

at 30%. For 2025, Baxter restructured the individual performance assessment so that it was based 50% on “People Metrics” and 50% on “Quality Metrics.”

160. Accordingly, the Patient Safety and Quality component of the annual incentive gave the Executive Defendants a direct financial motive to conceal Novum’s defects, because the metric expressly rewarded executives for reporting that Baxter’s products were safe, that its quality systems met internal benchmarks, and that Baxter had received no new regulatory actions. Similarly, Adjusted Net Sales was supported by continued Novum sales, and therefore further incentivized the Executive Defendants to conceal the material problems with Novum as long as possible.

161. For 2022, Baxter’s financial performance produced a weighted payout of only 35% of target: Adjusted Net Sales reached 97.0% of target for a 69% payout, while Adjusted EPS and Free Cash Flow each fell below threshold and paid 0%. In contrast, Patient Safety and Quality paid out at a full 100%, because “no new Warning Letter or global equivalent was issued during 2022.” Accordingly, Defendant Almeida received \$675,675 against a target annual incentive amount of \$2,145,000 (approximately 52% of his \$1,300,000 base salary) and Defendant Saccaro received \$267,750 (approximately 31.5% of his \$850,000 base salary).

162. For 2023, Baxter’s financial performance produced a weighted payout of 102% of target for Defendants Almeida and Grade and 97% of target for Defendant Knight: Adjusted Net Sales reached 101.0% of target for a 121% payout; Adjusted EPS achieved 100.6% of target for a 112% payout; and Adjusted Free Cash Flow was below target for a 56% payout. Defendant Knight’s financial performance payout was separately measured on Medical Products and Therapies segment’s Adjusted Net Sales, which reached 100.7% of target for a payout of 100%. Patient Safety and Quality paid out at 105%, with Defendants stating that although one new

Warning Letter was received in 2023, “the company met its internal benchmarks for other key areas, including Food and Drug Administration observations.” Accordingly, Defendant Almeida received \$2,187,900 against a \$2,145,000 target (approximately 168% of his \$1,300,000 base salary); Defendant Grade received \$167,671 (102% of his \$164,384 base salary); and Defendant Knight received \$771,091 (approximately 96% of her \$800,000 base salary).¹¹

163. For 2024, Baxter’s financial performance produced a payout of 96% of target for Defendants Almeida and Grade and 92% of target for Defendant Knight: Adjusted Net Sales was 101.1% of target for a 122% payout; Adjusted EPS was 94.5% of target for an 86% payout; and Adjusted Free Cash Flow was below target for a 53% payout. Defendant Knight’s financial performance payout was separately measured on Medical Products and Therapies segment’s Adjusted Net Sales, which reached 100.7% of target for a payout of 100%. Patient Safety and Quality paid out at 103%, with Defendants again asserting that the Company “met its internal benchmarks in key areas such as CAPA (Corrective and Preventative Actions) effectiveness and product quality, notwithstanding the incurrence of certain regulatory actions.” Accordingly, Defendant Almeida received \$2,016,300 against a \$2,145,000 target (approximately 155% of his \$1,300,000 base salary), Defendant Grade received \$839,608 against an \$812,000 target (approximately 103% of his \$812,000 base salary), and Defendant Knight received \$1,039,500 against a \$945,000 target (approximately 116% of her \$900,000 base salary).

164. For 2025—the year the Company finally disclosed the truth about Novum and implemented a mid-year ship-hold on the Novum LVP—Baxter’s financial performance resulted in a dramatically reduced payout of 54%: Adjusted Net Sales reached 97.6% of target for a 76%

¹¹ Defendants Grade and Knight each received a prorated amount of their annual cash incentive for their partial-year service.

payout; Adjusted EPS was 85.8% of target and produced a 64.4% payout; and Free Cash Flow was below threshold and paid 0%. Baxter's restructured individual performance assessment scored People Metrics at 110% but Quality Metrics at only 90%, for a final weighted assessment of 100%. The reduced quality score reflected "two new regulatory actions for 2025"—the FDA recalls arising from the very Novum defects the Executive Defendants had concealed. Accordingly, Defendant Grade received \$459,000 against an \$850,000 target (54% of his \$850,000 base salary).¹²

165. As such, while actively mispresenting and concealing material problems with Novum and falsely touting its rollout, the Executive Defendants collected millions of dollars in annual cash bonuses that depended on the very quality and sales metrics their concealment protected, including Defendant Almeida's \$2,187,900 for 2023 and \$2,016,300 for 2024, Defendant Grade's \$839,608 for 2024, and Defendant Knight's \$1,039,500 for 2024.

2. Defendants Received Substantial PSU Awards

166. The Executive Defendants also received, and stood to receive, "Performance Stock Units" ("PSUs"), giving them a sustained incentive throughout the Class Period to maintain Baxter's reported sales, returns, and stock price at artificially inflated levels by concealing problems with Novum and its rollout. Specifically, the vesting of PSUs is subject to a three-year performance period and is measured by the achievement of the following performance metrics: Total Shareholder Return ("TSR"), Adjusted Return on Invested Capital ("ROIC"), and Adjusted

¹² Defendant Knight forfeited her 2025 annual incentive opportunity in connection with her departure, and Defendant Almeida was not eligible for any bonus under the 2025 annual incentive plan.

Net Sales Compound Annual Growth Rate (“CAGR”).¹³ The weighting for the three metrics also changed during the Class Period. For 2023, each metric was weighted equally at 33.3%. For 2024, TSR was the only performance metric used due to “complexity in setting three-year financial PSU targets to accurately reflect performance before and after the sale of [Baxter’s] Kidney Care business.” And for 2025, ROIC and CAGR were each weighted at 50%, with TSR as a modifier applied to that financial result at 120% for performance above the 75th percentile, 100% between the 25th and 75th percentiles, and 80% below the 25th percentile.

167. These metrics gave the Executive Defendants a direct financial incentive to mispresent and conceal the problems with Novum and its rollout because each one depended on Novum’s success. For example, CAGR and ROIC would have fallen had Defendants disclosed Novum’s defects, paused its shipping, and incurred the resulting remediation costs, returns, and inventory write-downs. Likewise, Baxter’s stock price and its stock performance were artificially propped up so long as the Executive Defendants continued to conceal problems with Novum and its rollout. Further, because PSUs vest only at the end of a three-year performance period, and only to the extent the specified metrics are achieved, the Executive Defendants, whose PSU performance periods ran through the Class Period, were financially incentivized to keep the metrics as high as possible until each period closed.

¹³ According to Baxter’s Proxy, TSR measures Baxter’s stock’s performance against similar companies’ stock performance in the S&P 500 Healthcare Equipment & Services Index. Adjusted ROIC performance is measured by considering each applicable calendar year’s adjusted operating income less adjusted income tax expense, divided by average invested capital and adjusted for any business or asset acquisition or divestiture with annualized revenue of greater than \$75 million at the time of the acquisition or divestiture. CAGR is calculated by taking Adjusted Net Sales for the last calendar year of the three-year performance period and comparing it against Adjusted Net Sales for the calendar year immediately preceding the grant date.

168. The PSUs the Executive Defendants received during the Class Period were substantial, and each had a performance period that overlapped with the Class Period. For the 2023 PSU grant, which had a performance period from January 1, 2023 through December 31, 2025, Defendant Almeida received a target of 135,769 PSUs (maximum 271,538 shares) with a grant date fair value of \$4,875,920, Defendant Saccaro received a target of 44,433 PSUs (maximum 88,866 shares) with a grant date fair value of \$1,595,738, Defendant Grade received a target of 50,378 shares (maximum 100,756 shares) with a grant date fair value of \$1,693,042, and Defendant Knight received a target of 43,199 PSUs (maximum 86,398 shares) with a grant date fair value of \$1,551,426.

169. For the 2024 PSU grant, which had a performance period from January 1, 2024 through December 31, 2026, Defendant Almeida received a target of 142,891 PSUs (maximum 285,782 shares), valued at \$8,176,223 on the grant date, and Defendant Grade received a target of 42,867 PSUs (maximum 85,734 shares), valued at \$2,452,850 on the grant date.

170. For the 2025 PSU grant, which had a performance period from January 1, 2025 through December 31, 2027, Defendant Grade received a target of 59,075 PSUs (maximum 118,150 shares), and Defendant Knight received a target of 71,347 PSUs (maximum 142,694 shares), with target grant date values of approximately \$2,280,295 and \$2,753,994, respectively.

171. The Executive Defendants ultimately realized the benefit of these incentives when the PSUs vested and converted into Baxter common stock. Specifically, the 2023 PSUs were measured against the same metrics and certified at 57% of target in February 2026, with TSR at the 3rd percentile paying nothing, ROIC of 6.2% against a 7.2% target paying 67%, and CAGR of 3.0% against a 2.9% target paying 105%. As a result, at vesting, Defendant Almeida earned 83,386

shares, valued at approximately \$2,933,245, and Defendant Grade received 30,505 shares, valued at approximately \$1,073,065.¹⁴

172. In sum, throughout the Class Period, more than 80% of each Executive Defendant's compensation turned on the very metrics that Novum's undisclosed defects would have depressed. The Executive Defendants were therefore financially motivated to conceal and misrepresent the problems with Novum and its rollout, and they collected millions of dollars in annual cash bonuses and vested equity through their misrepresentations to investors.

D. Departures Of Baxter's Executives Involved With The Novum Support Scierter

173. The circumstances surrounding executive departures of those involved in developing and launching the Novum Products further support scierter. Defendant Knight's departure from Baxter was particularly suspicious given her central role in the Novum Products that were subsequently recalled and put under the ship-hold. Knight was promoted to Chief Operating Officer in February 2025 based on her leadership of the Novum launch. As Knight stated during Baxter's Q1 2024 Earnings Call, she "spearheaded numerous vital initiatives . . . including the recent successful launch of our Novum IQ infusion pump platform in the United States." During the February 20, 2025 earnings call, Knight described the Novum launch as "a pretty big bet" and investors were "seeing it pay off." Yet only months later, after the Novum LVP was subject to a Class I Recall and a shipping and installation hold, Knight departed the Company. The timing of Knight's departure, coming after the very product she championed was revealed to be

¹⁴ The value of PSUs is determined by the closing price of Baxter's common stock on the vesting date. Further, Defendant Knight forfeited her 2023 PSUs in connection with her departure in 2025. Likewise, because of Defendant Saccaro's departure in 2023, he forfeited his 2023 PSUs.

defective, strongly supports an inference that Defendants knew about the problems with the Novum LVP when they were making false statements touting the Platform to investors.

174. Similarly, Defendant Almeida's sudden retirement in February 2025, in the middle of Baxter's efforts to both market the Novum Products and quell customer concerns over the products' safety, further supports the inference of scienter. Analysts and commentators described Defendant Almeida's departure as "abrupt" and without warning. For example, on February 3, 2025, Evercore ISI analyst Vijay Kumar noted that investors would likely question the "abrupt nature of" Defendant Almeida's departure. The timing of Defendant Almeida's departure, in the midst of a tumultuous make-or-break time for the Company, strongly supports an inference that Defendants knew about the problems with the Novum LVP when they were making false statements touting the Platform to investors.

E. Defendants' Statements Concerned Matters Critical To Baxter's Success And Demonstrated Their Knowledge And Familiarity With The Topics Of Their False Statements

175. That the Novum Products were a critical source of growth for the Company and were central to Defendants' representations to investors also supports scienter. Throughout the Class Period, Defendants repeatedly emphasized the Novum Platform's importance to Baxter's business. For example:

- June 5, 2024: Grade described the Novum LVP as a "key element" for Baxter's growth.
- September 5, 2024: Grade stated that the Novum would "continue to be a growth driver in MPT."
- November 20, 2024: Grade concluded that Novum was "a key driver from a growth standpoint" for Baxter in 2025.
- January 13, 2025: Almeida stated that "the launch of Novum has been fundamentally important for the growth of this business in 2025 and beyond."

- February 20, 2025: Knight stated that Baxter placed “a pretty big bet” on the Novum and was “seeing it pay off,” calling it “a huge key part of [Baxter’s] innovation” and “a great success story.”

176. Moreover, Defendants often spoke with specificity and frequently in response to direct analyst questions about the very topics of their false statements. These detailed, affirmative representations demonstrate that Defendants closely tracked the Novum Products and possessed intimate knowledge of and familiarity with their development, performance, and role in the Company’s growth strategy.

177. For example, as described above, during the Class Period, each of the Executive Defendants made multiple statements touting the Novum Products to investors:

178. **Defendant Almeida**: repeatedly touted the Novum Products to investors. For example, on April 28, 2022—the same day Baxter announced the FDA had placed the Novum LVP application “on hold”—Defendant Almeida stated, “We have this product currently working in Canada and is, from my perspective, a great product. . . . We designed that from scratch. It was the first electromechanical product designed by Baxter from scratch. We put the resources in place and we’re still very optimistic about what it can do in the marketplace. So it’s a great technology.” On October 27, 2022, Defendant Almeida told investors that Baxter had “successfully resolved the issue that was the primary subject of the FDA’s last additional information request” and that Baxter would “submit data that we believe demonstrate successful resolution of the issue.”

179. **Defendant Knight**: made statements touting the Novum Products, including that she “spearheaded” Baxter’s rollout of the LVP. For example, On May 25, 2022, during the Company’s 2022 Investor Conference, Defendant Knight stated that Baxter’s “customers in Canada are already enjoying [the Novum] platform today, and we’re getting great feedback. . . . I’m optimistic as ever about the launch of Novum IQ.” She further stated that “[w]e’ve also designed Novum IQ to be 95% field serviceable” and that “[t]hose are game changers in the

industry . . . we're already seeing the benefits in markets in Canada.” Further, on February 20, 2025, Knight claimed that she “spearheaded” the Novum launches, made statements to investors describing how the Company “internally develop[ed]” the devices.

180. **Defendant Grade**: made statements touting the Novum Products after becoming CFO in October 2023. For example, on June 5, 2024, Defendant Grade described the Novum LVP as a “key element” for Baxter’s growth and represented that Baxter expected “some incremental growth from [Novum] in the latter part of this year.” On June 12, 2024, Grade told investors that “when you think about MPT again, the introduction of Novum . . . is actually going to have starting to have strong impact.” On September 5, 2024, Grade stated that the Novum would “continue to be a growth driver in MPT” and that the “launch itself has gone well.” On November 20, 2024, Grade stated that the Novum rollout had “a feature set that’s been really well-received” and “a rollout process that’s actually gone really well,” and that Baxter’s Canadian rollout allowed the Company “to just work out any last minute kind of bugs and kinks,” resulting in “a really smooth and impactful rollout of Novum here in the US.”

181. **Defendant Saccaro**: made statements about the Novum Products during his tenure as CFO. For example, in early 2022 Defendant Saccaro detailed “things that I think will differentiate [Novum] . . . Things like a drug safety library [and] simple and easy to use interface.” Defendant Saccaro also touted that Novum was “an innovation that we’ve been working on for years” and that “the pump is exciting [because] it really leverages all of the best things that we have with our pump.”

182. **Defendant Trachtman**: also made statements touting the Novum Products to investors. On February 23, 2022, Defendant Trachtman assured investors that “[w]e’ve taken our time to ensure the thoroughness and comprehensiveness in our submission and the responses to

the update” and that “our timeline remains to launch in the first-half, with most of the sales coming really in the second-half of the year.” When asked whether the Spectrum recall would impact Novum, Trachtman stated, “[T]his does not have an impact on Novum. So this does not delay anything with Novum.” On March 17, 2022, Trachtman stated that “we are set to launch here in the first half of the year” and “[w]e’ve worked very collaboratively with FDA to address all their questions.” On September 14, 2022, Trachtman told investors that Baxter “would expect overall infusion pump sales next year of LVP to be north of \$100 million.”

183. Defendants’ repeated statements about the Novum Products demonstrate that they closely tracked these products and understood their importance to Baxter’s financial performance and growth strategy. Moreover, the specificity and detail with which Defendants spoke—often in direct response to analyst questions probing the Novum Products’ status and trajectory—further confirms that Defendants possessed particularized knowledge of the subjects about which they made materially false and misleading statements. This strongly supports the inference that Defendants knew or were severely reckless in not knowing that their statements touting the Novum Products were materially false and misleading.

VI. DEFENDANTS’ MATERIALLY FALSE AND MISLEADING STATEMENTS

184. Throughout the Class Period, Defendants made a number of statements regarding the Novum Products that were either outright false by misrepresenting material facts or were misleading “half-truths” that omitted material information necessary to make the statements not misleading. Both are equally actionable under the federal securities laws.

185. Defendants misrepresented material facts concerning the success of the Novum’s launch and market performance in Canada, and the competitive superiority of the Novum LVP’s safety and connectivity features, resolution of issues and concerns with the LVP from the Canadian launch, and purported success launching the product in the U.S.

A. Defendants Misrepresented The Novum's Launch And Market Performance In Canada

186. On February 23, 2022, Defendant Saccaro made false and misleading statements during the Citi Research Healthcare Conference. When asked by a Citi analyst about the Novum products, Defendant Saccaro stated, “[T]he pump is exciting [because] *it really leverages all of the best things that we have with our pump, including . . . the medication safety provisions that we have with respect to it, simple and easy user interface and then now adds to it a whole platform.*”

187. Less than a month later, on March 7, 2022, Defendant Saccaro again touted the products during the Raymond James Institutional Investors Conference. When asked “about Novum, arguably your highest profile, new product approval here in 2022 driving a segment that accounts for what, 20% of sales. So can you just talk about Novum and what it means for the business?,” Defendant Saccaro stated, “It’s an innovation that we’ve been working on for years and really *there are a few things that I think will differentiate it. . . . the Novum pump incorporates all of our learnings from being in the large volume pump business for perhaps the last 20 years into this next generation pump. Things like a drug safety library, things like simple and easy to use interface*, all of these things have been incorporated into the new pump and we will be thrilled to bring this to market.” Saccaro added, “[W]e’ve been doing quite well with the Spectrum pump that we have on the market today. *It’s a testament to the quality of that pump as well.*”

188. Defendant Saccaro made further false and misleading statements on March 17, 2022 at the Barclays Global Healthcare Conference. When asked if Baxter “having the three pumps on one platform” was “a game-changer,” Defendant Saccaro stated in part, “*you take the best of*

Spectrum, like the master drug library, like the simple user interface, among other things, and you now have a large volume pump with that.”

189. On April 28, 2022, Defendant Almeida made false and misleading statements during the Company’s Q1 2022 earnings call. Analysts asked Defendants whether the “delay” in receiving FDA approval of the LVP changed the “longer term” potential of the device. In response, Defendant Almeida stated that this development “does not change the faith I have in the [Novum] product line,” because *“[w]e have this product currently working in Canada and is, from my perspective, a great product.”*

190. On May 25, 2022, during the Company’s 2022 Investor Conference, Defendant Knight made false and misleading statements touting the safety and quality of the Novum Products. In describing the Dose IQ Safety Software used in the LVP, Defendant Knight touted its *“dose error reduction system,”* which she claimed *“enhance[d] infusion safety by creating one of the highest drug library compliances in the industry.”* Pointing to the Baxter’s supposed success launching the device in Canada, Knight stated, *“I remain very, very confident in [the Novum] platform, because of the feedback we’ve gotten from our customers . . . our customers in Canada are already enjoying this platform today, and we’re getting great feedback. . . . I’m optimistic as ever about the launch of Novum IQ.”* Knight further stated, “this infusion platform is so essential because *we’re known today in the market for our ease-of-use, our patient safety, as well as our cutting-edge clinical safety software.*

191. On February 9, 2023, during a conference call to discuss Baxter’s earnings for the fourth quarter and full fiscal year 2022, analysts questioned Defendants about Baxter’s anticipated performance in fiscal year 2023. In response, Defendant Almeida stated, “[t]he market is very anxiously waiting for our [Novum LVP] pump. . . . *the product is doing very well in Canada.*”

192. On September 7, 2023, during the Wells Fargo Healthcare Conference, Defendants were asked whether Baxter’s claimed “updates” to the device in Canada “potentially affect[ed] FDA approval of Novum [LVP] in the US.” In response, Defendant Almeida stated that when Baxter “launched [the LVP] in Canada, [the Company] found a couple changes that we need to make to [the LVP’s] software and hardware . . . that we’re currently undertaking.” Yet, Almeida reassured investors that the LVP was ***“working on the market today. . . . this product is absolutely what it needs to go into the US market.”***

193. On September 5, 2024, during the Wells Fargo Healthcare Conference, Defendants Grade and Trachtman made false and misleading statements. In response to questions about Baxter’s “drivers of . . . growth,” Defendant Grade touted the Novum launch, including in Canada: ***“The launch itself has gone well. I think we find ourselves in a really good place from a product availability perspective. Demand has been really good.”***

194. These statements in ¶¶186-93 were materially false and misleading and misrepresented and failed to disclose facts necessary to make Defendants’ statements not misleading. Contrary to Defendants’ claims, such as that the LVP was “currently working in Canada,” with “differentiated” safety features, generating “great feedback” from Canadian customers, and “doing very well” in the Canadian market, Baxter’s Canadian launch encountered widespread customer complaints and serious safety issues as a result of systemic defects. For example, FE-2 reported that Baxter was aware of the LVP’s software and infusion inaccuracy problems starting in 2022. FE-3 reported that these infusion inaccuracy problems occurred in Canada, which resulted in complaints from a major hospital system that Baxter was not doing anything to remediate the issues. Regulatory records, including complaints to the FDA and Health Canada, further corroborate the LVP’s over- and under-infusion problems and safety incidents that

occurred during the Canadian rollout of the device. As multiple former Baxter employees herein reported, these issues resulted from systemic defects in the software and design of the LVP, which were known by the start of the Class Period. For example, FE-1, FE-2, FE-4, and FE-8 each confirmed different problems with the LVP—including design flaws, software defects, connectivity issues, and infusion inaccuracy. Baxter had no viable solutions for these problems to make the product safe and commercially viable. Defendants’ above statements misrepresented these material facts.

B. Defendants Misrepresented The Superiority Of The Novum’s Specific Product Features, That Baxter Had Successfully Resolved Issues And Concerns With The Pumps, And The Success Of The U.S. Launch

195. On April 27, 2023, during a conference call to discuss Baxter’s first-quarter earnings for fiscal year 2023, Defendants were asked “about the opportunity for share gains” with the Novum LVP launch. In response, Defendant Almeida touted the Novum LVP’s supposed advantages and drew explicit comparisons over other competitors’ pumps under FDA recalls: *“there’s an opportunity. There’s a significant amount of pumps on recall at the moment, including brand new pumps, which just launched . . . Class 1 the other day. . . . we have significant opportunities to gain market share once Novum is approved.”* Almeida added “demand for pumps is high” because Baxter was *“facing competitors who have consent decree and recalls.”*¹⁵

196. During the July 27, 2023 earnings call, analysts questioned Almeida about how Baxter’s supposed “upgrades” of the Novum Products based on events in Canada impacted Baxter’s pending application for FDA approval of the LVP. When asked to explain the “nuances”

¹⁵ Portions of Defendants’ public statements and disclosures emphasized in ***bold italic*** type are specifically alleged to be materially false and misleading.

of the impact, Defendant Almeida stated, “*we had some software updates. . . . we have some available to go through working with Health Canada to make sure they are okay with us moving forward.*” Defendant Almeida continued, “*We also have other changes that we’re going to be making in the next couple of months to make sure that [the Novum LVP] is – all the potential upgrades and improvements are in place.*” Defendant Almeida added, “then as we work with the FDA, *our application has those changes factored in.*” Defendant Almeida concluded, “[w]e *continue to upgrade like we would have done to any other products to address any concerns on the market.*”

197. On September 7, 2023, during the Wells Fargo Healthcare Conference, in response to analyst questions about the LVP’s performance, Defendant Almeida stated, “*It is a product that has good precision*, better than some products on the market today in the US and *has also a very good interface with the rest of hospital systems choice.*”

198. On February 8, 2024, during a conference call to discuss Baxter’s earnings for the fourth quarter and full fiscal year 2023, Defendants were asked to “comment on the status of Novum IQ, the resubmission, and your thoughts on potential approval in 2024.” In response, Defendant Almeida stated that Baxter had “*nothing else [] to do*” to ensure the safety and regulatory compliance of the pumps.

199. On April 1, 2024, Baxter issued a press release announcing that the FDA approved the Novum LVP for sale in the U.S. The release touted the Novum Product’s ability to perform “*Over-the-air software updates.*”

200. Following Baxter’s April 2024 launch of the LVP in the U.S., Defendants made a series of misleading half-truth statements to investors regarding the sustainability of the financial performance of the Novum LVP. For example, on August 6, 2024, during a conference call to

discuss Baxter's second-quarter earnings for fiscal year 2024, Defendant Almeida stated that Baxter, *"anticipate[d] continued strong, steady uptake from Novum across the balance of 2024 and beyond through the upgrades of existing customers and conversions of new customers."* When asked by analysts whether Baxter's projected LVP sales and market share gains were "sustainable," Defendant Almeida stated that *"Baxter will continue to gain 1%, plus the Novum, can get up to 2% market share points on a yearly basis . . . Baxter has converted some really large and important accounts from the competition with our Novum pump."*

201. On September 5, 2024, during the Wells Fargo Healthcare conference, analysts were highly focused on Baxter's early customer responses to the Novum LVP rollout in the U.S. The analyst stated, "It sounds like you guys are having some early success. What's resonating with customers?" Defendant Grade responded, *"we're off to a really good start in that . . . the demand has been at levels probably even above what we expected."* Defendant Grade further claimed that Baxter's Canadian rollout enabled Baxter to launch the product in the U.S. without issue: "an important part of this, is that product was actually launched in Canada for a couple of years . . . *we actually have the ability to – if there's some bugs or some tweaks that we had to do within that product, we got a lot of that taken care of by the time we actually launched it in the US. . . the reception of that has been really strong and again the launch itself has gone well, and the demand for the product has been outstanding."*

202. During the September 5, 2024 conference, Defendants were asked by analysts about the Novum's technical features that were "resonating" with customers. In response, Defendant Trachtman stated, "the features of Novum, *it has over the air firmware updates that we can obviously apply those remotely . . . it allows for many of the pumps to be remote serviceability . . . 95% of our pumps will be able to be serviced that way."* Defendant Trachtman continued, *"We*

have the most advanced safety features and the largest drug library out there . . . any changes to the drug library can be applied wirelessly as well.”

203. On November 8, 2024, Baxter issued a press release, also filed on Form 8-K with the SEC (signed by Defendant Grade), that reported the Company’s earnings and operating results for the third quarter of fiscal year 2024. In the November 8, 2024 release, Defendants stated, *“Medical Products & Therapies sales grew high single digits, reflecting . . . the successful U.S. launch of the Novum IQ large volume infusion pump with Dose IQ Safety Software.”* That same day, during Baxter’s conference call to discuss its third-quarter earnings for the 2024 fiscal year, analyst questioned Defendants about the “framework for fiscal 2025 guidance.” When asked about their claims that Baxter would achieve “4%-5% organic growth,” Defendant Grade stated that Baxter was “holding our guidance on the 4% to 5%” because the Company had a “revenue ramp . . . in the year.” Building on Defendant Grade’s answer, Defendant Almeida stated, “what are the builders for this of 4% to 5% . . . *our [Novum] pump which is doing extraordinarily well in 2024, following 2025.* Just to underscore again, *50% growth in 2024 with significant potential for growth in 2025.*”

204. On November 20, 2024, during the Jefferies London Healthcare Conference, Defendants were asked about the “trajectory” of the Novum launch in the U.S. and “how that could translate to further share gains in 2025.” In response, Defendant Grade stated, “Novum has actually been introduced again *with a feature set that’s been really well-received and a rollout process that’s actually gone really well. In fact, again, I think one of the underappreciated pieces of that.*” Defendant Grade continued, “We had that rollout in Canada for a while before we actually rolled it in the US. And so, *there’s a lot of opportunity to just work out any last minute kind of bugs and kinks in a way that’s actually had a really, again, a really smooth and impactful rollout*

of Novum here in the US.” When questioned further about Baxter’s market share growth, Defendant Grade stated that Baxter was taking a “couple of points of share in the year with Novum. We’ve got a number of really nice successes, both in terms of replacements with our existing customers as well as competitive wins.” Defendant Grade concluded, *“we anticipate that trajectory continuing into next year . . . even through the end of 2026, we expect a really solid replacement cycle in that space. . . . that is a key driver from a growth standpoint for us next year.”*

205. On December 5, 2024, during the Evercore ISI HealthCONx Conference, Defendants were asked to give investors a “review” of Baxter’s third-quarter performance. In response, Defendant Grade stated, *“the Novum pump has just continued to [perform] . . . that’s been a really successful launch for us.”*

206. On January 13, 2025, during the JP Morgan Healthcare Conference, analysts questioned Defendants about Baxter’s “capital equipment as we’re moving into 2025.” In response, Defendant Almeida stated, *“we don’t see any issues with infusion pumps. . . . As a matter of fact, we see us with great plans in 2025 to continue to take market share,”* nor did Baxter *“see any issues with hospitals ordering things that we sell.”*

207. On February 20, 2025, Baxter held a conference call to discuss the Company’s fourth-quarter and year-end 2024 earnings. Defendant Knight, joining as recently promoted COO, touted her leadership of Baxter’s Novum launch. Defendant Knight stated, “I spearheaded numerous vital initiatives . . . including *the recent successful launch of our Novum IQ infusion pump platform in the United States.*” On the same call, Defendant Grade stated, “Sales in the quarter benefited [sic] from significant growth for our US infusion systems portfolio, as *the rollout of our Novum IQ pump platform continues to build momentum with orders coming in from both*

new and existing customers.” Defendant Grade also stated, “For MPT, we expect sales to increase approximately 5%, *driven by continued momentum with our Novum LVP launch.*”

208. During the February 20, 2025 call, Defendants were asked to “highlight” Baxter’s “new product investments.” In response, Defendant Grade stated, “*the Novum pump has been a resounding success. It’s a differentiated product that, again, has gotten a great customer response. The launch has gone extremely well.*”

209. On March 3, 2025, during the Raymond James Institutional Investors Conference, Defendant Grade stated, “*with Novum. . . . The demand has been outstanding. The performance of the product itself has been outstanding. . . . we have, again, a very competitive product . . . we’ve continued to increase our share by competitive wins as well as replacements.*”

210. Defendants were also asked about the infusion pump opportunity to gain market share with the Novum Products. When asked, “you’ve talked about share being in the 20s today. Where can it go?” Defendant Grade stated, “[w]e’re in the middle of . . . a solid replacement cycle that’s happening . . . from a share perspective, we’ve always talked about . . . our Spectrum pump was taking a point a year in share, and that *our Novum pump actually we think is two times that. We’ve had substantial competitive wins as well as replacements with the pump.*” Defendant Grade continued, “*the [Novum Products] launch itself went extremely well . . . the fact that this was rolled out in Canada for a year in advance is they give the opportunity to work out any kinks and tweaks on that . . . this thing has been extremely well received.*”

211. On March 5, 2025, during the TD Cowen Healthcare Conference, analysts questioned Defendants about their claims that the Novum “launch has gone well” and drove “strong growth in 2024.” When Defendants were asked “whether that growth was driven by replacements versus winning share,” Defendant Grade stated, “*the launch itself . . . actually [has]*

gone really well. And the product has been extremely well received. The demand level is high.”

Defendant Grade further stated that, “with Novum, *we’ve actually doubled [Baxter’s market share growth] . . . we’re taking a couple of points of share a year here . . . we got about a half a year out of that growth last year . . . we’ll now get a full year of it here in 2025.”*

212. During the March 5, 2025 conference, Defendants were also asked about their claims that “additional layer of growth rate for the franchise” that the Novum would supposedly create for Baxter. In response, Defendant Trachtman stated, “with Novum IQ, a lot of the digital capabilities that we have with that platform . . . really leverage these digital capabilities across the portfolio. . . . So that’s the promise, and that was unlocked really with the Novum gateway.” Trachtman added, “*we’ll look at – to which markets outside the US and Canada we’ll further expand, so looking at targeted geographic expansion for the Novum platform, going forward.”*

213. On June 10, 2025, during the Goldman Sachs Global Healthcare Conference, the analyst asked Defendants to discuss the “underlying trends that materialized throughout the quarter that supported the 5-plus percent growth.” In response, Defendant Grade stated, “*certainly continued progress from Novum. We’ve had strong growth in our pump sales, and so that continues to be a driver . . . overall some positive trends there.*” When asked about “product lines or businesses you want to highlight within MPT,” Defendant Grade stated, “*from a Novum perspective . . . that launch has gone really well. The product is performing really well . . . our share gains with Novum, we believe, have doubled from where we were in the past.*”

214. These statements in ¶¶195-213 were materially false and misleading and misrepresented and failed to disclose facts necessary to make Defendants’ statements not misleading. Contrary to Defendants’ claims, such as their statements touting the LVP as a “differentiated product” with “advanced safety features” and “precision” infusion accuracy,

multiple former Baxter employees reported that the LVP suffered from infusion inaccuracy problems that jeopardized the safety and functionality of the device. For example, FE-8 reported that, well before Baxter reported issues with flow rate accuracy tolerance in April 2025, it was known internally that the LVP's flow rate accuracy tolerance was potentially more than 10%, and that flow rate issues from the horizontal design were known from the outset and not resolved. FE-1 similarly confirmed the LVP over-infused and under-infused patients, as did FE-2 who reported that the LVP could not accurately infuse patients at high rates of infusion (e.g., 1,200 milligrams per hour) and that even 1% deviations in this critical function meant the device did not meet safety and quality standards. Additionally, contrary to Defendants' claims about the LVP's "very good interface" with hospital systems and "remote serviceability," FE-4 reported that the pumps suffered from wireless connectivity defects that prompted Baxter to send software engineers on-site to hospitals to alter software and firmware in the LVP.

215. Additionally, contrary to Defendants' claims that Baxter had resolved issues prior to the U.S. launch, such as that "any last minute kind of bugs and kinks" were "taken care of by the time [the LVP] launched it in the US," multiple former Baxter employees confirmed that the software defects and infusion inaccuracy problems persisted from the time of the Canadian launch throughout Baxter's rollout in the U.S. For example, FE-8 reported that Baxter identified design flaws and infusion inaccuracy problems with the LVP prior to the U.S. launch, which remained unresolved through May 2024, post-dating the launch. Thus, Defendants' claims that the LVP was "absolutely what it needs to go into the US market" and Baxter had "nothing else [] to do" to ensure the safety and regulatory compliance of the pumps were false and misleading. Similarly, FE-9 corroborated that throughout the time of the Novum launches, Baxter maintained an internal list of hundreds of known software bugs that posed quality issues. Further, FE-2 reported that the

LVP generated complaints, including from a major partner in the U.S. from 2024 to 2025, and Baxter scuttled its planned European launch of the devices.

216. These undisclosed facts contradicting Defendants' above statements are further corroborated by regulatory records, including complaints to the FDA and Health Canada, which confirm that the LVP's over- and under-infusion problems and safety incidents continued through time of the U.S. launch and only escalated in volume and severity throughout the Class Period. Thus, Defendants' claims that Baxter's Canadian launch of the LVP led to "a really smooth and impactful rollout" in the U.S., received a "great customer response," to the LVP, and Baxter did not "see any issues with infusion pumps," were materially false and misleading.

217. Based on the foregoing reasons, Defendants' statements touting LVP sales as a sustainable source of reported sales growth and market share gains were also false and misleading. Defendants' claims that the Novum's "extraordinary" performance in the U.S. market led to "50% growth in 2024 with significant potential for growth in 2025," and "doubled" Baxter's market share through "competitive wins as well as replacements" lacked any reasonable basis in fact, and failed to account for the systemic software and device defects that rendered the LVP unfit for sale. Defendants had no reasonable basis to issue Baxter's projections of continued growth anchored on the LVP, thereby misrepresenting Baxter's true financial condition and growth prospects.

C. Defendants Continued To Mislead Investors, Even As Negative Information Was Revealed

218. On July 31, 2025, during Baxter's second-quarter earnings call where it announced the ship-hold, Defendants continued to mislead investors by downplaying the severity of the issues behind the ship-hold.

219. During the July 31, 2025 earnings call, analysts sharply questioned Defendants about the financial consequences and extent of the ship-hold. When asked by analysts if the hold

was “a temporary pause” or “something more durable,” Defendant Knight responded, ***“the field actions that we have out there pertain to a very small subset of clinical use cases.”*** Knight stated that issues behind the hold were ***“transient in nature”*** and touted the LVP’s ***“continued ability to convert competitive accounts,*** claiming that Baxter ***“signed a number of new contracts recently and our customers are looking forward to the Novum platform and the advantages that it offers. . . . it really positions us well for when this hold is released.”*** Defendant Grade further reassured investors who were concerned about “what else could go wrong,” that Baxter’s reduced guidance ***“captur[ed] the downside risk that we think is appropriate at this time.”***

220. Defendants also continued to tout the Novum’s contributions to Baxter’s projected revenue growth targets. When asked by analysts “what needs to go right” to achieve its “4% to 5% revenue growth” targets, Defendant Grade stated, ***“we’re very bullish on the Novum platform. . . . we’ve had a lot of competitive wins . . . that’s certainly something we anticipate being a driver of growth.”*** Another analyst asked Defendants, “how you would rate the current issues with Novum in terms of severity, whether this is something more severe, could take years or it is more temporal.” In response, Defendant Knight stated, “this was something that we did voluntarily and temporarily just to start to work with our customers.” Knight repeated her claim that the issues involved ***“a very small subset of clinical use cases”*** and stated, ***“this is very different than maybe what you’ve seen historically with competitors.”***

221. On October 30, 2025, during Baxter’s third-quarter earnings call where it disclosed the continuation of the ship-hold, Defendant Grade continued to mislead investors about the severity of the issues behind the hold. During the October 30, 2025 call, analysts asked Defendants, “On the Novum, has Baxter identified the root cause? Any sense on when these issues might be resolved,” and “this was not just a software update, right?” In response, Defendant Grade stated,

“there are a number of customers that are able to safely use our pump, and there are certain protocols that we’ve put out in order to do that.”

222. These statements in ¶¶219-21 were materially false and misleading and misrepresented and failed to disclose facts necessary to make Defendants’ statements not misleading. Contrary to Defendants’ claims that the issues behind the LVP ship-hold were “transient” and applied to only “a very small subset of clinical use cases,” multiple former employees herein reported that the LVP suffered from systemic software defects and design flaws, for which Baxter had no identified means remediate. For example, Baxter’s defects with the Novum throughout 2025 were so severe they led the Company to cancel the planned European launch, as FE-2 reported. Similarly, by July 2025, the LVP experienced nearly 1,000 reports of problems resulting in customer complaints and safety incidents, including over 100 reports of serious patient injury. Further, contrary to Defendants’ claims that the LVP remained “a driver of growth” with the “continued ability to convert competitive accounts,” in reality Baxter suffered significant customer losses resulting in lost sales and market share. For example, FE-1 reported that by early 2025, Baxter received complaints from a major customer that they experienced life-threatening problems using the LVP, resulting in Baxter losing significant business. As Baxter later admitted in February 2026, it had no identified solutions, and the only solutions it was exploring would “require regulatory clearance or approval,” thus undermining Defendants’ claims of continuing growth and competitive sales.

VII. PRESUMPTION OF RELIANCE

223. At all relevant times, the market for Baxter common stock was an efficient market for the following reasons, among others:

- a. Baxter common stock met the requirements for listing, and was listed and actively traded on the New York Stock Exchange (“NYSE”), a highly efficient and automated market;

- b. As a regulated issuer, Baxter filed periodic public reports with the SEC and NYSE;
- c. Baxter 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. Baxter was followed by several securities analysts employed by major brokerage firm(s) who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firm(s). Each of these reports was publicly available and entered the public marketplace.

224. As a result of the foregoing, the market for Baxter common stock promptly digested current information regarding Baxter from all publicly available sources and reflected such information in the price of Baxter common stock. Under these circumstances, all purchasers of Baxter common stock during the Class Period suffered similar injury through their purchases of Baxter common stock at artificially inflated prices and the presumption of reliance applies.

VIII. CLASS ACTION ALLEGATIONS

225. Lead Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all purchasers of Baxter common stock during the Class Period (the “Class”). Excluded from the Class are Defendants and their families, directors, and officers of Baxter and their families and affiliates.

226. 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. In 2026, Baxter had over 500 million shares of common stock outstanding, owned by thousands of investors.

227. 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 the Executive Defendants are personally liable for the alleged misrepresentations and half-truths described herein;
- e. Whether Defendants knew or recklessly disregarded that their statements and/or half-truths were false and misleading;
- f. Whether Defendants' conduct impacted the price of Baxter common stock;
- g. Whether Defendants' conduct caused the members of the Class to sustain damages; and
- h. The extent of damages sustained by Class members and the appropriate measure of damages.

228. Lead Plaintiffs' claims are typical of those of the Class because Lead Plaintiffs and the Class sustained damages from Defendants' wrongful conduct.

229. Lead Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel experienced in class action securities litigation. Plaintiffs have no interests which conflict with those of the Class.

230. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Joinder of all Class 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 suit as a class action.

IX. CLAIMS FOR RELIEF

COUNT I

**For Violations Of Section 10(b) Of The Exchange Act And Rule 10b-5
Against All Defendants**

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

232. 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 Lead Plaintiffs and other Class members, as alleged herein; and (ii) cause Lead Plaintiffs and other members of the Class to purchase Baxter common stock at artificially inflated prices.

233. 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 Baxter common stock in an effort to maintain artificially high market prices for Baxter common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5, promulgated thereunder.

234. 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 the Company's financial well-being, operations, and prospects.

235. During the Class Period, Defendants made the false statements specified above, which they knew or recklessly disregarded to be false and 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.

236. Defendants had actual knowledge of the misrepresentations and half-truths of material facts set forth herein, or recklessly disregarded the true facts that were available to them. Defendants engaged in this misconduct to conceal Baxter's true condition from the investing public and to support the artificially inflated prices of Baxter common stock.

237. Lead Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Baxter common stock. Lead Plaintiffs and the Class would not have purchased Baxter common stock at the prices they paid, or at all, had they been aware that the market prices for Baxter common stock had been artificially inflated by Defendants' fraudulent course of conduct.

238. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases of Baxter common stock during the Class Period.

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

COUNT II

For Violations Of Section 20(a) Of The Exchange Act Against The Executive Defendants

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

241. The Executive Defendants acted as controlling persons of Baxter 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, intimate knowledge of the Company's actual performance, and/or their power to control public statements about Baxter, the Executive Defendants had the power and ability to control the actions of Baxter and its employees, and the content of Baxter's SEC filings and other public statements. By reason of this conduct, the Executive Defendants are liable under Section 20(a) of the Exchange Act.

X. PRAYER FOR RELIEF

242. WHEREFORE, Lead 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 compensatory damages in favor of Lead Plaintiffs 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 Lead Plaintiffs 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.

XI. JURY DEMAND

243. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Lead Plaintiffs demand a trial by jury in this action of all issues so triable.

Dated: August 20, 2026

Respectfully submitted,

**BERNSTEIN LITOWITZ BERGER
& GROSSMANN LLP**

/s/ Katherine M. Sinderson

Katherine M. Sinderson (admitted *pro hac vice*)
Alexander Noble (admitted *pro hac vice*)
1251 Avenue of the Americas
New York, New York 10020
Telephone: (212) 554-1400
Facsimile: (212) 554-1444
KatieM@blbglaw.com
Alexander.Noble@blbglaw.com

-and-

Matthew Arrow (admitted *pro hac vice*)
2121 Avenue of the Stars, Suite 2575
Los Angeles, California 90067
Telephone: (310) 819-3481
Facsimile: (212) 554-1444
Matthew.Arrow@blbglaw.com

-and-

Avi Josefson (Bar No. 6272453)
875 North Michigan Avenue, Suite 3100
Chicago, Illinois 60611
Telephone: (312) 373-3880
Facsimile: (312) 794-7801
avi@blbglaw.com

LABATON KELLER SUCHAROW LLP

Michael P. Canty (admitted *pro hac vice*)
James T. Christie (admitted *pro hac vice*)
Nicholas Manningham (admitted *pro hac vice*)
Kaicheng Yu (*pro hac vice* forthcoming)
140 Broadway
New York, New York 10005
Telephone: (212) 907-0700
Facsimile: (212) 818-0477
mcanty@labaton.com
jchristie@labaton.com
nmanningham@labaton.com
nyu@labaton.com

*Counsel for Lead Plaintiffs Nebraska State
Investment Council, National Elevator Industry
Pension Plan and Louisiana Sheriffs' Pension &
Relief Fund and Lead Counsel for the Class*

**KLAUSNER KAUFMAN JENSEN
& LEVINSON**

Robert D. Klausner
7080 Northwest 4th Street
Plantation, Florida 33317
Telephone: (954) 916-1202
bob@robertdklausner.com

*Additional Counsel for Louisiana Sheriffs'
Pension & Relief Fund*