UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

BARRY HOLTZMAN, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. BETA BIONICS, INC., SEAN SAINT, and STEPHEN FEIDER, Defendants.	Case No. CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

Plaintiff Barry Holtzman ("Plaintiff") on behalf of himself and all others similarly situated, by and through Plaintiff's undersigned attorneys, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of U.S. Securities and Exchange Commission ("SEC") filings of Beta Bionics, Inc. ("Beta Bionics" or the "Company"), the Company's press releases, analyst reports, media reports, and other publicly disclosed information about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a securities class action brought on behalf of all persons and entities who purchased or otherwise acquired Beta Bionics common stock between July 30, 2025 and February 24, 2026, inclusive (the "Class Period"), against Beta Bionics and certain of its senior officers to recover damages caused by Defendants' violations of the federal securities laws. Plaintiff brings this federal class action under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§78j(b) and 78t(a), and U.S. Securities and Exchange Commission ("SEC") Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

2. Beta Bionics is a commercial-stage medical device company that offers an automated insulin delivery system for the treatment of diabetes, known as the iLet Bionic Pancreas insulin pump ("iLet"). Throughout the Class Period, Defendants touted the safety, efficacy, and commercial success of iLet—the Company's sole commercialized device. In October 2025, Beta Bionics disclosed that it had received an FDA Form 483 raising concerns about iLet. Defendants stressed that the letter had nothing to do with the safety or efficacy of the device itself. Rather, Defendants stated that the FDA had only taken issue with the

Company's interpretation of which customer complaints needed to be reported to the FDA, such that the Company would have to backfile some additional customer complaints that were very minor in nature and required no medical intervention. Further, Defendants assured investors that the Company was swiftly implementing the FDA's required changes to its complaint reporting system, and accordingly that they did not "foresee any ongoing challenge with this at all."

3. Defendants' statements were materially false and misleading. The FDA had raised numerous serious issues with the iLet device itself, namely that the device was malfunctioning and dosing patients with dangerously high levels of insulin, causing hypoglycemic events. Thus, contrary to Defendants' assertions that the complaints back-filed with the FDA pursuant to the Form 483 were of no moment and entirely benign, they instead numbered in the thousands and included hundreds of life-threatening events requiring significant medical intervention. Nor was the FDA satisfied with the Company's response to the issue, as the Company had utterly failed to implement any meaningful corrective actions.

4. The truth began to emerge on January 8, 2026, when Beta Bionics reported an unexpected miss on new iLet patient starts. Investors immediately connected this underperformance to there being much more serious issues with iLet than what Defendants had disclosed. The Capitol Forum ("CF"), a research thinktank, soon issued a report on January 12, 2026, disclosing the results of its own investigation showing that iLet was malfunctioning and dosing users with dangerous levels of insulin. On January 16, 2026, CF issued another report exposing how the Company's back-filed customer complaints involved numerous serious cases of hospitalization, contrary to Defendants' strong reassurances.

5. On January 30, 2026, Beta Bionics' SEC Form 8-K disclosed that the Company had received a warning letter from the FDA related to its earlier Form 483, and that the issues raised in the warning letter went far beyond mere complaint handling. Then on February 12, 2026, CF issued yet another report

based on its investigation of more back-filed customer complaints, revealing hundreds of additional reports classified as "life threatening" and "requiring intervention." On February 17, 2026, Defendants discussed but continued to dramatically downplay the event reports and the resulting FDA warning letter, claiming that "medical intervention" could include something as benign as giving a patient candy to correct their blood sugar.

6. Finally, on February 24, 2026, the full truth was revealed when the FDA publicly released its warning letter detailing a litany of violations and Defendants' failure to correct them, and contradicting months of Defendants' public statements that all back-filed complaints were for entirely benign issues. The warning letter made clear that Defendants' prior interpretation of FDA reporting requirements had not been reasonable, and had excluded numerous serious patient incidents that clearly should have been reported.

7. As a result of these disclosures, the market learned of fundamental problems with iLet that had been concealed by Defendants, leading to a series of precipitous stock drops. On January 8-9, 2026, Beta Bionics stock price plummeted from $31.99 per share to $20.14 per share, a 37% one-day decline that wiped out hundreds of millions of dollars in market capitalization. Following the Company's January 30, 2026, 8-K, the stock dropped further from $14.79 per share to $13.83 per share. By April 10, 2026, the Company's stock price closed under $9 per share.

II. JURISDICTION AND VENUE

8. The claims alleged 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).

9. 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).

10. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act because Beta Bionics is headquartered and maintains its principal executive offices in this District, Defendants conduct business in this District, and substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this District.

11. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and 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 and markets.

III. PARTIES

A. Plaintiff

12. Plaintiff Barry Holtzman, as reflected in the Certification submitted herewith, purchased Beta Bionics common stock at artificially inflated prices during the Class Period and suffered damages as a result of Defendants' violations of the federal securities laws alleged herein.

B. Defendants

13. Defendant Beta Bionics is a commercial-stage medical device company engaged in the design, development, and commercialization of products and solutions for insulin-requiring people with diabetes (PWD). Beta Bionics is headquartered in Irvine, California. Beta Bionics' common stock trades on the Nasdaq Global Market under the ticker symbol "BBNX."

14. Defendant Sean Saint ("Saint") has served as the President, Chief Executive Officer ("CEO"), and a member of the board of Beta Bionics since August 2022.

15. Defendant Stephen Feider ("Feider") has served as the Chief Financial Officer ("CFO") of Beta Bionics since August 2022.

16. Saint and Feider are collectively referred to as the "Individual Defendants." The Individual Defendants, together with Beta Bionics, are referred to as "Defendants."

17. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of the Company's public statements, including the Company's quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers, and individual and institutional investors. They were provided with copies of the Company's results, reports and press releases alleged herein to be false and misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with the Company, their direct participation in the management of the Company, their direct involvement in the day-to-day operations of the Company, and their access to material non-public information available to them but not to the public, these Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and misleading.

IV. SUMMARY OF THE FRAUD

18. Beta Bionics is a commercial-stage medical device company focused on the treatment of diabetes. The Company's flagship product is the iLet Bionic Pancreas, an insulin delivery system for diabetes types 1 and 2 that purports to be fully autonomous, determining 100% of insulin doses without manual carbohydrate counting or correction calculations by the user.

19. Throughout the Class Period, Beta Bionics received thousands of complaints from iLet customers, including numerous reports of serious, life-threatening hypoglycemia caused by device malfunctions that required hospitalization to treat. The root of these malfunctions was iLet's extremely

aggressive dosing algorithm. Although Beta Bionics had been developing iLet for almost 20 years, the Company never managed to manufacture a feasible safety net to prevent excess dosing. Consequently, the Company abandoned the built-in safety net and rushed the device to market despite the possibility of over-aggressive dosing.

20. Beta Bionics did not report these serious safety events to the FDA, or the market, in real time. Rather, in June 2025, the FDA conducted an inspection concerning the iLet device and issued the Company a Form 483—a non-public report indicating that the FDA inspector has observed conditions that may violate federal laws and requiring the recipient to take remedial actions. The Form 483 detailed more than 18,000 unreported complaints from iLet users over a two-year period since the device's launch in mid-2023. Contemporaneous SEC filings disclose that there were 29,419 users of iLet by late-2025, meaning that, even though the same user can submit multiple complaints, a significant percentage of iLet users must have experienced malfunctions. The FDA concluded that the Company had failed to investigate and report potentially life-threatening events, and that "no corrective actions were taken and there is no justification for why corrective actions were not taken, considering the risk to patients from the malfunctions." Nevertheless, the content of the Form 483 was not made public until a report by the Capitol Forum ("CF"), a highly reputable research thinktank, in December 2025.

21. The Company did not acknowledge the existence of the Form 483 until October 2025, at which point Defendants dramatically mischaracterized and downplayed the FDA's concerns, reassuring the market that iLet had no serious issues. Defendants repeatedly stressed that the Form 483 had nothing to do with iLet itself but was issued only because the Company's definition of a "reportable [safety] event" differed slightly from the FDA's definition. Defendants even asserted that this difference in interpretation was "not unusual in our industry"

because FDA guidelines were purportedly "unclear." According to Defendants, then, the Form 483 was "very benign," the event reports the FDA wanted back-filed were minor and required no medical intervention, and those reports would be promptly back-filed and could even be previewed by investors if desired.

22. The truth began to be revealed to the market on January 8, 2026, when Beta Bionics reported an unexpectedly low amount of iLet patient starts, one of the Company's most important indicators of growth. Although the market connected this miss to potential issues with iLet from the Form 483—made public by CF in December 2025, but obscured by Defendants' insistence that the FDA only took issue with a minor difference in interpretation of reporting rules—the full extent of the fraud was not yet known. In response to this disclosure alone, the Company's stock price collapsed from $31.99 per share to $20.14 per share in a single day.

23. Throughout January 2026, CF continued to issue reports based on its investigation of the thousands of back-filed iLet reports, showing that, contrary to Defendants' statements, the FDA's concerns went to the heart of iLet's safety. CF also spoke to former Beta Bionics employees who discussed iLet's aggressive dosing algorithm and the Company's abandonment of the built-in safety net to prevent dangerous over-dosing.

24. On January 30, 2026, Beta Bionics' SEC Form 8-K revealed that the FDA had issued the Company a warning letter in connection with its earlier Form 483. The Company now admitted that the FDA's concerns went beyond mere complaint handling and in fact concerned Beta Bionics' quality management system and failure to take corrective action in response to the Form 483. In reaction to this admission, the Company's stock price fell once more from $14.79 per share to $13.83 per share. However, the Company continued to downplay the FDA's concerns to investors on its February 17 earnings call. Defendants admitted that they had received and failed to report some complaints requiring medical intervention, but they stated that the FDA's definition of "medical intervention"

could include giving someone candy to correct their blood sugar. Defendants thus concealed that, whatever minor events *might* be classified as requiring medical intervention, the Company had *in fact* received complaints of life-threatening events requiring hospitalization. These continued misleading reassurances prevented the market from learning of the full extent of the fraud.

25. The full truth finally emerged on February 24, 2026, when the FDA publicly released the warning letter. The letter was 10 pages long and riddled with serious violations relating to the iLet device itself. In it, the FDA explicitly rejected Beta Bionics' framing of regulators' concerns, stating that any malfunction that could lead to death or serious injury must be reported to the FDA. The FDA further explained that any hypoglycemia requiring medical intervention—even if that intervention is "glucose drinks or candies"—must be reported because untreated and/or repeated hypoglycemic episodes can lead to serious injury, reduced cognitive function, increased risk of repeat episodes, and even death.

V. DEFENDANTS' FALSE AND MISLEADING STATEMENTS[1]

26. Throughout the Class Period, Defendants repeatedly assured investors that the FDA's regulatory concerns expressed in the Form 483 related only to a minor difference in regulatory interpretation, not the underlying safety of their flagship iLet device, and that all back-filed reports were entirely benign. Defendants continued to misleadingly reassure investors and deny any fundamental concerns with iLet as more information emerged showing the back-filed complaints were less benign than previously reported, and thus that the FDA's objections went to the heart of iLet's safety.

A. False Statements During the Second Quarter 2025 Earnings Call

27. At the start of the Class Period, during Beta Bionics' second quarter 2025 earnings call on July 29, 2025, Defendant Saint touted to investors that "***iLet***

[1] All emphasis is added.

demands the least engagement from the user and delivers the most automated adaptation of any [Automated Insulin Delivery] system[,] setting a new standard for our industry. We also highlighted the ***superior clinical outcomes of the iLet with our real-world data for the first two years of iLet's launch***."

28. On the same July 29 earnings call, Defendant Feider told investors, "absolutely the message of iLet simplicity is resonating. ***[Healthcare professionals] are seeing good results from their patients and becoming more comfortable prescribing the iLet***, and I think that's evidenced by our results."

29. The statements in ¶¶27-28 were false and misleading when made because Defendants omitted mention of the FDA Form 483 and iLet's underlying safety issues. Contrary to Saint's statement that the iLet "demands the least engagement from the user" and is "the most automated" insulin pump on the market, the CF's January 12, 2026, interviews with former Beta Bionics employees and patients exposed how the Company had failed for almost two decades to develop a working failsafe to prevent excess dosing, and thus how Defendants had rushed iLet to market with a dangerously aggressive automated dosing algorithm. Moreover, the FDA had already issued its Form 483—pointing to thousands of unreported safety complaints, many requiring medical intervention and hospitalization—in June 2025. Therefore, it was misleading for Saint to tout "the superior clinical outcomes of the iLet with our real-world data," and for Feider to state that healthcare professionals "are seeing good results from their patients," while omitting that the FDA had taken issue with thousands of unreported patient complaints. Even if the FDA had not issued the Company a Form 483, it would have been misleading for Defendants to tout the device's "superior" real-world outcomes without also discussing the serious medical events iLet had caused, and of which Defendants knew due to thousands of customer complaints.

B. False Statements During the Third Quarter 2025 Earnings Call

30. On Beta Bionics' third quarter 2025 earnings call, held on October 28, 2025, Saint reiterated that "the iLet's highly differentiated, fully adaptive, closed loop algorithm is producing ***phenomenal real-world outcomes, and those outcomes are resonating with users, caregivers, providers and payers***."

31. On the same earnings call, Feider stated that "[w]e believe the iLet is a game changer given its ***unique simplicity and ease of use, powered by the most advanced adaptive algorithm available***."

32. On the same October call, Defendants also discussed the June 2025 Form 483 for the first time. In his prepared remarks, Saint told investors:

> In late June, the FDA issued a Form 483 following an inspection. ***The Form 483 is primarily related to our customer complaint handling system and our criteria for reporting complaints to the FDA***, which are ultimately reflected in the FDA's manufacturer and user facility device experience database, also known as the MAUDE database.
>
> ***The results of the FDA's inspection is not unusual in our industry***, as numerous precedents the agency has set for our peers at similar stages would suggest. ***We believe that in those instances, Beta Bionics and our peers likely developed similar definitions for what constitutes a reportable complaint prior to the FDA's feedback***, and each company has successfully taken the steps required to align reporting with the FDA's standards. We are no different, and ***our remediation efforts to the Form 483 are straightforward and well underway***.
>
> * * *
>
> To cite some examples of how our definition of reportable complaints has changed, ***prior to the 483, we were not reporting complaints such***

> ***as the device's screen cracking or a hypo or hypoglycemic event that did not require medical intervention***.
>
> * * *
>
> In terms of what to expect going forward, since we received the Form 483 in June, we've submitted monthly progress reports to the agency. ***We're confident that our new complaint handling system and reporting system meets or exceeds the expectations laid out by the agency in their Form 483 observations***.

33. In response to an analyst question on the October call about how serious this "new information" was, Saint reiterated his reassurance that, "***We're very far along in our remediation efforts, new systems are fully in place at this time, and . . . . we don't foresee any ongoing challenge with this at all***." Feider added:

> ***[T]he interpretation of the rules for what's considered a reportable complaint and what's considered a non-reportable complaint actually leaves a lot of room for interpretation***, ... [T]o us, ***this is a very benign issue as long as we actually do what we say we're going to do***. And so we're bringing it to your attention because we feel it's important to be transparent. There may be some misinformation out there about why we've seen an uptick in reportable complaints in the MAUDE database. ***We don't see it as an issue at all***, and it's kind of on brand for us to just answer the mail and so hence why we brought it up today.

34. On the same call, another analyst asked Defendants for more detail on "the real-world performance and feedback and retention [of iLet] that you're seeing despite some of the complaints received?" Saint again minimized the severity and volume of complaints the FDA ordered the Company to backfile, telling investors, "***I wouldn't read anything into the word 'complaint' in this***

case. The insulin pump industry is—if you look at the complaint rates that all insulin pump companies receive, it's somewhat shocking at some level. And the primary reason for that is that definition that Stephen alluded to earlier where ***really anything—anybody calls in with a problem with your product or an experience issue and it gets reflected as a complaint*** . . . ."

35. By the end of the October 28 call, analysts seemed to be reassured by Defendants' minimization of the issues underlying the Form 483, with one calling the letter "such a distraction for investors" and asking Defendants to help them "kind of calm the obsession with counting MAUDE entries?" Saint answered that "***the guidelines associated with what constitutes a complaint or report*** . . . ***are unclear at best***, ..." With respect to the substance of the back-filed complaints themselves, Saint added that "***We don't see an underlying problem in our data here. The 483 itself had nothing to do with the actual complaints being received or the number of them. It had to do solely with the definition of the reports being filed as complaints, and that's all***."

36. Defendants' statements in ¶¶30-35 were false and misleading when made because they portrayed the Form 483 as relating only to a difference of interpretation of reportable events and downplayed the seriousness of those events. Saint's and Feider's statements in ¶¶30-31 were misleading because they touted iLet's performance but omitted the thousands of safety complaints the Company had received. It was misleading for Saint to tell investors, in ¶32, that the Form 483 concerned only a minor difference in interpretation of reporting rules, and that the complaints to be back-filed were only benign reports requiring no hospitalization, when, in fact, the Form 483 identified over 18,000 complaints out of less than 30,000 total iLet users, including numerous life-threatening hypoglycemic events that the Company had "failed to investigate," or even report to the FDA, with no justification. Saint and Feider further misled investors by, in ¶33, assuring them that the Company's remediation efforts were advanced and the FDA's issues were

"very benign," when they failed to accurately describe the scope and severity of the FDA's observations which made remediation much more complex and extensive than Defendants indicated to investors. Lastly, in ¶¶34-35, it was misleading for Saint to stress that complaint *could* be extremely benign, and that there was no "underlying problem in our data here," while omitting that the Company had *in fact* received hundreds of complaints of life-threatening events requiring hospitalization, and that the FDA had raised this issue in its Form 483.

C. Defendants' False Statements in the Company's January 30, 2026, Form 8-K

37. On January 30, 2026, Beta Bionics filed an SEC Form 8-K disclosing that the Company had received a warning letter from the FDA in connection with the agency's earlier Form 483. Defendants admitted that the warning letter and thus the Form 483 implicated more than just a minor difference in interpretation of reportable complaints, stating that "***[t]he Warning Letter highlights non-conformities observed by the FDA in relation to the Company's Quality Management System, Medical Device Reporting, and Correction and Removals***, which were previously communicated by the FDA in the Form 483."

38. Defendants' statements in ¶37 were false and misleading when made because they continued to downplay the seriousness of the Form 483 and warning letter. It was false to state that "[t]he Warning Letter highlights non-conformities observed by the FDA in relation to . . . Medical Device Reporting, and Correction and Removals," while continuing to conceal that the unfiled reports contained hundreds of extremely serious safety events that the FDA concluded Beta Bionics had unjustifiably failed to investigate or even report to the agency.

D. False Statements During the Fourth Quarter 2025 Earnings Call

39. During Beta Bionics' fourth quarter 2025 earnings call on February 17, 2026, Defendants further reassured investors about the FDA warning letter received in connection with the Form 483 and first disclosed in the Company's

January 30 8-K. Saint stated that, "[i]n the [FDA's] view, ***a reportable hypoglycemia event includes those that are self-treated with glucose drinks or candies***. By contrast, prior to receiving feedback from the agency, our definition of a reportable hypoglycemia event included only those requiring third-party assistance . . .." Saint also admitted that the FDA had taken issue with the Company's corrective and preventative action ("CAPA") system, a set of protocols relating to the investigation of customer complaints. Saint minimized the FDA's negative observations, stating that, "***the agency found areas where we could have—could have opened a CAPA and did not or could have done a better job with what we call VOE, verification of effectiveness, which is the process to ensure that changes we make through the CAPA process work***."

40. The statements in ¶39 were false and misleading when made because Defendants continued to minimize the seriousness of the safety complaints underlying the FDA's Form 483 and warning letter. Saint's statement that, according to the FDA, "a reportable hypoglycemia event includes those that are self-treated with glucose drinks or candies" was misleading because, while this accurately describes some of the complaints back-filed with the FDA pursuant to the Form 483 and warning letter, hundreds of other complaints that Beta Bionics had also failed to timely report involved life-threatening safety events requiring hospitalization. Moreover, it was misleading for Saint to state that the FDA had identified cases where the Company "could have opened a CAPA and did not" was misleading where the FDA had in fact concluded that Beta Bionics had, without justification, failed to investigate clearly serious, life-threatening customer reports.

VI. THE TRUTH IS REVEALED

41. On January 8, 2026, after markets closed, Defendants were forced to partially reveal the truth. During an otherwise positive earnings reports, Beta Bionics surprised investors with a miss on the key metric of new iLet patient starts. And investors immediately connected the miss to underlying problems with iLet

and prior reports and investigations of the FDA's Form 483, though the market had previously credited Defendants' minimization of the issues therein. While Defendants attempted to minimize the miss as normal quarter-to-quarter variation, investors saw now that the facts reported by the CF in December—that Beta Bionics had received over 18,000 complaints out of less than 30,000 patients and failed to investigate, report to the FDA, or take corrective action—were credible and beginning to tell in the Company's performance. As a result, Beta Bionics common stock declined dramatically during trading on January 9, 2026, from $31.99 per share to $20.14 per share, a 37% drop that wiped out hundreds of millions in market capitalization.

42. Throughout January 2026, CF released additional critical reports based on their further investigation of iLet and the FDA Form 483. On January 12, the CF published its investigation of iLet itself, including interviews with former patients and Beta Bionics employees who exposed how the Company could not in almost 20 years design a feasible built-in safety net to prevent excess dosing and so rushed iLet to market with its potentially dangerous, aggressive dosing algorithm. By January 16, the CF had analyzed more of the back-filed safety event reports and discovered numerous complaints requiring hospitalization and other serious injuries or illnesses, contradicting the Company's insistence that only very benign cases needed to be back-filed.

43. On January 30, 2026, Beta Bionics' Form 8-K admitted that the FDA had sent the Company a warning letter connected to its earlier Form 483. The Company did not publish the letter itself, but Defendants conceded that the FDA's concerns were more serious than the minor difference in reporting-rule interpretation Defendants had previously acknowledged. Rather, the FDA took issue with Beta Bionics' quality management system for iLet and the Company's failure to take corrective action based on the Form 483. However, Defendants continued to conceal the level of seriousness of the thousands of customer

complaints back-filed with the FDA, which the Company had previously assured the market were entirely benign. Analysts sounded a note of caution about this negative development but continued to credit management's reassurances and saw no underlying issues with iLet. For instance, Leerink analysts wrote on January 30 that the warning letter "could fuel heightened investor skepticism" but "management highlighted there have been no new issues," and "[w]e continue to expect that the company's differentiated technology and favorable catalyst path can create potentially meaningful upside opportunities . . . ." In response to this disclosure, the Company's stock price dropped from $14.79 per share to $13.83 per share.

44. On February 12, 2026, the CF published yet another report of their analysis of more back-filed reports. The CF reported that it had found hundreds of complaints classified as "life-threatening" and "requiring intervention," further contradicting Defendants' assurances that the back-filed reports contained entirely benign cases that required no medical intervention.

45. Management felt pressure to respond on its February 17, 2026, earnings call, where Defendants discussed but continued to downplay the warning letter. For instance, Defendants admitted for the first time that some of the back-filed complaints required medical intervention but minimized this fact by pointing out that the FDA's definition of "medical intervention" could include giving a patient candy to correct their blood sugar. Defendants thus continued to mislead investors by leaving out that the back-filed reports also contained conditions serious enough to require hospitalization and be classified as "life-threatening." Analysts believed Defendants' minimization, with Truist reiterating on February 17 that the warning letter "focuses on quality-system controls, complaint/MDR [Medical Device Report] handling and related procedures, not on the safety or performance of the company's insulin pump itself." Indeed, the market credited

Defendants' reassurances, and the Company's stock price recovered somewhat the following day, opening at $12.89 per share and closing at $13.61.

46. The full truth was finally revealed on February 24, 2026, when the FDA publicly released the warning letter. The long, 10-page report explicitly contradicted Beta Bionics' complacent framing of the FDA's concerns—and the underlying issues with iLet—making clear that any malfunction that could be life threatening must be reported to the FDA. The letter elaborated that any hypoglycemia requiring medical intervention was reportable because any such episode, even if resolved by giving a patient candy, raises the chances of future hypoglycemic episodes, likely more severe than the first and potentially leading to irreversible side effects, including death. Consequently, Beta Bionics' stock continued to drop, from an open on February 24 at $13.55 per share to a close on February 25 at $12.89. Following the full disclosure of the truth, the Company's stock price continued to slide and, by April 10, 2026, closed under $9 per share.

VII. ADDITIONAL SCIENTER ALLEGATIONS

47. During the Class Period, Defendants acted with scienter in that they knew, or recklessly disregarded, that the public documents and statements they issued or disseminated to the investing public during the Class Period were materially false or misleading. Defendants knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements and documents as well as actions intended to manipulate the market price of Beta Bionics common stock, as primary violations of the federal securities laws. Defendants, by virtue of their receipt of information reflecting the true facts regarding Beta Bionics and their control over, receipt, and/or modification of Beta Bionics' materially false and misleading statements, were active and culpable participants in the fraudulent scheme alleged herein.

48. Defendants knew or recklessly disregarded the false and misleading nature of the information regarding the flagship iLet device, the FDA Form 483,

and the FDA warning letter, that they caused to be disseminated to the investing public. On January 30, 2026, Defendants admitted in a Form 8-K that the FDA warning letter relating to the earlier Form 483 warned of violations not limited to mere complaint handling—as Defendants had previously insisted—implicating iLet's quality management system and the Company's failure to take corrective action. Furthermore, on February 17, 2026, Defendants admitted that some of the complaints the FDA ordered the Company to backfile did in fact require medical intervention, contrary to Defendants' earlier assurances that the back-filed complaints were only very minor cases not requiring medical intervention. The fraudulent scheme described herein could not have been perpetuated during the Class Period without the knowledge and complicity of, or at least the reckless disregard by, personnel at the highest levels of the Company, including the Individual Defendants.

49. Given their positions within Beta Bionics, the Individual Defendants controlled the contents of Beta Bionics' public statements during the Class Period. The Individual Defendants were each provided with, or had access to, the statements alleged herein to be false and misleading prior to, or shortly after their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected.

50. Because of their positions and access to material nonpublic information, the Individual Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations that were being made were false and misleading. Each of the Defendants is responsible for the accuracy of Beta Bionics' corporate statements, and is, therefore, responsible and liable for the representations contained therein.

VIII. LOSS CAUSATION

51. Plaintiff and other class members were damaged as a result of Defendants' fraudulent conduct as alleged herein. During the Class Period, Defendants engaged in a scheme to deceive investors by issuing a series of material misrepresentations, and omitting material facts and uncertainties required to be disclosed, relating to Beta Bionics' operations, business, financial performance, and prospects.

52. As a direct result of Defendants' scheme, misrepresentations of material fact, and omissions of material fact, the price of Beta Bionics common stock was artificially inflated throughout the Class Period.

53. Class members unknowingly and in reliance on Defendants' materially false or misleading statements and/or omissions purchased Beta Bionics common stock at artificially inflated prices on the NASDAQ. But for Defendants' misrepresentations, omissions, and fraudulent scheme, Plaintiff and other class members would not have purchased Beta Bionics common stock at the artificially inflated prices at which it traded during the Class Period.

54. The truth about Defendants' fraud was revealed through corrective disclosures made on and between January 8, 2026, and February 24, 2026. In response to these corrective disclosures, the price of Beta Bionics common stock fell precipitously as the artificial inflation caused by Defendants' unlawful conduct was removed from Beta Bionics' stock price.

55. This decline in Beta Bionics' stock price following the corrective disclosures is directly attributable to the market absorbing information that disclosed the falsities in or misleadingly omitted from Defendants' material misrepresentations and omissions.

56. Plaintiff and other class members suffered economic losses as the price of Beta Bionics' stock fell in response to the corrective disclosures. It was foreseeable that such disclosures would cause Beta Bionics' stock price to decline.

Thus, Defendants' wrongful conduct, as alleged herein, directly and proximately caused the damages suffered by Plaintiff and other class members.

IX. NO SAFE HARBOR

57. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pled in this complaint. Many of the specific statements pled herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pled herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false and/or the forward-looking statement was authorized and/or approved by an executive officer of Beta Bionics who knew that those statements were false when made.

X. PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

58. At all relevant times, the market for Beta Bionics common stock was an efficient market for the following reasons, among others:

(a) Beta Bionics common stock met the requirements for listing and was listed and actively traded on the NASDAQ, a highly efficient, national stock market;

(b) as a regulated issuer, Beta Bionics filed periodic public reports with the SEC;

(c) Beta Bionics regularly communicated with public investors via established market communication mechanisms, including the regular dissemination of press releases on the national circuits of major newswire services

and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Beta Bionics was followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

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

60. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business, operations, and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

XI. CLASS ACTION ALLEGATIONS

61. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3), individually and on behalf of a Class consisting of all persons and entities that purchased or otherwise acquired the publicly traded

common stock of Beta Bionics between July 30, 2025, and February 24, 2026, inclusive.

62. Excluded from the Class are: (i) Defendants; (ii) present or former executive officers of Beta Bionics, members of Beta Bionics' Board, and members of their immediate families (as defined in 17 C.F.R. § 229.404, Instructions (1)(a)(iii) and (1)(b)(ii)); (iii) any of the foregoing persons' legal representatives, heirs, successors, or assigns; (iv) any entity in which Defendants have or had a controlling interest; and (v) any affiliate of Beta Bionics.

63. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Beta Bionics' securities were actively traded on the NASDAQ. While the exact number of class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery from Defendants, Plaintiff believes that there are at least hundreds, if not thousands, of members in the proposed Class. Class members may be identified from records maintained by Beta Bionics or its transfer agent and may be notified of the pendency of this action by mail using a form of notice customarily used in securities class actions.

64. Plaintiff's claims are typical of all other class members' claims, as all class members are similarly affected by Defendants' wrongful conduct in violation of the federal securities laws complained of herein.

65. Plaintiff will fairly and adequately protect the interests of the class members and has retained counsel competent and experienced in class and securities litigation.

66. Common questions of law and fact exist as to all class members and predominate over any questions solely affecting individual class members. Among the questions of law and fact common to the class are: (i) whether Defendants' acts and omissions as alleged herein violated the federal securities laws; (ii) whether Defendants' statements to the investing public during the Class Period

misrepresented or omitted material facts about Beta Bionics' operations, business, performance, and future prospects; (iii) to what extent the class members have sustained damages; and (iv) the proper measure of such damages.

XII. CLAIMS FOR RELIEF

COUNT I

For Violation of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

67. Plaintiff repeated and realleges each and every allegation contained in the foregoing paragraphs as it fully set forth herein.

68. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were 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. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of Beta Bionics common stock during the Class Period.

69. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Beta Bionics common stock. Plaintiff and the Class would not have purchases Beta Bionics common stock at the prices they paid, or at all, if they had been aware that the

market price have been artificially and falsely inflated by Defendants' misleading statements.

70. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Beta Bionics common stock during the Class Period.

COUNT II

For Violation of § 20(a) of the Exchange Act Against the Individual Defendants

71. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

72. The Individual Defendants acted as controlling persons of Beta Bionics within the meaning of Section 20(a) of the Exchange Act. By reason of their positions within the company, and their ownership of Beta Bionics stock, the Individual Defendants had the power and authority to cause Beta Bionics to engage in the wrongful conduct complained of herein. Beta Bionics controlled the Individual Defendants and all of its employees. By reason of such conduct, Defendants are liable pursuant to Section 20(a) of the Exchange Act.

XIII. PRAYER FOR RELIEF

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

(a) Awarding compensatory damages in favor of Plaintiff and the 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;

(b) Awarding Plaintiff and the Class their reasonable costs and expenses incurring in this action, including reasonable counsel fees and expert fees; and

(c) Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

XIV. JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: September 4, 2026