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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

BARRY HOLTZMAN, Individually
and on Behalf of All Others Similarly
Situating,

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

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

12 **I. NATURE OF THE ACTION**

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

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

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

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

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

25 5. On January 30, 2026, Beta Bionics' SEC Form 8-K disclosed that the
26 Company had received a warning letter from the FDA related to its earlier Form
27 483, and that the issues raised in the warning letter went far beyond mere
28 complaint handling. Then on February 12, 2026, CF issued yet another report

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

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

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

22 **II. JURISDICTION AND VENUE**

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

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

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

6 11. In connection with the acts, transactions, and conduct alleged herein,
7 Defendants directly and indirectly used the means and instrumentalities of
8 interstate commerce, including, but not limited to, the United States mail, interstate
9 telephone communications, and the facilities of the national securities exchanges
10 and markets.

11 **III. PARTIES**

12 **A. Plaintiff**

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

17 **B. Defendants**

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

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

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

1 16. Saint and Feider are collectively referred to as the “Individual
2 Defendants.” The Individual Defendants, together with Beta Bionics, are referred
3 to as “Defendants.”

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

19 **IV. SUMMARY OF THE FRAUD**

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

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

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

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

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

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

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

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

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

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

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

15 **V. DEFENDANTS’ FALSE AND MISLEADING STATEMENTS¹**

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

24 **A. False Statements During the Second Quarter 2025 Earnings** 25 **Call**

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

28 ¹ All emphasis is added.

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

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

9 29. The statements in ¶¶27-28 were false and misleading when made
10 because Defendants omitted mention of the FDA Form 483 and iLet's underlying
11 safety issues. Contrary to Saint's statement that the iLet "demands the least
12 engagement from the user" and is "the most automated" insulin pump on the
13 market, the CF's January 12, 2026, interviews with former Beta Bionics employees
14 and patients exposed how the Company had failed for almost two decades to
15 develop a working failsafe to prevent excess dosing, and thus how Defendants had
16 rushed iLet to market with a dangerously aggressive automated dosing algorithm.
17 Moreover, the FDA had already issued its Form 483—pointing to thousands of
18 unreported safety complaints, many requiring medical intervention and
19 hospitalization—in June 2025. Therefore, it was misleading for Saint to tout "the
20 superior clinical outcomes of the iLet with our real-world data," and for Feider to
21 state that healthcare professionals "are seeing good results from their patients,"
22 while omitting that the FDA had taken issue with thousands of unreported patient
23 complaints. Even if the FDA had not issued the Company a Form 483, it would
24 have been misleading for Defendants to tout the device's "superior" real-world
25 outcomes without also discussing the serious medical events iLet had caused, and
26 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*

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

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

16 36. Defendants’ statements in ¶¶30-35 were false and misleading when
 17 made because they portrayed the Form 483 as relating only to a difference of
 18 interpretation of reportable events and downplayed the seriousness of those events.
 19 Saint’s and Feider’s statements in ¶¶30-31 were misleading because they touted
 20 iLet’s performance but omitted the thousands of safety complaints the Company
 21 had received. It was misleading for Saint to tell investors, in ¶32, that the Form 483
 22 concerned only a minor difference in interpretation of reporting rules, and that the
 23 complaints to be back-filed were only benign reports requiring no hospitalization,
 24 when, in fact, the Form 483 identified over 18,000 complaints out of less than
 25 30,000 total iLet users, including numerous life-threatening hypoglycemic events
 26 that the Company had “failed to investigate,” or even report to the FDA, with no
 27 justification. Saint and Feider further misled investors by, in ¶33, assuring them
 28 that the Company’s remediation efforts were advanced and the FDA’s issues were

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

8 **C. Defendants’ False Statements in the Company’s January**
 9 **30, 2026, Form 8-K**

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

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

25 **D. False Statements During the Fourth Quarter 2025 Earnings**
 26 **Call**

27 39. During Beta Bionics’ fourth quarter 2025 earnings call on February
 28 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

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

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

24 **VI. THE TRUTH IS REVEALED**

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

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

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

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

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

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

16 45. Management felt pressure to respond on its February 17, 2026,
17 earnings call, where Defendants discussed but continued to downplay the warning
18 letter. For instance, Defendants admitted for the first time that some of the back-
19 filed complaints required medical intervention but minimized this fact by pointing
20 out that the FDA's definition of "medical intervention" could include giving a
21 patient candy to correct their blood sugar. Defendants thus continued to mislead
22 investors by leaving out that the back-filed reports also contained conditions
23 serious enough to require hospitalization and be classified as "life-threatening."
24 Analysts believed Defendants' minimization, with Truist reiterating on February
25 17 that the warning letter "focuses on quality-system controls, complaint/MDR
26 [Medical Device Report] handling and related procedures, not on the safety or
27 performance of the company's insulin pump itself." Indeed, the market credited
28

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

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

15 **VII. ADDITIONAL SCIENTER ALLEGATIONS**

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

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

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

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

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

1 **VIII. LOSS CAUSATION**

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

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

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

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

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

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

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

3 **IX. NO SAFE HARBOR**

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

18 **X. PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET**

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

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

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

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

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

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

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

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

24 **XI. CLASS ACTION ALLEGATIONS**

25 61. Plaintiff brings this action as a class action pursuant to Federal Rule of
26 Civil Procedure 23(a) and (b)(3), individually and on behalf of a Class consisting
27 of all persons and entities that purchased or otherwise acquired the publicly traded
28

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

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

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

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

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

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

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

4 **XII. CLAIMS FOR RELIEF**

5 **COUNT I**

6 **For Violation of § 10(b) of the Exchange Act and 7 Rule 10b-5 Promulgated Thereunder Against All Defendants**

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

10 68. During the Class Period, Defendants disseminated or approved the
11 false statements specified above, which they knew or recklessly disregarded were
12 misleading in that they contained misrepresentations and failed to disclose material
13 facts necessary in order to make the statements made, in light of the circumstances
14 under which they were made, not misleading. Defendants violated Section 10(b) of
15 the Exchange Act and Rule 10b-5 in that they:

- 16 (a) employed devices, schemes, and artifices to defraud;
- 17 (b) made untrue statements of material fact or omitted to state
18 material facts necessary in order to make the statements made, in light of the
19 circumstances under which they were made, not misleading; or
- 20 (c) engaged in acts, practices, and a course of business that
21 operated as a fraud or deceit upon Plaintiff and others similarly situated in
22 connection with their purchases of Beta Bionics common stock during the Class
23 Period.

24 69. Plaintiff and the Class have suffered damages in that, in reliance on
25 the integrity of the market, they paid artificially inflated prices for Beta Bionics
26 common stock. Plaintiff and the Class would not have purchases Beta Bionics
27 common stock at the prices they paid, or at all, if they had been aware that the
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1 market price have been artificially and falsely inflated by Defendants' misleading
2 statements.

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

6 **COUNT II**

7 **For Violation of § 20(a) of the Exchange Act** 8 **Against the Individual Defendants**

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

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

18 **XIII. PRAYER FOR RELIEF**

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

20 (a) Awarding compensatory damages in favor of Plaintiff and the
21 other Class members against all Defendants, jointly and severally, for all damages
22 sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial,
23 including interest thereon;

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

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

1 **XIV. JURY DEMAND**

2 Plaintiff hereby demands a trial by jury.

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