

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

ARKANSAS TEACHER RETIREMENT
SYSTEM, THE CITY OF BRISTOL
PENSION FUND, and THE CITY OF
OMAHA POLICE AND FIRE RETIREMENT
SYSTEM, on behalf of themselves and all
others similarly situated,

Plaintiffs,

v.

INSULET CORPORATION, DUANE
DESISTO, ALLISON DORVAL, BRIAN
ROBERTS and CHARLES LIAMOS,

Defendants.

Civ. A. No. 15-12345-MLW

CLASS ACTION

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

JURY TRIAL DEMANDED

ECF CASE

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Plaintiffs Arkansas Teacher Retirement System, the City of Bristol Pension Fund and the City of Omaha Police and Fire Retirement System (collectively, “Lead Plaintiffs” or “Plaintiffs”), by and through their undersigned counsel, allege the following upon information and belief, except as to those allegations concerning Lead Plaintiffs, which are alleged upon personal knowledge. Lead Plaintiffs’ information and belief is based upon, *inter alia*, counsel’s investigation, which includes review and analysis of: (a) regulatory filings made by Insulet Corporation (“Insulet” or the “Company”) with the United States Securities and Exchange Commission (“SEC”); (b) press releases and media reports issued by and disseminated by the Company; (c) analyst reports concerning Insulet; and (d) other public information regarding the Company or the industry in which it operates. Plaintiffs’ investigation also included interviewing or consulting with various individuals, including former Insulet employees who worked at the Company during the Class Period and current and former employees of entities that did business with the Company during the Class Period, who are knowledgeable about defendant Insulet’s business, operations and business practices, and/or about the industry and markets in which Insulet operates. Except as alleged herein, the underlying information relating to Defendants’ (defined below) misconduct and the particulars thereof are not available to Plaintiffs and the public and lie within the possession and control of Defendants or other Insulet insiders, thus preventing Plaintiffs from further detailing Defendants’ misconduct. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION

1. This is a securities fraud class action brought on behalf of purchasers of Insulet’s publicly traded common stock from May 7, 2013 through April 30, 2015, inclusive (the “Class Period”). The claims asserted herein are alleged against Insulet and certain of its current and

former senior executives (collectively, “Defendants”), and arise under §10(b) and §20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder.

2. Insulet is headquartered in Billerica, MA, and is a manufacturer of insulin infusion pumps that are used to treat people with diabetes. In contrast to traditional insulin pumps, Insulet’s “pods” are tubeless, are worn on the body for three consecutive days, and are controlled by a handheld, wireless device known as a personal diabetes manager (“PDM”). In 2013, Insulet began selling a new (and purportedly improved) version of its infusion system, known as the OmniPod Eros (“Eros”). The Eros is more than a third smaller and a quarter lighter than the original OmniPod, while ostensibly maintaining the same features and operating capabilities.

3. The Class Period starts on May 7, 2013, the first trading day after Insulet’s former CEO, Defendant Duane DeSisto, touted the Company’s launch of its new Eros system by stating that customers’ initial feedback was excellent, that Insulet had transitioned all of its new customers to the new Eros, and that as a result Insulet’s growth was surging in both the US and overseas. Thereafter, Insulet and its executives continued to make similarly positive statements to investors and analysts throughout the Class Period, including statements that touted the growth of Insulet’s OmniPod business and increases in the number of new Eros patients.

4. Defendants’ statements, however, were materially false and misleading. In truth, from the introduction of its new Eros OmniPod in early 2013, Insulet was encountering significant manufacturing and quality issues. Those problems were reflected in a significant number of manufactured lots of Eros product that did not meet quality standards – notably with regard to defective needle and alarm mechanisms – and in frequent production shortfalls. Because diabetes patients who use the OmniPod device require multiple daily doses of insulin, Insulet needed to deliver a steady and reliable supply of product in order to meet demand and avoid losing customers who were unable to obtain product as needed. But instead of enforcing FDA and Company quality

requirements, Defendants routinely engaged in the improper practice of blending shipments into “mixed lots” – *i.e.*, taking product from lots that had high defect rates and mixing them with product from higher quality lots – to maximize the amount of product (including defective product) that it could ship and to maintain the false appearance that its “roll-out” of the new Eros product was not being impaired by any product quality issues. Unsurprisingly, but unbeknownst to investors until the end of the Class Period, the result of such undisclosed practices was increased alienation and frustration on the part of Insulet’s distributors and patients, short-term sales “growth” that was distorted by distributors’ lack of confidence in Insulet’s ability to supply quality product, and a *decline* in Insulet’s critically important U.S. sales and new patient starts.

5. When discussing Insulet’s manufacturing capabilities and production quality, Defendants repeatedly misrepresented and failed to disclose that the Company was experiencing significant problems and, on the few occasions when it referenced any quality problems at all, they assured investors that any problems that the Company had experienced were unexceptional and had been fully addressed and corrected. Indeed, prior to his departure in the third quarter of 2014, Defendant DeSisto (Insulet’s CEO) insisted that Insulet’s quality control process caught any unreliable OmniPod Eros production lots before they left Insulet’s facilities, and that defective pods from substandard production lots therefore never reached the Company’s patients or distributors.

6. In reality however, and unbeknownst to investors until much later, Insulet’s manufacturing and quality control issues were chronic and serious, and had a significant adverse impact on Insulet’s ability to (a) add new customers and (b) convert its existing customers (especially in the US) to the Eros. These problems caused Insulet’s growth in its critical and higher-margin US markets to stagnate and ultimately decline. But rather than disclose the true nature and extent of Insulet’s manufacturing and quality problems – and how those issues had

adverse effects that compounded the significant problems that Insulet had experienced over the course of the launch of its Eros product in 2013 and 2014 – Defendants repeatedly misrepresented and concealed the truth from investors.

7. For example, Insulet manipulated the way it reported “new patient starts,” which was a critical metric for analysts and investors, so as to trick financial analysts into believing that the Company was experiencing strong new patient growth in the US, when in fact its new patient growth in the US was actually beginning to *decline* by 2014. Similarly, although it reported large increases in sales to its international distributor Ypsomed Distribution AG (“Ypsomed”), it failed to disclose that those sales were a reflection of Ypsomed’s desire to build up inventory in response to Ypsomed’s concerns about Insulet being able to maintain quality product supply into 2014, given the extent of Insulet’s undisclosed manufacturing and product quality issues. As a result, investors (and analysts) would later be shocked to discover in 2015 that the problems with the Eros roll-out had been much worse than previously disclosed, that those problems had caused the Company’s European sales to be artificially inflated during the Class Period well beyond then-existing and sustainable end-user demand in Europe, that the Company’s misleading reporting had conveniently masked a decline in new patient growth in the US, and that Insulet’s much touted growth prospects had been built on a foundation of quicksand.

8. In response to the combination of undisclosed manufacturing and growth problems, beginning in late 2014 Insulet engaged in a dramatic replacement and restructuring of its executive management. First, on September 16, 2014, Insulet announced that Defendant DeSisto was retiring and would be replaced by Patrick Sullivan as CEO. As Mr. Sullivan assumed control of the Company, a host of additional executive departures soon followed. For example, Defendant Roberts resigned in November 2014, Defendant Dorval resigned in March 2015, and Defendant

Liamos left the Company in May 2015, all while Insulet and its new CEO tried to come to grips with the undisclosed realities of the Company's business.

9. The truth concerning the problems at Insulet began to emerge to the public after the close of the market on January 7, 2015, when Insulet disclosed that (a) it was appointing six new executives from outside of the Company into key leadership positions, and (b) its fourth quarter 2014 revenue would be \$5 to \$8 million less than the Company's recent guidance (*i.e.* down from \$76-\$81 million to only \$71-73 million, or down roughly 7% to 10%), due largely to reduced demand for Eros product from Insulet's distributors (who were seeking to reduce their existing inventory levels). On this news, Insulet shares declined by almost 9% on heavy volume.

10. Just one week later, on January 14, 2015, the Company presented at a JP Morgan Healthcare Conference. During his transcribed remarks at that conference, Insulet's recently appointed CEO Patrick Sullivan stated that analysts' expectations of Insulet's performance in 2015 were "a tad bit high," and that earnings for the first quarter of 2015 were expected to be flat sequentially over the fourth quarter of 2014.

11. Immediately after his presentation at that conference, CEO Sullivan held a breakout session with analysts during which he admitted that Insulet's new OmniPod system had experienced serious problems, that the Company's new patient growth in the US had actually been ***declining*** rather than increasing over the past year, and that Insulet would be changing the deceptive way in which it had been reporting OmniPod sales during the Class Period. These remarkable disclosures were not revealed to investors until they were reported by leading analysts in reports published after the close of trading on January 14, 2015. As further detailed herein, analysts and investors had understood the Company's disclosures concerning "new patient" starts and "new patient increases" (frequently expressed as a percentage) as reflecting increases in the Company's new patients ***in the US***. However, on January 14, 2015 Insulet's management

admitted that the Company had, since at least early 2014, been reporting “new patient starts” in a manner that combined new patients in both the US and in Europe. As analysts explained following this admission, during the Class Period the Company had reported revenue on large amounts of OmniPod sales to Ypsomed (its European distributor) that were unsustainable because Ypsomed had built up inventory levels in 2013-14 well beyond what it could reasonably sell without significantly reducing its future stocking orders. Thus, Insulet’s reported “new patient” data had not only been inflated by the Company’s previously undisclosed change in reporting that had boosted the numbers by including overseas patients, but the number of overseas new patient starts was itself apparently inflated by basing it on the artificially high level of Ypsomed “inventory stocking” sales recorded during 2013 and 2014 (which were at levels far above what Ypsomed could sustain based on its actual end-user demand). Indeed, as Sullivan was forced to admit, rather than having experienced a substantial increase in new US patient starts during 2014, the number of Insulet’s new US patients *had actually declined by 9%*.

12. In response to CEO Sullivan’s statements to analysts on January 14, analysts and investors immediately realized that Insulet was in far worse shape than even its disclosures of January 7 had indicated, and that Insulet management had been misleading investors as to the Company’s true health, (including with respect to the critical new patient starts metric). For example, as a JP Morgan analyst report dated January 15, 2015 stated: “[*Yesterday’s disclosures indicate that the US OmniPod underlying business was in worse condition than prior management comments led us to believe, and the mishandling of the Eros launch was more damaging than widely assumed.* Part of what we learned [yesterday] is that following a strong Eros launch in 2013, new patient starts began to slow in the US in early 2014, *but this was masked* ... by a large OUS [outside-the-US] stocking order from Ypsomed.” (Emphasis added.)¹

¹ Throughout this Complaint, all emphasis in quotations is added unless otherwise indicated.

13. Similarly, as a William Blair & Co. analyst report published on January 16 stated: ***“Management disclosures have been incomplete, at best... [while] misleading investors as to the underlying health of the core OmniPod business. We now know that US patient starts were down 9% in 2014 from 2013....”*** (Emphasis in original).

14. The news that Insulet’s (mis)handling of the Eros product launch in 2013 had been far worse than feared – and that the Company had been masking the deterioration in its core business by manipulating its use of the “new patient starts” metric (while simultaneously also concealing how it had used large Ypsomed OUS stocking orders to further conceal the shocking decline in Insulet’s primary US business) – had an immediate and stark impact on Insulet’s share price. Specifically, in response to information concerning Sullivan’s admissions that reached the market prior to the opening of trading on January 15, 2015, the price of Insulet’s stock declined again, from a closing price of \$38.50 on January 14, 2015 to \$31.86 per share at the close on January 15 – a further one-day decline of over 17%, on extremely heavy volume.

15. Then, after markets closed on April 30, 2015, Insulet again reported extremely disappointing revenue of just \$61 million for the first quarter of 2015 (the quarter ended March 31, 2015), compared to Insulet’s prior guidance, issued just two months earlier, of \$67 million to \$69 million. During the Company’s earnings conference call later that day, Insulet blamed these results on Ypsomed’s efforts to reduce the amount of its excess OmniPod inventory, which it had built up through large purchases from Insulet in prior quarters because of its undisclosed concerns about Insulet’s ability to keep it adequately supplied with non-defective product.

16. On April 30, Insulet also disclosed that (a) it had generated only \$39.2 million from its US OmniPod business in the first quarter of 2015, or approximately 4% *less* than it had generated from its US business in the first quarter of the prior year (2014) and that (b) Insulet’s overall revenue had declined more than 11% (from \$69.2 million to \$61.2 million) over the same

period. Contrary to Defendants' numerous Class Period statements that attributed Insulet's increasing revenue to the adoption of the Eros by new users and a growing "customer base," the April 30 disclosures revealed the extent to which previously reported revenue growth was in fact largely attributable to Ypsomed building a large inventory stockpile beyond existing patient demands in Europe as a "hedge" against Insulet's production woes, and the extent to which Insulet's US business was contracting even more sharply than revealed by its January 2015 disclosures. On this news, the price of Insulet's stock dropped from \$29.85 at the close on April 30, 2015 to \$26.97 per share on May 1 – for a further one-decline of almost 10%.

17. Insulet's admissions concerning its inability to produce defect-free product also further confirm the allegations below, reflecting that these problems, and their adverse impact on the Eros roll-out effort, were known to senior Insulet management from the beginning of the Class Period. For example, a January 27, 2015 JP Morgan analyst report described how Insulet CEO Sullivan had admitted to analysts earlier that month that "*as the Eros launch progressed, quality issues came to light, including occlusions and increased alarms,*" and that these problems had affected the product's acceptance, reputation and growth. Moreover, on June 5, 2015 the US Food and Drug Administration ("FDA") sent a warning letter (the "2015 FDA Warning Letter") to Insulet that confirmed that it had manufactured *and shipped* defective lots of OmniPod Eros product between mid-2013 and the first half of 2014 – lots which FDA inspectors had concluded were "adulterated" in that "the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation" were in violation of both "current good manufacturing practice requirements" ("CGMP") and Insulet's own "quality assurance final acceptance criteria." In response, on August 27 2015, Insulet confirmed that it had recalled 40,846 boxes of OmniPod product manufactured between the second half of 2013 and the end of 2015 "due to the possibility that some of the Pods from those lots may have a higher rate of failure than

[permitted under] Insulet’s current manufacturing standards.” Similarly, on an August 12, 2015 conference call just two weeks earlier, CEO Sullivan admitted that despite Defendants’ prior assurances that any significant manufacturing quality issues with the Eros product had been “corrected” in early 2013, product quality problems had actually continued into 2013 and 2014

18. By this complaint, Plaintiffs now seek recovery for themselves and all other class members to compensate them for the severe and substantial losses and damages that they have suffered as a result of Defendants’ fraudulent scheme and their repeated violations of the securities laws and their disclosure obligations thereunder.

JURISDICTION AND VENUE

19. The claims asserted herein arise under §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. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and pursuant to §27 of the Exchange Act, 15 U.S.C. § 78aa.

20. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b). Insulet maintains its executive offices in this District and many of the acts and conduct that constitute the violations of law complained of herein, including the dissemination to the public of materially false and misleading information, occurred in and/or were issued from this District. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

21. Plaintiff Arkansas Teacher Retirement System (“Arkansas Teachers”) is a public pension fund based in Little Rock, Arkansas that provides retirement benefits to Arkansas’ public school and education employees. As of March 31, 2014, Arkansas Teachers had over \$14 billion

in assets under management. Arkansas Teachers purchased Insulet common stock on the NASDAQ stock market (“NASDAQ”) during the Class Period and suffered damages as a result of the federal securities laws violations alleged herein.

22. Plaintiff the City of Bristol Pension Fund (“City of Bristol”) is a public pension fund based in Bristol, Connecticut that provides retirement benefits to Bristol’s employees. As of June 31, 2015, City of Bristol had over \$550 million in assets under management. City of Bristol purchased Insulet common stock on the NASDAQ during the Class Period and suffered damages as a result of the federal securities law violations alleged herein.

23. Plaintiff City of Omaha Police and Fire Retirement System (“Omaha P&F”) is a public pension fund based in Omaha, Nebraska that provides retirement benefits to Omaha’s police and fire department employees. As of June 31, 2015, Omaha P&F had approximately \$600 million in assets under management. Omaha P&F purchased Insulet common stock on the NASDAQ during the Class Period and suffered damages as a result of the federal securities law violations alleged herein.

24. Defendant Insulet is incorporated in Delaware and maintains its principal executive offices at 600 Technology Park Drive, Suite 200, Billerica, MA, 01821. Insulet’s primary business is the development, manufacture, and sale of its proprietary OmniPod Insulin Management System. Insulet generates nearly all of its revenue from sales of its OmniPod System and other diabetes related products, such as blood glucose testing supplies, traditional insulin pumps, pump supplies, and pharmaceuticals to customers and third-party distributors who resell the products to patients with diabetes. Insulet’s common stock trades on NASDAQ, an efficient market, under the ticker symbol “PODD.” As of April 28, 2015, there were approximately 56.75 million shares of Insulet common stock outstanding.

25. Defendant Duane DeSisto (“DeSisto”), was at all relevant times Chief Executive Officer (“CEO”), President, and a Director of Insulet until September 16, 2014, when he resigned these offices and was replaced in those positions by Patrick J. Sullivan (“Sullivan”), who has served as the CEO, President, and a Director of Insulet since that date.

26. Defendant Charles (Charlie) Lamos was a member of the Board of Directors of Insulet since 2005, and at all relevant times until he resigned as a director as of May 13, 2015. In addition, from January 10, 2011 until January 21, 2014, Defendant Lamos also served as Insulet’s Chief Operating Officer (“COO”). Defendant Lamos resigned as COO on January 21, 2014 and began serving as Insulet’s Director, Advanced Technology, which position he held at least through February 11, 2015.

27. Defendant Brian Roberts (“Roberts”) was at all relevant times Insulet’s Chief Financial Officer (“CFO”) until November 6, 2014, when he left the Company and was replaced in that position by Defendant Dorval.

28. Defendant Allison Dorval (“Dorval”), was the Company’s CFO at all relevant times after November 6, 2014, when she was appointed to replace defendant Roberts in that position. Prior to her appointment as CFO, Dorval had served as Insulet’s Controller from 2010 to 2014. On March 30, 2015, the Company announced that Dorval was being replaced as CFO effective May 4, 2015 to pursue “other professional opportunities” (which were not specified).

29. Defendants DeSisto, Dorval, Roberts and Lamos are collectively referred to hereinafter as the “Individual Defendants.” The Individual Defendants, because of their positions with Insulet, possessed the power and authority to control the contents of Insulet’s reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. Each Individual Defendant was provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance

and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each Individual Defendant knew that the adverse facts and omissions specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations and omissions which were being made were then materially false and/or misleading.

DEFENDANTS' FRAUDULENT SCHEME

I. THE NATURE OF INSULET'S BUSINESS

30. Insulet's primary business is the development, manufacture and sale of the Company's proprietary insulin management system, which is marketed under the "OmniPod" brand name. OmniPod is an insulin infusion system for people with insulin-dependent diabetes that is worn anywhere on the body for approximately three days at a time, and that allows patients to receive their insulin without the customary injections. After three days, the person attaches a new OmniPod, purchased from Insulet or one of its distributors, to their body.

31. Because diabetes is a chronic, life-threatening disease for which there is no known cure, the number of new patients that purchase Insulet's OmniPod system (also known as "new patient starts") is an extremely important financial metric for investors and analysts. Once a person becomes an Insulet customer and adopts the OmniPod system, it is reasonable to assume that such new patients will become repeat customers, and will thereby provide a recurring stream of revenue to the Company for years into the future. Moreover, the number of new patients that Insulet was able to add in the US (as opposed to new international patients) was of particular importance because new US patients generated much higher margins of approximately 60% for Insulet, as opposed to margins of just 20% from new patients based outside of the US ("OUS").

32. Insulet began selling OmniPod product in the US in 2005, mainly by selling the product directly to consumers or through distribution partners. In January 2010, Insulet entered

into an exclusive distribution agreement with Ypsomed to sell OmniPod product in Europe through 2018. Under that distribution agreement, Insulet supplies OmniPod to Ypsomed, but Ypsomed is ultimately responsible for re-selling product to end-user patients.

33. In 2013, Insulet began selling a new and purportedly improved OmniPod system, called “Eros.” The Eros pod purportedly maintains all of the convenience features of the prior OmniPod designs, but is significantly smaller and lighter. In connection with its OmniPod Eros product launch, Insulet announced that would start all of its new patients going forward on the new Eros version, and that it would transfer all of its then-existing patients (who had previously been using the prior version of the Company’s OmniPod system, referred to herein as the “OmniPod 2”) to the new Eros version.

II. THE SERIOUS AND UNDISCLOSED ADVERSE FACTORS IMPACTING INSULET’S BUSINESS DURING THE CLASS PERIOD

34. Unbeknownst to investors, immediately before and during the Class Period, Insulet’s new OmniPod Eros manufacturing operations and product launch efforts were plagued by a host of severe problems. These problems (a) seriously undermined Insulet’s ability to develop robust growth in “new patient” starts, and also (b) alienated many of the Company’s pre-existing customers, who grew increasingly frustrated with the delays they experienced in getting transitioned to the new OmniPod Eros system, as well as with the defective product quality issues that they (as well as new patients) experienced once they were belatedly transitioned to the highly touted Eros system. These significant and serious problems included the following: (a) problems with the “firing” of the Eros pods’ needles, which needed to fire properly to start and maintain the flow of insulin into the patient through the needle insertion site; (b) problems with defective pods that leaked, which also resulted in patients not receiving their insulin; and (c) problems with defective alarms, which resulted in the pods constantly alarming for no legitimate reason.

A. Needle Mechanism Failures

35. From the inception of production of the OmniPod Eros, Insulet consistently experienced manufacturing problems that resulted in defective pods where the needle did not properly “fire.” For example:

- a. According to a senior quality engineer at Insulet from August 2011 until July 2014 who was responsible for corrective actions, preventative actions and dealing with non-conforming product, the OmniPod Eros was plagued by needle mechanism failure problems for more than a year prior to the start of the Class Period through the day s/he left Insulet in mid-2014. As s/he explained, a patient would have to first attach the Eros pod to his or her body, and then have to “fire” the unit’s needle into their skin to receive their dosage of insulin. As s/he added, the “needle mechanism failures” were a “major issue for [Insulet],” but even though Insulet’s most senior executives – including Defendant DeSisto (CEO) and Defendant Lamos (COO) – were aware that the Company was “giv[ing] product to patients that we know may not work,” in the end the decision was always made to ship the product because getting product shipments out the door was critical to Insulet’s survival. *See also* §III.B below.
- b. A former senior Insulet officer responsible for manufacturing operations who left in the first half of 2014 after more than five years with the Company, was part of the engineering team that converted from the OmniPod 2 to the Eros. As s/he explained, when Insulet switched its design from the OmniPod 2 to the Eros, the Company “changed how the needle fired.” The way the needle was firing, and the way the device was put together, the needle was “getting hung up” in the sheath (also referred to as a cannula). When the needle fires, a piece of metal with the sheath at the end of it goes into the patient, but if the sheath is damaged on the way in the needle pulls back and the person is left with the sheath in them but no needle (so the patient may think they are getting insulin when they are not). In sum, “the accusation that we had needle firing issues is absolutely true ...” Patients were “pissed off” because when the needle didn’t fire right, patients would have to take the Eros pod off and replace it. As s/he explained, “*every single lot was failing.*”
- c. Insulet’s former officer responsible for manufacturing operations further stated that s/he was “pretty sure” there were times when Insulet’s head of quality control (Ruthann DePietro or Tracey Wielenski) would refuse to sign off on the shipment of product – but when that happened Defendant Lamos would sign off. The manufacturing operations officer was familiar with the sign-off process because s/he was the person who would sign on behalf of engineering/operations.

- d. Similarly, a pump trainer consultant for Insulet from mid-2013 through the end of the Class Period, also confirmed the existence of significant needle mechanism problems with the OmniPod Eros system, such that the needle would not always be injected into the patient. In fact, s/he personally tested the OmniPod system for a time, and personally experienced pods with needles that did not properly “fire” or insert. S/he further stated that as far as s/he knew, Insulet never addressed this problem with its patients. S/he added that although the “tubeless” nature of the OmniPod system was great, the product defect aspects of the pod (including the frequent alarming problem discussed below) were “life threatening, especially for children,” as children were less likely to monitor their OmniPod for problems and as a result would be more likely to not get the right amounts of insulin they needed.
- e. A former customer care supervisor who joined Insulet at the beginning of 2014 and stayed with the Company through the end of the Class Period also responded “oh yeah, it was pretty regular” when asked if s/he was aware of quality or defective manufacturing issues with the Eros product – particularly with respect to the needles not firing correctly.

B. Leaking Pods

36. Similarly, from the inception of production of the OmniPod Eros, Insulet also consistently experienced manufacturing problems that resulted in defective pods that leaked. For example:

- a. According to the senior quality engineer who worked at Insulet from 2012 to mid-2014, and who was responsible for corrective actions, preventative actions and dealing with non-conforming product, the OmniPod Eros suffered from leakage problems for more than a year prior to the start of the Class Period through the day s/he left Insulet in mid-2014. As this Insulet senior quality engineer explained, “leaks within the pod” obviously posed problems for Eros users because they would not be getting the full dosage of insulin that they required. As with the needle mechanism failure problems, Insulet’s most senior executives – including Defendants DeSisto (CEO) and Lamos (COO) – were aware that the Company was “giv[ing] product to patients that we know may not work,” but in the end the decision was always made to ship the product because getting product shipments out the door was critical to Insulet’s survival. *See also* §III.B below.
- b. According to a regional sales manager at Insulet from 2011 until late 2013, among the product defect problems that s/he recalled from 2013 were leaky pods around the infusion site, where the insulin would leak and the patient would not get the full amount. This regional sales manager also specifically recalled a quarterly sales meeting held at the Mohegan Sun Casino and attended by approximately 65 people (10-12 from the various regions) where Insulet’s then Chief Commercial Officer (Peter Devlin) and Vice President of Sales (Patrick Treanor) told the gathered sales representatives that “internationally there was less than a handful of [product] complaints” about Eros – which left this sales manager incredulous because “we

had at least a handful of [product] complaints” just in the room where the meeting was held. Indeed, one Insulet employee that s/he knew actually stopped using Eros altogether because they did not trust the product.

C. Defective Alarms

37. Similarly, from the inception of production of the OmniPod Eros (as well as during the production of the predecessor original OmniPod product), Insulet also consistently experienced manufacturing problems that resulted in defective pods where the pod’s alarm would not function properly and would instead generate false alarms. For example:

- a. As stated by a regional sales manager who worked at Insulet for more than four years until leaving during the first quarter of 2014, “we had a lot of alarming pods.” Pods would alarm for no reason, and the problem increased during the Eros launch. Patients would call customer support, and there would be screaming patients who would call to complain that “they couldn’t get past 12 or 48 hours without a [false] alarm” (pods were meant to last up to 80 hours or three days before an alarm was meant to sound for things such as a low battery or a deactivated pod). This regional sale manager stated that when there was an increase in alarms, Defendant Liamos (Insulet’s COO) would travel to Insulet’s production plant in China (where the Eros was manufactured) in an effort to fix the quality problems; s/he further recalled thinking at the time “if we continue to have this amount of pod problems, how can we continue to sell the product?”
- b. As stated by the former senior quality engineer at Insulet from 2012 to mid-2014, who was responsible for corrective actions, preventative actions and dealing with non-conforming product, the OmniPod Eros suffered from a software defect that caused “unnecessary alarms for occlusion,” which indicated that the pump was occluded when in fact it was not. Indeed, s/he recalled that toward the end of 2013 or beginning of 2014, the Company’s key European distributor, Ypsomed, became concerned about the needle and alarm defects in Eros. (*See also* ¶40(f), below.) Nonetheless, despite known high defect rates, in the end Insulet’s decision was always made to ship the product because getting product shipments out the door was critical to Insulet’s survival. *See also* §III.B below.
- c. As stated by the former senior Insulet officer responsible for manufacturing operations, Insulet’s problems with improperly alarming pods began prior to the class period, as the OmniPod 2 system’s software was “very, very sensitive.” As s/he further explained, the system’s high sensitivity would cause the system’s alarm to go off based on its detection of an “occlusion” (i.e., blockage) even when there was no such problem – which in turn caused Insulet to “get a lot of complaints” from patients. Unfortunately, these “alarm” problems carried over to the development of the OmniPod Eros, with Insulet’s European distributor Ypsomed reporting continuing issues with the occlusion alarm in 2012 and 2013. As s/he stated, “Time went by and customers got frustrated.” There were times when

DePietro refused to sign off on product due to the alarm problems, and Defendant Lamos would override her and sign off.

- d. A sales territory manager at Insulet from approximately late 2012 through early 2014 similarly confirmed that there were constant problems and customer complaints involving manufacturing defects with the Eros pods, most of which involved “alarming pods.” Patients would call this sales territory manager directly about problems: “the phone wouldn’t stop ringing” and it was like “drinking out of a firehose.” The calls started in or around May of 2013, almost immediately after the Eros pod was launched in the US. As s/he stated, “it was crazy It happened all the time with customer complaints.” The sales territory manager was confident that senior management was aware of the problems because “it was a pretty flat managerial structure” at Insulet and this manager (and other territory sales managers) could, for example, “pick up the phone” and call Pat Treanor, the VP of sales, directly. S/he further stated that Defendants Lamos (the COO) and DeSisto (the CEO) were aware of the alarm issue and that the sales reps were receiving huge numbers of complaints. Indeed, this was “common knowledge” at Insulet. Sales reps would talk to each other and discuss how their customers had “got a bad lot,” but management would never admit to the sales force in the field that there were any “bad lots.”
- e. The former customer care supervisor who worked at Insulet from the beginning of 2014 through the end of the Class Period was also familiar with OmniPod’s false alarm problems, including irate customers who would complain about, e.g., the Eros alarm going off for no reason in the middle of the night and waking patients up.

III. DEFENDANTS’ MANUFACTURING PROBLEMS AND DELIBERATE DECISIONS TO KEEP SHIPPING DEFECTIVE PRODUCT LEAD TO STILL FURTHER PROBLEMS

38. As discussed in §II above, the defects in Insulet’s OmniPod Eros product were pervasive and severe, and defied “quick fix” solutions that would have enabled the Company to quickly put these problems behind it. However, rather than candidly disclose the true scope of the product quality problems that faced the Company, Defendants sought to conceal these problems.

A. Production Problems Seriously Interfere with the Launch of the OmniPod Eros

39. Typical of Defendants’ approach was to repeatedly tell investors that Insulet could not keep up with demand for the new Eros product, but while not disclosing that this situation was

the result of production delays caused by Insulet's inability to "de-bug" its manufacturing processes. For example:

- a. As Insulet's former senior officer responsible for manufacturing operations stated, quality issues contributed to Insulet not being able to meet the demand.
- b. As the former regional sales manager who worked at Insulet from January 2010 through March 2014 similarly stated, Insulet's senior management was "very creative with investor calls." For example, s/he described how, repeatedly in the years prior to his/her departure in the first half of 2014, it was apparent that the sales force was "not making the numbers [management] wanted" -- and the volume of phone calls from "irate customers" that Insulet was experiencing only confirmed that the Company could not be doing well. Nonetheless, s/he observed that Insulet's senior management always managed to "spin" the Company's quarterly reports to make it seem as if things were going well.

B. Defendants' Deliberate Shipment of Defective Product and Other Irregular Practices

40. Moreover, in order to further conceal the extent of the Company's Eros problems, Defendants (led by Defendants DeSisto and Lamos, the CEO and COO, respectively) resorted to systematically shipping out batches of Eros product even though they *knew* (or at minimum recklessly disregarded) that the lots that they were shipping did not meet the requisite outgoing quality levels. For example:

- a. As stated by the senior quality engineer at Insulet from August 2011 until September 2014, despite the known needle, leakage and false alarming problems with the OmniPod Eros, there was always a "big push" to release even defective product shipments into the market. When s/he joined Insulet in August 2011, Insulet required an outgoing quality level of 98%, which meant that Insulet had a high confidence level that what it was releasing was good product and Insulet would not ship product that did not meet the requisite level. However, by the second and third quarters of 2013, Insulet released product that it knew had an outgoing quality level of as low as 68%. Such product would include both "Severity-A" failures, such as the needle mechanism failure and leaking pod problems discussed in II.A above, and "Severity B" failures, such as the defective alarm problem discussed in §II.C above. S/he further noted that Defendants CEO DeSisto and COO Lamos had "signature authority" to release product and that Lamos "was the biggest push there." Specifically, products with "Severity A" failures, such as the needle mechanism and leaking pod issues discussed above, required senior management, typically Lamos or DeSisto, to sign off, in addition to a quality and regulatory signature from Ruthann DePietro. S/he confirmed that if DePietro wouldn't sign, Lamos would sign for her. S/he further recalled "ongoing back and forth

discussions” along the lines of “Do we give product to patients that we know may not work? Or do we not give it to them?” ***In the end, however, the decision was always made to ship because if Insulet did not ship the product the Company might fail.***

- b. Insulet’s former senior quality engineer further confirmed that it was her/his responsibility to clear lots that were flagged as defective, which meant having to go to Defendant DeSisto (the CEO), Defendant Lamos (the COO), DePietro or Tracey Wielenski (V.P. for global regulatory, clinical affairs and quality assurance from January 2013 to March 2015) to get signatures to approve such lots for shipment. S/he recalled that s/he took issue with Insulet shipping lots out to the public that they knew were going to fail, which included lots that were tagged with an orange paper indicating that it was a non-conforming lot. As s/he put it, “it was an issue when the statement ‘ship it’ became pretty popular. No matter what, we’re gonna ship it.” As/he recalled, others would look at a lot, typically valued at around \$250,000, and ask “How can we throw that away?” Indeed, s/he confirmed: ***“There was never a lot rejected.”***
- c. As Insulet’s former senior quality engineer further described, one popular “solution” to the quality problem was to deliberately ***“blend”*** defective with non-defective lots. S/he explained the process as follows: If a lot did not meet the requisite outgoing quality level, Insulet had to go through what was meant to be a rigorous process to determine if patients would be better off with the defective devices than not before it would ship them. ***If a lot was at 70 or 74%, for example, even though DePietro or Wielenski might not “sign off” on releasing the lot, “Duane [DeSisto] and Charlie [Lamos] would” – and there was “never a case that they scrapped a non-conforming product, no matter what the quality level.”*** For example, s/he recalled a time when a lot “went down to 68%,” which meant that 32% of the lot would result in Severity A or Severity B failures. As s/he explained: “[W]e were letting [lots] go at 68%.” In sum, based on internal documentation of the outgoing quality levels, these lots “should not be released,” and “the only way it gets released is senior management,” typically Defendants Lamos or DeSisto, signed off on it.
- d. Moreover, when asked about the “process” that the Company used to justify sending out non-conforming shipments, Insulet’s former senior quality engineer simply said “they put together a story.” To try to conceal the extent of defective lots and maintain product shipments, Insulet’s senior quality engineer further explained how Insulet would blend lots with lower defect rates with lots that had 80% to 90% failure rates, so that the overall expected failure rate for a given shipment as a whole would be decreased.
- e. Insulet’s former senior quality engineer served in roles that were similar or more senior than her/his role at Insulet at other medical product companies, and noted that having some product defect issues in a given lot is part of the normal course of business – but none ever released lots with the kind of high failure rates that repeatedly occurred at Insulet. Instead, based on her/his more than three years with Insulet, the OmniPod product defect rates were ***“much more extreme”*** than what

s/he had ever seen, *and the rule at Insulet was that they were “not scrapping lots” and “losing a quarter million dollars” on a defective lot.*

- f. Insulet’s former senior quality engineer from 2009 through 2014 similarly stated that “every single lot was failing.” S/he was also familiar with Insulet’s practice of “*blending*” unacceptable lots with better quality lots in order to justify sending out greater overall amounts of product. S/he was “positive that the Quality Department was extremely unhappy with blending.” Indeed, s/he explained that this was one of the main reasons why, in several cases, DePietro refused to sign off on product. In those instances, Defendant Lamos would sign for DePietro. S/he further confirmed that patients getting defective pods would, understandably, become aggravated. For example, Ypsomed was vocal in complaining that there were a lot of patients in Germany who became aggravated with the quality of Insulet’s pods, and was so upset that Insulet that privately agreed to start shipping Ypsomed “lots that tested better.”
- g. As the former regional sales manager at Insulet from January 2010 until March 2014 stated, “I know it’s a sales business but at some point you’ve crossed the line.” While s/he noted that having some defective product was to be expected, the problem at Insulet was that management was “so focused on sales that they didn’t want to hurt the numbers,” which is what would have happened had the Company not sent out so much defective product. In sum, as s/he observed, “if you know these pods are not going to work, don’t send them out.” S/he also heard reports from other sales managers and the home office that management was “cherry-picking the pods [for shipment]” and knew which areas were going to get hit with the poorer quality pods; in other words, Insulet was knowingly “rotating shoddy pods, when there was a bad test lot, to various territories.” Accordingly, s/he would try to find out internally what lot numbers were “having issues” so s/he would have some advance notice if “sh—tty box[es]” were being sent to their customers. S/he even recalled that the son of a senior Insulet manager ended up receiving pods from a defective lot, and was furious because the manager thought s/he should have at least been told in advance that the product was from a lot that Insulet had flagged as defective.
- h. A reimbursement coordinator at Insulet from 2010 to May 2014 described that another manipulative tactic that Insulet engaged in was to send pods to patients even if they were not covered by their insurance. This “happened on numerous occasions.” Although doing so was technically against company policy, no one ever seemed to do anything about it – even though the Company was aware of the problem because when such pods were returned, the returns “got taken off the salespeople’s numbers,” meaning that their compensation was reduced. This practice was “pretty well known [among] reimbursement personnel and sales people” at Insulet, including her/his supervisor, Jillian Avery Snow (the Company’s senior manager for intake operations). Indeed, s/he raised her/his concerns about this practice with Avery Snow repeatedly throughout her/his employment with Insulet, including through multiple meetings with Avery Snow. In addition, s/he personally kept track of “habitual” bad practices, such as the Company’s practice of shipping pods to patients that were not covered by their insurance. S/he was

concerned that Avery Snow was not being proactive in handling this issue and instead would “blow things off. Rather than try to correct the problem, Avery Snow would simply say “it is what it is” and “turn the other cheek to things that weren’t being done appropriately.” When asked if senior management also seemed disinterested in addressing these issues, she responded that, “Sales was a priority for them so they let a lot of things go. They didn’t want to affect their sales.”

- i. The sales territory manager at Insulet from approximately late 2012 through early 2014 similarly confirmed that sales personnel would have their commissions “docked” if product was returned, regardless of the reason. If a quota was 40 new patients, and the sales person only made 39 sales, “that would cost a couple grand or more in commission.”

C. Customer Complaints and Product Servicing Problems

41. Further contributing to Insulet’s difficulties in transitioning their existing customers over to Eros were serious problems with Insulet’s customer service capabilities, which were significantly understaffed in relation to the Eros roll-out problems that the Company experienced.

For example:

- a. The regional sales manager who worked at Insulet from 2011 until late 2013, confirmed that Insulet “absolutely” was experiencing significant problems with converting their customers over to Eros in 2013 (before s/he left the Company at the end of that year). In particular, there were “significant problems converting because we didn’t man our customer care environment enough.” Patients would contact customer service and not get callbacks “for two or three weeks, if at all” – a problem that s/he attributed to a severe understaffing problem and Insulet’s “lack of bandwidth to run [customer service].” Poor product quality compounded the problem, because -- although there was limited supply of Eros pods – patients would have to order new pods when the ones they had failed. These problems lasted at least through her/his departure in late 2013, and s/he added that it was “well documented on email” at Insulet that there were significant issues with product quality, customer service, patients that ran out of supplies due to receiving defective product, and related problems that the Company experienced in trying to navigate these issues.
- b. As the former regional sales manager who worked at Insulet from 2010 through early 2014 similarly noted, Insulet patients also experienced shortages because of the number of pod replacements that would be required because of defective pods, leading to dissatisfied customers. Indeed, during the Class Period, her/his sales reps “were so busy putting out fires that they [didn’t have time] to sell [to new customers].” In other words, they had to spend all their time dealing with complaints from existing customers so that they wouldn’t lose them as customers. As s/he put it, “2013 was a year of complaints and issues ...” and Insulet “went through hell a couple of times.” Moreover, so many customers demanded to speak

to a more senior manager about defects in their pods that Insulet's chief commercial officer Peter Devlin, its vice president of sales Pat Treanor, and its senior director for managed care and national accounts, Dino Tsamparlis, amongst others, would end up talking to irate patients. It was the "Peter, Pat and Dino show ... Peter, Pat, everyone was talking to patients." When asked how Devlin, Treanor and other more senior managers would deal with these calls, s/he stated that "they would just say that they're looking into the quality of the pods," but would also try to "figure out a way to blame the customer" and explain away defective product problems as "user error." In the meantime, during 2013 and through the time s/he left the Company in the first half of 2014, "there were so many [Insulet] customer service people that quit [that] it created a lot of angry customers."

c. *See also* §III.D(2), below.

D. Deteriorating Demand

42. By 2014 the demand for Insulet OmniPod products had leveled off, further exacerbating the Company's difficult competitive and operational circumstances during the Class Period – even though at the same time the Company was leading investors to believe that it was continuing to experience strong growth in demand for its OmniPod infusion products.

(1) Ypsomed and Flattening Demand in Europe

43. Over the course of the Class Period Insulet's key European distributor, Ypsomed, built up a massive backlog of OmniPod inventory because of its concerns about Insulet's ongoing ability to timely produce a sufficient volume of reliable, defect-free product. In other words, knowing that it would experience substantial customer attrition if patients ran out of properly functioning OmniPods, and knowing that Insulet had both quality control and related production volume problems, Ypsomed built-up a large inventory of product, which by the end of 2014 vastly exceeded demand from European end-users. For example:

- a. The former senior quality engineer at Insulet stated that s/he was familiar with Ypsomed in part because s/he had worked with them in previous jobs, and s/he confirmed that Insulet "absolutely" pushed Ypsomed to purchase more product than it could sell. As s/he added: "The push was at the end of the quarter, all the time to [have Ypsomed and other distributors] buy unnecessary inventory so [Insulet] could hit their numbers at the end of the quarter." The need for this "push" was "discussed openly" within Insulet. S/he was aware of these discussions largely in the context of her/his tracking of defective product and because s/he was

responsible for doing investigative analysis to determine if product could be released. The push to ship defective product lots would arise at the end of each quarter, when management would need to get defective lots “released in a timely manner.” Such discussions were “common knowledge” at Insulet. As noted in §III.D(2) below, however, Ypsomed was actually more fortunate than Insulet’s US distributors, who were also asked to “[take] product they didn’t need” – but who would typically get poorer quality lots than Ypsomed. This was because Ypsomed specifically expressed that they did not want poorer quality lots.

- b. As Insulet’s former senior officer responsible for manufacturing operations also confirmed, Ypsomed was “mad” at Insulet because, although they were contractually obligated to buy a certain amount of Insulet pods, “sales weren’t good” because Ypsomed did not get enough Eros pods, and to the extent that it did get the new Eros pods many of its customers were upset by the manufacturing defects in that product.

44. At the same time, in its public statements through January of 2014, Insulet misleadingly and deceptively reported “new user” increases and growth in a manner that included both US and “OUS” (foreign) patients, despite knowing that the market and Wall Street analysts believed that the “new user” counts and increases reflected only new patients from within the US. These two aspects of the deception thus significantly inflated and overstated the actual patient demand for the OmniPod Eros in both the US and overseas. However, as noted above and discussed further below, by the end of 2014 Ypsomed no longer needed to purchase more OmniPods to meet current demand, and (as Defendants knew) would have to go through a prolonged “destocking” process during the first half of 2015, which meant that Defendants would no longer be able to conceal the truth about OmniPod demand.

(2) Demand in the United States

45. Similarly, as various sources have confirmed, throughout the Class Period Insulet also regularly pressed its US distributors to purchase more product (including defective product) than they needed to meet their current end-user demand, all while many patients in the US (to the extent not fed up with the product quality issues discussed above after they started to receive the

Eros) became fed up with delays in getting signed for the Eros product in the US in the first place.

For example:

- a. As the former senior quality engineer at Insulet stated, “The push was at the end of the quarter, all the time to [have distributors] buy unnecessary inventory so [Insulet] could hit their numbers at the end of the quarter.” The need for this “push” was “discussed openly” within Insulet. S/he was aware of these discussions largely in the context of her/his tracking of defective product, because the push to ship defective product lots would also arise at the end of each quarter, when management would need to get defective lots “released in a timely manner.”
- b. That senior quality engineer also noted that the initial Eros product shortages in the United States during the US Eros roll-out took a significant toll on Insulet’s ability to sign up new patients, as the majority of prospective new patients would get fed up with the length of time it could take to get signed up for and receive the new Eros product. “We had a lot of complaints about turnaround time,” and although the sales staff would get “lots of leads” the “majority” of new prospects would choose another pump because of delivery and customer service problems. S/he also noted that when prospective new patients would send in their forms to various companies so they could start getting needed insulin products, the wait time was longer at Insulet than it was at Insulet’s competitors.
- c. The sales territory manager at Insulet from approximately late 2012 through early 2014 also confirmed, the Eros product shortages meant that Insulet’s efforts in 2013 to significantly increase their direct marketing efforts to endocrinologists were problematic. As this sales territory manager stated, many doctors wouldn’t recommend the product if there was no ready product inventory. In addition, even when doctors would recommend a patient, Insulet’s customer service and enrollment practices were too slow to be competitive, as Insulet would need to contact patients at least three times to get consent to investigate their insurance provider, do a benefits investigation, and then (after Insulet obtained a signed statement of medical necessity from the patient’s doctor) get a final “yes or no” from the patient. As a result, there was “mammoth attrition” because new patients would drop off during the process, as the sales cycle became so stretched out that new patients would go with a different product.
- d. A consultant who was brought in to help improve Insulet’s sales and related new-patient intake training from early 2014 through 2015 also described how Insulet had on average a 30 day wait time for a customer to receive a pod – whereas “Medtronic had [this process] down to a science,” with the result that its customers would be able to get their pods much quicker.
- e. In short, as the sales territory manager noted in paragraph c above, even though Insulet did a good job of creating initial demand for Eros in the first half of 2013, at the beginning of its planned Eros product launch in the US, matters quickly devolved into a “major inventory issue,” “running out of pods” and a substantial inability to execute on the promises that Insulet had made to its existing patients to

convert them promptly to the new Eros product – the net result of which resulted was a “big ol’ disaster” that “everyone” in the Company knew about.

- f. Similarly, the customer care supervisor who joined Insulet at the beginning of 2014 and stayed with the Company through the end of the Class Period stated that (although it was before his/her time) s/he had heard “all the stories” about how it had been “a nightmare” trying to convert existing OmniPod customers to the new Eros product in 2013 because of manufacturing defect issues and related supply problems – and because existing customers were upset about Insulet sending the Eros product only to new patients in 2013 despite their prior loyalty to the OmniPod. Indeed, s/he stated, “That’s one of the biggest complaints we got.” A “considerable number” of patients left because of quality issues. As s/he further reported, because there was not a “patient retention team” at the time, “a lot of [existing] customers left.” Insulet’s lack of adequate customer service staffing, however, continued into 2014 and 2015, as Insulet “never had enough staffing.” For example, when a patient got new insurance, there were never enough staff to handle the paperwork, “and when you’re doing hundreds and thousands of intakes a month, things fall through the cracks.” More specifically, Insulet lost significant numbers of customers because of inadequate customer support staffing, as patients would have to constantly call and follow-up with everything, and would ultimately get frustrated and go elsewhere.

IV. CLASS PERIOD EVENTS

A. Insulet and Defendants DeSisto and Roberts Tout the Launch of the OmniPod Eros

46. The Class Period starts on May 7, 2013 -- the first trading day after Insulet held its earnings conference call for the first quarter of 2013. During that May 6 conference call, defendant and then-CEO DeSisto touted Insulet’s launch of its new OmniPod system, stating *inter alia* that during the quarter “[Insulet] transitioned all [of our] new customer starts to the new OmniPod, **and the initial feedback has been excellent.**” As Defendant DeSisto further represented, new referrals and overall OmniPod shipments had also **increased by more than 40%** since March 1, 2013 as compared to the prior year. Indeed, according to DeSisto, in the prior month (April 2013) these metrics had increased even more rapidly, by more than 50% compared to the prior year.

47. On that conference call, defendant DeSisto also represented that Insulet was seeing increased demand in Europe, given that “Ypsomed continues to accelerate the rate of patient additions.” Similarly, then-CFO Brian Roberts told investors that international sales “was

probably *more than triple* what that number was” over the prior year, and that “Ypsomed has done a great job of accelerating demand.” While Insulet disclosed that it had experienced a component issue with its new OmniPod that resulted in lower than expected planned production, DeSisto downplayed the issue and told investors that the Company “had quickly identified and remedied the problem” and “remain[ed] confident that nearly all customers will be transitioned by the end of the third quarter.” During his questioning by analysts, Defendant DeSisto also reiterated that the product component problem had already been fixed, and that none of the defective product had ever “left the building.”

48. Securities analysts reported on and accepted Defendants’ statements concerning the Eros roll-out, patient growth and the fixing and full resolution of any manufacturing problems. On May 7, 2013, JP Morgan issued an analyst report that repeated the Company’s commentary by stating that “Insulet’s new OmniPod launch has been well received in the marketplace.” Noting that “[t]here was increasing investor concern in recent weeks around a delay to the Eros OmniPod launch,” JP Morgan also reported that it had been reassured by the Company that “the [component] issue” that had briefly contributed to this delay “has since been corrected and affected product never left the plant.” Similarly, a May 7, 2013 report by Jefferies recounted that the Company had experienced a “minor manufacturing issue,” but that it had “since been resolved.” Analysts from JMP Securities similarly reported on May 7, 2013 that Insulet had experienced a “minor component issue,” but emphasized Defendants’ representations that this “minor” issue “had been identified and remedied.” Other analysts from Oppenheimer and Piper Jaffray, published similar reports on May 7, 2013.

49. Defendants’ statements as set forth in ¶¶46-47 were, however, materially false and misleading for the reasons set forth in greater detail in §VI below.. In truth, Insulet’s rollout of its new OmniPod Eros was experiencing *serious* setbacks due to significant manufacturing and

quality problems with the new Eros pods, and the Company was ill-equipped to convert its existing customer base over to the new Eros product. As a result, Insulet was unable to build enough inventory of the new OmniPod Eros, causing significant and increasing customer frustration -- and a sharp decline in new US patient starts. At the same time, Insulet was misleading investors as to the level of international demand for its product. In particular, and unbeknownst to investors, Insulet's distributor in Europe, Ypsomed, was purchasing substantially more product than it had present demand for, and was doing so because of its concern about Insulet's undisclosed manufacturing defect problems and related concerns about being able to secure sufficient quantities of Eros product in the future that were free from material defects.

50. Reflecting the market's acceptance of Defendants positive statements about the Eros and the "quick and complete" remediation of a "minor" manufacturing issue in the prior quarter (and the Company's implicit representation that it was now free of any significant defective product issues), on May 7, 2013, the price of Insulet's common stock opened at \$25.84 per share—up from the closing price of \$24.87 the prior day. Over the course of trading on May 7, Insulet common stock reached an intraday high of \$29.00 before closing at \$28.57 per share. The \$25.83 per share intraday low at which Insulet stock traded on May 7 was the lowest price at which it traded during the Class Period.

51. On August 7, 2013, after the close of the financial markets, Insulet announced its financial results for the second quarter of 2013 and held an earnings conference call. Defendants reassured investors that the Company had had an "outstanding quarter," and reiterated that Insulet had no outstanding material manufacturing issues and thus had the ability to increase manufacturing production to ensure that the Company would have sufficient inventory to keep the Eros roll-out on track. In addition, management advised that, as a result of certain cuts to Medicare reimbursement rates for diabetes testing supplies, Insulet would stop selling those supplies

altogether – and that as a result, the quarterly revenue Insulet generated from its wholly-owned Neighborhood Diabetes subsidiary would decline from roughly \$12 million to roughly \$7 million per quarter (or from roughly \$48 million to roughly \$28 million per year). But analysts were not unduly concerned by this disclosure, as Insulet’s margins on Neighborhood Diabetes’ remaining revenue streams were relatively low, and the \$5 million loss in revenue from the sale of diabetes testing supplies would in any event be offset by the growth in Insulet’s OmniPod business.

52. Defendants’ statements and assurances on August 7, 2013 as set forth in ¶51 above were accepted by the market. For example, in an analyst report dated August 8, 2013 based on defendants’ representations, JP Morgan told investors that “[d]espite modest disruption to near term ordering patterns [as a result of transition existing patients to the new Eros product], the new OmniPod launch is by all accounts going very well.” Moreover, JP Morgan noted that “We view new patient adds as the key leading indicator for Insulet’s growth,” and viewed Defendants’ commentary and reported results as a “solid update” (even though they also caused JP Morgan to now “assign no value” to Insulet’s remaining, low-margin Neighborhood Diabetes business).

53. Investors reacted positively to Defendants’ misstatements and related commentary concerning the second quarter of 2013, as Insulet shares rose by \$3.10 per share –an increase of 10.1% -- on the next trading day (August 8, 2013) to close at \$33.78.

54. Defendants’ statements as set forth in ¶51 were, however, materially false and misleading for the reasons set forth in greater detail in §VI below. In sum, and unbeknownst to investors, the Company was having significant problems transitioning its existing client base over to the new OmniPod, and concealed the extent to which Insulet needed to rely on its low-margin Neighborhood Diabetes subsidiary to support reported revenue growth. Further, Defendants’ false assurances to investors regarding the success of the new OmniPod launch concealed the true extent

of the Company's defective product problems and kept the price of Insulet common stock artificially inflated.

55. On November 7, 2013, Insulet held its third quarter 2013 earnings conference call. On that call, the then-CEO, Defendant DeSisto, again touted the Company's purported success in launching the OmniPod Eros. As DeSisto stated: "OmniPod continues to receive an extremely enthusiastic response in the market place. Demand for the OmniPod continues to exceed our expectations with new patient starts more than 40% higher than a year ago, with no signs of this growth slowing in Q4." DeSisto also represented to investors that "[i]nternational demand for the new OmniPod [Eros] also continues to be strong. . . . since the beginning of the year, diabetes revenues have increased by more than 100% as compared to the prior year."

56. Further, Defendant DeSisto represented that Insulet had nearly finished transitioning its existing customer base to the new OmniPod Eros system. The then-CFO, Defendant Roberts, also assured investors' that although Insulet had "[gone] through customer service bumps and bruises" during the transition, the only "bumps and bruises" that Defendants referred to involved the administrative problems of having to deal with so many customers who wanted to be transitioned to the Eros as quickly as possible. Indeed, far from disclosing the Company's continuing product defect problems, Defendant Roberts assured investors that "We think the patient base is happy with the product and things are going great."

57. Analysts responded positively to Defendants' materially false and misleading statements. In an analyst report dated November 8, 2013, JP Morgan declared Insulet's performance "impressive," noting that during the third quarter Insulet "completed the heavy lifting of transitioning of its existing base to the new, smaller OmniPod. New patient additions remained robust during the quarter, growing over 40% YOY on a tougher sequential comp."

58. Defendants' statements as set forth in ¶¶55-56 were, however, materially false and misleading for the reasons set forth in greater detail in §VI below. In sum, and unbeknownst to investors, the Company was having problems transitioning its existing client base over to the new OmniPod and Insulet's growth was declining as a result. Further, defendant DeSisto's false assurances to investors regarding the success of the new OmniPod launch concealed the existence and extent of the significant product problems, and thereby kept the price of Insulet common stock artificially inflated.

B. In 2014 Defendants Continue to Misrepresent the Success of the OmniPod Eros and Mislead the Market Concerning the Number of "New" Patients

59. On February 27, 2014, Insulet held its earnings conference call for the fourth quarter of 2013. During that call, defendant DeSisto heralded 2013 as a "monumental year for Insulet," emphasizing that "[w]e finished the year with new patient additions growing at a rate north of 40% year-over-year." Further, according to DeSisto, "we have also been thrilled with the performance [of] the OmniPod internationally. . . . Ypsomed's customer base more than doubled in 2013." Indeed, DeSisto told investors that Ypsomed was not having any problems meeting the minimum purchase requirements under its contract with Insulet, and that Ypsomed's business would double yet again in 2014. Following the announcement of these purportedly strong results for fiscal 2013, Insulet's shares increased by \$2.17, up 5%, to close at \$47.41 in trading on February 28, 2014.

60. Analysts were successfully misled by Defendants' fraudulent statements. On February 28, 2014, JP Morgan issued an analyst report praising Insulet's 40% "[n]ew customer growth," stating that "[t]he company has moved past manufacturing supply constraints and end user demand remains robust for OmniPod both in the US and Europe[.]"

61. Defendants' statements as set forth in ¶59 were, however, materially false and misleading for the reasons set forth in greater detail in §VI below. In sum, and unbeknownst to

investors, Ypsomed did not have sufficient current end-user demand to sell the amounts of product that corresponded to its minimum purchase requirements under its contract with the Company. Instead, Ypsomed purchased the volume of OmniPods it did because it was concerned about Insulet's ability to timely produce enough reliable product to meet future demand, and was thus accumulating a significant backlog of inventory based on its concerns that many of OmniPods it received would be defective and that Insulet's ability to maintain a steady flow of acceptable product was unreliable. Additionally, defendant DeSisto's statements regarding Insulet's ostensibly tremendous growth were materially false and misleading because DeSisto concealed that the Company was experiencing severe problems manufacturing and rolling-out Insulet's new OmniPod infusion system, which would cause growth to decline.

62. On May 7, 2014, Insulet held its first quarter 2014 earnings conference call. On that call, defendant CEO DeSisto stated that Insulet had added approximately 20% new patients over the prior year, and was on track to grow at a rate of at least 25% during all of 2014. DeSisto also explained that "Ypsomed reported an increase of 117% year-over-year in their diabetes direct business." When pressed by an analyst during the May 7, 2014 call, Defendant Roberts (Insulet's CFO at the time) refused to respond to a question from Bill Plovanic, an analyst from Canaccord Genuity, who inquired about whether Insulet's international revenue exceeded 10%. Instead, Defendant Roberts stated "we're not going to comment specifically on what the revenue number is..."

63. Based on Defendants' statements, JP Morgan issued an analyst report on May 8, 2014, stating that "[n]ew customer growth decelerated to 20% in the first quarter from 40%+ the past two quarters, but has rebounded in 2Q with new patient growth up 40% so far vs. 1Q14." In addition, JP Morgan reiterated its view that "[Insulet] has moved past manufacturing supply constraints and end user demand remains robust for OmniPod both in the US and Europe[.]"

64. The statements set forth in ¶62, however, materially false and misleading for the reasons set forth in greater detail in §VI below. In sum, and unbeknownst to investors, but as investors would learn towards the end of the Class Period, the Company changed its reporting from prior quarters and included both US and non-US patients in the 20% new patient additions disclosed by DeSisto on May 7. Insulet intentionally made this shift in order to conceal a staggering decline in US new patient additions that resulted from Insulet's botched roll-out of its new OmniPod system. The Company did not tell investors that the 20% growth in new patients included both US and international patients and Defendant Roberts's evasion concerning the component of revenue represented by Insulet's international business (i.e., Ypsomed) furthered the deception that growth was substantially due to "new" patients in the US.

65. On August 7, 2014, Insulet held its earnings conference call for the second quarter of 2014. During that call, Defendant DeSisto announced that new patient starts increased at a rate of just 20% year-over-year because of a change to reimbursement policies made by a significant managed care plan. At the same time, defendant DeSisto assured investors that Insulet would be able to resolve the issues with the managed care provider in the coming months, that it was "backlogging" all new patient starts, and that it was very excited about its prospects for the second half of 2014.

66. The statements set forth in ¶65 were, however, materially false and misleading for the reasons set forth in greater detail in §VI below. In sum, and unbeknownst to investors, Insulet again failed to inform investors that the reported 20% growth in new patient starts included non-US growth in new patients. This deception led investors to believe that the metric represented just new US customers. For example, as an analyst report issued by Canaccord Genuity on August 7, 2015 stated: "*US new patient adds were solid, +20% Y/Y*, and in-line with our estimate despite the disruption." Similarly, on August 8, 2014, JP Morgan stated that excluding the impact of the

payor reimbursement issue, “we estimate new patient growth would’ve been in the high-20%’s in 2Q.” It also noted that “underlying demand trends remain strong.”

67. On September 16, 2014, Insulet’s then-CEO, defendant DeSisto, abruptly resigned after 13 years at the Company, and was replaced as CEO by Patrick Sullivan.

68. On November 5, 2014, Insulet held its earnings conference call for its third quarter of 2014. On that call, the then-CFO, defendant Roberts, stated that the Company saw “probably somewhere in the 15% to 20% range, overall new patient starts year over year.” As Roberts also stated, the trajectory of new patient starts “still seems very solid here as we’re a month and a few days into the fourth quarter. So I think everybody’s feeling good about that.”

69. The statements set forth in ¶68, however, materially false and misleading for the reasons set forth in greater detail in §VI below. In sum, and unbeknownst to investors, the Company again included both US and non-US patient growth in its reported “15 to 20% ... overall new patient starts” – but without informing investors that this metric was no longer limited to US patients, as it had been in the past. Additionally, defendant Roberts knew that the trajectory of new patient starts was anything but “solid”, or something “feel[] good about.”

70. Also on November 5, Insulet announced that defendant Roberts had resigned from his position as CFO, effective November 6, and that Defendant Allison Dorval (who was then the Company’s controller) would be replacing Roberts as CFO on that date.

C. The Truth Begins to Emerge

71. After the close of the market on January 7, 2015, Insulet issued a press release announcing that it was reducing its revenue guidance for its fourth quarter (the quarter ending December 31, 2014) from \$76-\$81 million to \$71-\$73 million, and that it was cutting its full-year revenue estimate for fiscal 2014 from \$292-\$297 million to \$287-\$289 million.

72. Also on January 7, Insulet announced an extraordinary overhaul of the Company's executive management. More specifically, the Company announced that it was its Chief Commercial Officer (Peter Devlin) had resigned, and that it had hired a new Vice President of Sales, a new Vice President of Marketing, a new Vice President of Managed Care, a new Vice President of Customer Care, and a new Vice President of International.

73. In response to the Company's January 7 press release, analysts expressed immediate skepticism that the entirety of Insulet's fourth quarter of 2014 revenue "miss" could have been due to a delay in non-insulin product shipments (as they accounted for only a relatively small portion of Insulet's sales). Instead, and apparently based on additional guidance provided to them by the Company, analysts quickly attributed a material portion of the reduced guidance to reduced demand by distributors, who had begun to cut back on purchases of OmniPod Eros product. For example, as a JP Morgan analyst report issued later that day stated:

In what can only be described as a disappointing turn of events, Insulet pre-announced a surprisingly weak 4Q with guidance moving from \$76-81M (+11-18%) to \$71-73M (+4-7%) on delayed Amgen sales (\$4-6M) and US OmniPod destocking (\$1.5-\$2.5M). The abrupt shortfall in the quarter is likely to catch the Street off guard, especially given new CEO Patrick Sullivan's upbeat commentary since stepping into the role in September....

Management blamed the [4th quarter revenue] miss on a delay in non-insulin drug delivery products, which we interpret as an initial Amgen stocking order; however, such an order was never publicly contemplated in guidance....

In our view, this brings two major questions to the forefront: (1) is the 4Q US OmniPod weakness reflective of a more endemic problem with underlying growth trends; and (2) how much will 2015 numbers have to come down? We expect both questions to be answered in detail next Wednesday ... when CEO Patrick Sullivan presents at the JP Morgan Healthcare conference....

There appears to be diverging trends between direct US OmniPod sales and US distributor sales. US y/y growth in direct sales of OmniPod for diabetes was ~10% in the quarter, meaning US distributor sales were likely far below this and probably in negative territory....

The shortfall in US OmniPod sales outside of the Amgen order came from US distributors, where there was \$1-\$2M in destocking vs. a \$4M stocking order last

year on the OmniPod launch. Exiting 3Q13 when OmniPod supply was extremely tight, distributors (most of which stock inventory) padded their inventory levels in 4Q13 and probably 1Q14, followed by normal ordering patterns in 2Q-3Q14. Now entering 4Q14 with supply no longer an issue, several large distributors right sized their inventory to more normal levels, which led to a reduction of ~3 weeks of inventory. ***While it helps explain some of the miss in the quarter, it does little to assuage our fears about slowing underlying growth trends in this segment of the market (~35% of sales), although management believes that the destocking is now over.*** Since distributor vs. direct sales haven't been disclosed before, it[']s hard to gauge the exact impact, but we expect Insulet to provide a detailed breakout either at the JP Morgan conference next week or with 4Q earnings, and then on an ongoing basis.

74. Similarly, an analyst at Leerink published a "flash note" on January 7, 2015 which stated:

Today after market close, PODD preannounced 4Q14 sales of \$71-73M (+4-7%) from prior guidance of \$76M-\$81M and ***well below us and the Street*** at \$79.2 and 79.6M, respectively... In 4Q14, the majority of the miss came from late December approval of partner AMGN's (MP) Neulasta. The remainder was a result of more aggressive distributor inventory workdowns after several quarters of stocking not that PODD's 2H13 manufacturing issues are fully resolved, leaving distributors more comfortable with PODD's ability to supply the market. Ultimately, PODD did see 10% y/y and q/q 4Q14 growth in its direct US diabetes business, which makes up ~65% of total US OmniPod sales....

US Diabetes Shortfall driven by Distributor Inventory Levels. PODD noted that direct US diabetes sales – which make up 65% of total US diabetes sales – grew 10% y/y and q/q, as new patient adds again grew sequentially. But of the \$5M to \$8M 4Q 14 total sales shortfall, ~1.5M (assuming the midpoint of the range) came from the US diabetes business. According to PODD management, distributors more aggressively reduced inventory levels in the quarter after ramping inventory in the last few quarters in reaction to 2H13 supply constraints. While a reduction in distributor inventory levels could continue into 1Q15, it seems that the worst is now past and levels should stabilize or improve from here.

75. In the wake of the disclosures and related analyst commentary of January 7, 2015, the price of Insulet stock fell from \$44.53 per share at the close on January 7, 2015 to \$40.52 per share at the close on January 8, 2015 – a decline of approximately 9% on unusually heavy volume of over 3.5 million shares.

76. The Company's disclosures of January 7, however, were only partial, as Insulet's revised guidance did not disclose the true extent of the Company's weakened condition. For

example, the Leerink analyst report noted that although the pre-announced fourth quarter numbers were “clearly disappointing,” it added that “the majority of issues impacting 4Q sales guidance do seem transitory in nature based on our early read, with no real change to long-term pump market dynamics or the ultimate drug delivery market opportunity.” Similarly, a January 8, 2015 analyst report from Oppenheimer indicated that, in light of the Company’s estimates, “[w]e believe that inventory levels have now stabilized and [we therefore] model no further drawdowns in ’15.” Accordingly, the fraud continued.

77. Just one week later, after the close of the markets on January 14, 2015, the Company presented at the JP Morgan Healthcare Conference. Insulet’s recently installed CEO, Sullivan, stated that analysts’ expectations of Insulet’s performance in 2015 are “a tad bit high,” and that the Company expected its earnings for the first quarter of 2015 to be flat sequentially over the fourth quarter of 2014 with a 10%-15% decrease in the core OmniPod business. As Sullivan stated:

What I’d like to do now is take a couple of minutes to focus on some of the things, financial recap of Q4[2015]. Last week, we updated our top-line revenues for the fourth quarter in a press release.

Our overall business, as you look at – was up 17% year over year. The main reason why we released early was because we missed our projections in the fourth quarter primarily due to our drug delivery business and, to a lesser extent, *some destocking of distributors that we had on the US side.*

We’re going to give you much more color on the Q4 conference call ... [but] as for 2015, I’m extremely excited about the opportunities. [However,] *I’ve seen some of the [analyst] models that are out there, and I’d say in general they are a tad bit high...*

78. But more bad news was yet to come, as various analyst reports confirm that Sullivan provided additional information to analysts at a breakout session at the JP Morgan conference held shortly after he delivered his main remarks. In his remarks, which were not revealed to the market until they were published in analyst reports after the close of trading on January 14, 2015, Sullivan

admitted that the launch of Insulet's OmniPod Eros system had gone much worse than had previously been disclosed to financial analysts or investors; that as a result, instead of experiencing increasing new patient starts in the US, Insulet's new patient starts ***had actually declined by 9%*** in 2014; and that Insulet had effectively concealed these materially adverse facts by (a) changing the way it had reported OmniPod new patient starts and (b) using certain large "stocking orders" by Ypsomed in Europe to mask disappointing sales figures in the critical, higher margin US market.

79. In response to the disclosures of January 14, analysts and investors quickly concluded that Insulet was in far worse shape than even its disclosures of January 7 had indicated, and that Insulet management had in fact been misleading investors as to the Company's true health, particular with respect to the critical U.S. new patient starts metric. For example, as a JP Morgan analyst report dated January 15, 2015 stated:

At the JP Morgan Healthcare conference on [January 14], Insulet CEO Pat Sullivan made a number of new disclosures around the health of the US OmniPod business, ultimately revealing that it's in worse shape than ... prior management disclosure....

The heart of the matter lies in the old management team's disclosures around the business, in particular new patient growth; new patients in the US were actually down 9% in 2014 compared to the +15-29% that investors believed as a result of previous management commentary..... ***[T]here's a credibility issue here....***

To begin with, Mr. Sullivan disclosed that US new patient starts were down 9% in 2014 vs. the approaching +20% that prior management was committed to and was confident in as recently as the 3Q call [on November 5, 2014]. ***[Yesterday's] disclosures indicate that the US OmniPod underlying business was in worse condition than prior management comments led us to believe, and the mishandling of the Eros launch was more damaging than widely assumed. Part of what we learned [yesterday] is that following a strong Eros launch in 2013, new patient starts began to slow in the US in early 2014, but this was masked ... by a large OUS [outside-the-US] stocking order from Ypsomed.*** Based on [yesterday's] disclosures, we now calculate 1Q14 US new patient growth to be flat to up low single digits vs. management's April [2014] commentary of 20%....

In the quarters since, the business has struggled. ***In 2014, volumes improved sequentially, (-10%), but were[,] we [now] estimate[,] in all likelihood down 10%***

YoY [year-on-year]. Contrast this with prior management comments on the 2Q [2014] call: “So far year to date, we’re still up about 20% (in new patient starts).”

Our read is that early in 2014 management switched “new patient starts” from being a US metric to a global one. Recognize that in Europe Insulet operates through a distributor (Ypsomed), so there’s limited visibility into new patient adds or what’s going on at the patient level. *The Street was never told of this switch....*

80. Similarly, as reported in a William Blair & Co. analyst report published on January 16:

We received greater clarity into the global distribution of [Insulet’s] new patient starts from management reflecting weaker-than-expected domestic patient growth, along with some perspective on the likely pace of growth re-acceleration over the course of 2015...

Management disclosures have been incomplete, at best.... The ways in which the company discussed revenue targets, patient starts, and crucially, the components of guidance shifted over the course of 2014, misleading investors as to the underlying health of the core OmniPod business. We now know that ***US patient starts were down 9% in 2014 from 2013....***

(Emphasis in original.)

81. In response to the disclosures on January 15, 2015, including the news that (mis)handling of the Eros product launch in 2013 had been far worse than feared and that the Company had been masking the deterioration in its core business caused by manipulating its use of the “new patient starts” metric (while simultaneously also concealing how it had used a single, large Ypsomed OUS stocking order to further conceal a shocking decline in Insulet’s primary US business), the price of Insulet’s stock declined from \$38.50 at the close on January 13, 2015 to \$31.86 per share at the close on January 14 – a further one-day decline of approximately 17%, on heavy volume.

82. But rather than starting with a limited market release, Insulet opted for a full launch of the product and promised to “upgrade” its entire customer base in short order. This strategy backfired because Insulet was unable to build inventory and had difficulty processing the large amount of paperwork required to convert its existing customer base. Customers were, as a result,

frustrated, and the Company lost momentum. Further, according to CEO Sullivan, as the Eros launch progressed, Insulet learned of serious quality issues with the product, causing many physicians to stop prescribing Eros by the fourth quarter of 2013, leading to a sharp decline in new patient starts for the first quarter in 2014.

83. Indeed, as another JP Morgan analyst report dated January 27, 2015 reported in summarizing the fiasco and Defendants' related distortions and misrepresentations:

It's still early in the fallout from Insulet's 4Q miss, weak 1Q guidance, and subsequent disclosures at the JPM Healthcare conference. It's clear from all our conversations the past 10 days that investors are still trying to piece together (a) what went wrong; (b) *the disconnect between prior management's "reporting" on the business in 2013-2014 and what new management is reporting actually happened*; and (c) what it all means for the company going forward. The picture has, in our view, started to clear, but there is still no shortage of questions that matter to the 2015-16 outlook, including (1) the damage caused by Insulet's botched second-generation [Eros] launch; (2) the impact of new and increased competition; (3) the degree to which international revenues exceeded underlying demand in 2014, and the time it's going to take for demand to catch up (a headwind for international sales in 2015); and (4) the impact of a wholesale shakeup of senior management...

What wasn't clear [to financial markets] at the time was the reputational damage that resulted from the troubled [Eros] launch. We on the Street saw Insulet grow new patient starts by ~30% in 2013 and US OmniPod sales by ~20% on the back of the Eros launch, but what wasn't apparent was the mounting patient and physician frustration with the product. *According to new CEO Pat Sullivan, as the Eros launch progressed, quality issues came to light, including occlusions and increased alarms.* This was compounded by a significant pick-up in call center volumes that left patients waiting for hours to get help. By 4Q13 many physicians pulled back on their Eros prescriptions, which led to a sharp decline in new patient starts.

Adding to the underlying complexity were large distributor stocking orders in 4Q13 and 1Q14. In 4Q13, some US distributors (many of which have exclusive contracts with large managed care plans) questioned Insulet's ability to consistently supply Eros, and as a result they built a large inventory buffer. Also in 4Q13, Ypsomed, Insulet's European distributor, placed a \$4million bulk order, which ultimately slipped into 1Q14 due to capacity constraints.

In early 2014 management switched "new patient starts" from being a US metric to a global one, which masked the underlying impact of the US slowdown. Recognize that in Europe Insulet operates through a distributor (Ypsomed), so there's little to no visibility into new patient adds or what's going on at the patient

level. The Street, in short, was never told of this switch, and the “new patient starts” number became increasingly guesswork, given little to no visibility into the OUS business.

At the [January 14] JPM Conference, Mr. Sullivan disclosed that US new patient growth was down 9% in 2014 vs. the approaching 20% that prior management was committed to and was confident in as recently as the 3Q call. ***The underlying US business was clearly in worse condition than prior management disclosed, and the mishandling of the Eros launch did more damage than anyone appreciated.***

84. In sum, rather than reveal to investors its manufacturing defect problems, the adverse impact of those problems on the Eros roll-out, and the resulting slowdown in the Company’s growth, Insulet’s management intentionally or recklessly concealed the truth about the Company’s condition by changing the way it calculated and reported “new patient starts” from being just a US metric to a global metric. This shift was not disclosed to investors or analysts prior to January 15, 2015, leading investors to believe that the Company’s reported new patient starts reflected only new US patients.

85. Indeed, while Defendants previously reported to investors that Insulet’s new patient starts increased by approximately 20% year-over-year in 2014, Sullivan disclosed that the Company’s new patient starts in the US had actually decreased by 9% year-over-year. The 20% year-over-year increase included 57% growth from Ypsomed patient starts—even though investors and analysts had not been told that these Ypsomed new patients were apparently included in the 20% growth number. In fact, as of the end of 2014, 23% of Insulet’s patients, or about 17,500 of its 75,000 patients were outside of the US. This was well-above what analysts and investors had been advised, given the prior limited disclosures by the Company and the fact that Insulet had not previously broken out its revenues or patient base by geography.

86. Not only did Insulet deliberately inflate the number of its new patient starts by including sales to international customers, but it had also inflated its level of international sales. Specifically, under the Company’s distribution agreement with Ypsomed, Ypsomed was required

to purchase a minimum of \$100 million of product from Insulet from 2010-2015. Yet, through year-end 2012, Insulet's sales to Ypsomed were less than \$40 million. The gap in the agreement required Ypsomed to purchase substantially more product than it otherwise needed or could sell. While the distribution agreement between Insulet and Ypsomed is publicly available, Ypsomed's annual minimum purchase requirements are redacted and the Company's prior management never revealed to investors that Ypsomed was purchasing product it could not sell. As described above, Ypsomed's purchase volume was a function of (a) its concern about Insulet's ability to timely produce reliable product (to ensure an uninterrupted supply to patients Ypsomed had to "overbuy" and build up a massive backlog of inventory) and (b) its need to meet contractual obligations. Also obfuscating the true level of Insulet's growth is the fact that some of the Company's US distributors, who like Ypsomed, questioned Insulet's ability to consistently supply reliable Eros unites, placed huge orders in the fourth quarter of 2013 and first quarter of 2014 in order to build an inventory buffer.

87. The Company's disclosures of January 14, 2015, however, were incomplete and failed to reveal the full extent of Insulet's woes. Thus, Insulet's stock price remained artificially high.

88. On February 26, 2015, Insulet announced its earnings for its fourth quarter of 2014. On the earnings conference call the following day, the Company and its new management team finally heeded investors' calls for increased transparency and for the first time publicly reported revenue for both its US and International OmniPod franchise separately. Specifically, the Company disclosed that in 2014, OmniPod generated \$173 million in the US and \$50 million internationally. Insulet also reiterated that approximately 75% of its 75,000 patients as of the end of 2014 were in the US. In response to Insulet's poor results and related commentary, with analysts such as William Blair reporting that the belatedly disclosed details concerning Insulet's U.S.

revenue showed that it was even “worse than we thought” -- the Company’s shares closed down 3.6%, or \$1.18 per share, from \$30.19 at the close on February 26, to \$31.37 at the close on February 27, 2015.

89. While CEO Sullivan acknowledged Ypsomed’s significant destocking, he attempted to attribute it solely to the fact that Ypsomed was simply reducing its “safety stock of inventory” given Insulet’s improved production capacity. In light of this destocking, CFO Dorval announced 1Q 2015 guidance of between \$67 million and \$69 million. Nevertheless, CEO Sullivan represented to investors that the Company expected the destocking “to be finished this quarter and [Ypsomed would be] back to normal ordering patterns. . . in quarters two, three and four.”

90. Analyst commentary also found additional evidence in the Company’s February 26, 2015 disclosures that Defendants had previously misled investors. For example, as a February 26, 2015 William Blair analyst report noted with respect to Insulet’s additional disclosures as to the revenue it had historically received from one of its biggest – but lowest margin – U.S. distributors:

Neighborhood Diabetes was *How Much*? In providing a detailed breakdown of historical revenue for the first time today, management again surprised investors by doubling the previously endorsed \$30 million contribution from low-margin [U.S.] distributor Neighborhood Diabetes (ND) to \$60 million. *This is inconsistent with a disclosure by the former chief financial officer [defendant Roberts] on the second quarter 2013 investor call that led the sell-side to publish estimates showing ND at about \$30 million. As a result, investors have been paying a revenue multiple for the OmniPod franchise about 60 basis points or 10% higher than we believed.*

91. Similarly, the same William Blair report found further evidence in the Company’s February 26 disclosures that Defendants had used Ypsomed’s large stocking orders to “distort” Insulet’s reported results for at least 2014. As the report stated:

International Guidance Reflects De-Stocking, Suggesting 2014 Results were Distorted. Following recent domestic distributor restocking, management now

also expects destocking by its international partner Ypsomed in the first quarter. As a result, while the installed base should grow by 40% on strong demand, it expects overseas revenue for 2015 to be *flat*. We still believe our new patient add model is correct and that Ypsomed probably took on \$10 million to \$15 million of excess inventory last year to meet the required purchase minimums to extend [their distribution] contract out to mid-2018. While that is a bullish signal for long-term demand overseas, *it suggests that the 2014 OmniPod end-demand was weaker than the reported result.*

92. In addition, William Blair also noted:

After learning last month that new patient adds were well below what we have believed, *with fourth quarter disclosures we learned that a fair number of patients do not use OmniPod consistently.* While management is rebuilding the team and boosting investments in sales and marketing, we do not expect to see a significant change in the weak patient add performance until the second half and for revenues to recover with a lag, creating a significant second half acceleration (against easy comparisons).

As discussed above, we are discouraged by the piecemeal nature of the recent disclosures, but hopefully the story is now clear...

93. On March 4, 2015, Insulet CEO Sullivan, during a presentation at the Cowen & Co. Health Care Conference, again sought to assure investors that it was “very good to note that . . . we expect shipping product to Ypsomed this quarter. So, I think that destocking is essentially behind us in this first quarter.”

94. The representations that Ypsomed was concluding its destocking and would return to its prior purchasing patterns soothed investors’ concerns. Indeed, in the days following these assurances from Sullivan and Defendant Dorval, Insulet’s stock price climbed back to a high of \$35.62 on March 16, 2015.

95. On March 30, 2015, Insulet abruptly announced that the Company’s CFO Defendant Dorval – who had served as CFO for just over four months after replacing Defendant Roberts in November 2014 – was resigning, effective May 4, 2015.

96. After the close of the markets on April 30, 2015 – the last day of the Class Period – Insulet reported results for its first quarter of 2015. During the Company’s earnings call later

that day, CEO Sullivan announced disappointing revenue of just \$61 million, compared to Insulet's prior guidance of \$67 million to \$69 million, which had been issued just two months earlier. Sullivan attributed the bulk of this stunning decline to Ypsomed's decision to continue to destock a significant amount (approximately \$4 million) of the excess inventory it purchased in prior quarters. While Insulet did announce that it had improved its level of new patient starts, it also disclosed that it had generated *only \$39.2 million* from its US OmniPod business, which was approximately *4% less* than Insulet had generated in the first quarter of 2013. On this news, the price of Insulet's stock dropped from \$29.85 to \$26.97 per share, or almost 10%, on an unusually high trading volume of over 4.9 million shares.

V. POST-CLASS PERIOD EVENTS

97. On June 5, 2015 the US Food and Drug Administration ("FDA") sent a warning letter to Insulet CEO Sullivan concerning the safety of Insulet insulin pods that had been manufactured and shipped between mid-2013 and the first half of 2014 (the "2015 FDA Warning Letter"). In particular, the 2015 FDA Warning Letter summarized the findings of an inspection of Insulet's headquarters facility that had taken place between March 11 and March 27, 2015, and which had results in the FDA's issuance to Insulet of an FDA Form 483 "List of Inspectional Observations" (the "Form 483") on March 27, 2015. As subsequently stated in the 2015 FDA Warning Letter, the March 2015 inspection had found that certain lots of Insulet's EROS pods that the Company had released for shipment were "adulterated" in that "the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation" were in violation of both "current good manufacturing practice requirements" ("CGMP") and Insulet's own "quality assurance final acceptance criteria."

98. The 2015 FDA Warning Letter also noted that the Company's COO, Patrick Ryan, had responded to the Form 483 on April 16, 2015, but that the FDA had "reviewed the response

and ... concluded that it is inadequate,” as Insulet had not provided a sufficient description of the corrective actions it planned to implement to avoid further production and shipment of defective OmniPod products in the future. The FDA Warning Letter directed the Company to provide a list of those corrective actions and verification when the corrective actions were completed within 15 days.

99. On June 10, 2015, the Company issued a press release announcing the receipt of the FDA Warning Letter and stating that “[t]he issue noted in the warning letter relates to the Company’s release of certain lots of EROS OmniPods” that “were manufactured in mid-2013 and the first half of 2014.” Insulet’s press release did not disclose that the FDA had found the Company’s earlier April 16, 2015 response to be inadequate, but did state that Insulet “intends to respond to the issues raised in the [FDA Warning Letter] within 15 days and is committed to resolving this issue with the FDA.”

100. After the close of the market on August 12, 2015, Insulet announced its financial results for the second quarter of 2015 (the quarter ended June 30, 2015). On the subsequent conference call later that day, CEO Sullivan admitted that – despite Defendants’ prior assurances that any significant manufacturing quality issues with the Eros product had been “corrected” in early 2013 – product quality problems had actually continued into 2013 and 2014. As Sullivan stated:

As we’ve reported previously, we received a warning letter relating to observations noted during the FDA’s March 2015 inspection in our facilities in Billerica. The issue noted in the warning letter related to the Company’s release of certain products of the new generation OmniPod in mid-2013 and the first half of 2014 which had been identified during the March [FDA] audit as non-conformant to final acceptance criteria.

... [These] quality issues ... relate to the product issues associated primarily with the launch of the new OmniPod insulin delivery system back in 2013 and 2014. *Those issues remained.* They were product performance issues during – into 2013 and 2014. Those issues have been *largely* remediated. But I would say there’s always, in any disposable product, or any product for that matter, there’s always

sustaining engineering efforts that companies undertake to continuously improve the performance of the product in the field. And that's where we're in right now...

101. In addition to the costs of this recall, on the conference call Insulet's new CFO, Michael Levitz, also disclosed that as a result of allegedly new and improved "product quality" standards, in the second quarter "certain product and inventory did not meet the more stringent acceptance criteria that's now in place," with the result that the Company was increasing its write-offs for "scrap and warranty charges" by \$2.5 million in the quarter – which in turn "negatively impacted [Insulet's] second quarter gross margins by approximately 4 [percentage] points."

102. On August 27, 2015, the Company issued a press release confirming that it had recalled 40,846 boxes of OmniPod product in response to the FDA's Warning Letter "due to the possibility that some of the Pods from those lots may have a higher rate of failure than Insulet's current manufacturing standards." As the press release further stated:

There are two ways in which these pods can fail at a rate that is higher than Insulet's current standard. The cannula may either completely retract or fail to fully deploy [i.e., there may be a needle mechanism failure], which may result in the patient not receiving the expected insulin dose. Or the Pod may trigger an audible alarm indicating it will no longer deliver insulin and will need to be replaced. Both situations can result in the interruption of insulin delivery that can cause hyperglycemia, which, if left untreated, can result in diabetic ketoacidosis (DKA).

The affected lots have resulted in 90 Medical Device Reports of which 13 required medical intervention....

103. The August 27 press release also confirmed that "OmniPods from the affected lots" had been "distributed to customers from December 2013 to March 2015."

VI. DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

A. False and Misleading Statements and Omissions in Connection with the Announcement of Insulet's First Quarter 2013 Results

104. After the close of the market on May 6, 2013, Insulet announced its financial results

for the first quarter of 2013 and held an earnings conference call. During the call, Defendant DeSisto represented that “**2013 is off to a great start** as we continue to **make significant progress across all aspects of the business highlighted by the launch of our new OmniPod [Eros]**. . . . In late February, we transitioned all new customer starts [to] the new OmniPod and the **initial feedback has been excellent**. . . .**The results have been impressive**. . . . In summary we are extremely pleased with the launch of [the] next generation OmniPod **and initial feedback across the country has been exceptional**.”

105. Defendant DeSisto did note that Insulet had experienced an “unexpected component issue” that had resulted in lower than expected production in the latter few weeks of the first quarter, but represented that the problem **had already been fixed** and would only have a minor impact on the Company’s program to transition existing OmniPod 2 patients to the new Eros product. As DeSisto stated:

With [our] significant uptick in demand we did make the decision to delay the transition of existing customers [to Eros] for approximately 90 days in order to build additional OmniPod supply. While the manufacturing process continues to improve, we had an unexpected component issue that resulted in lower than planned production in the latter part of Q1 . . . [that] was quickly identified **and remedied**. . . . At this point, we expect that conversion [of existing patients to Eros] will start in the next few weeks and we remain confident that nearly all customers will be transitioned by the end of the third quarter.

Similarly, Defendant Roberts praised Defendant Liamos, for “doing a fantastic job working with [Insulet’s Chinese manufacturer, Flextronics] and all of our suppliers to really . . . move the manufacturing process here in the short term.”

106. Moreover, in response to an analyst question that sought further comfort that any manufacturing problems had been resolved, defendant DeSisto confirmed that they had been:

Analyst: Just first on the component issue, I want to make completely sure. **So you are fully resolved and you are building inventory**. Do you have inventory levels today that will support that transition [for existing patients] or do you think you will have that by the end of the month?

DeSisto: I think where we are, we will have inventory levels here in the next few weeks that we will start converting people in the quarter.... but today, as of today no. . . .

Analyst: ***And the component issue is fully resolved[?]*** They are shipping – you’re getting the components in so that you can build the inventory, so it’s just a [manufacturing] capacity issue?

DeSisto: . . . ***The answer to your question is yes.***

107. DeSisto also represented that the Company’s quality control programs were so effective that they ensured that defective product “never left the building.” As DeSisto stated in response to an analyst question:

Analyst: ***So where did you find the manufacturing and component issue, in the field or internally in QA [Quality Assurance]?***

DeSisto: . . . ***Where we found it was in QA.*** So line one was running pretty well. Line two, we’ve automated a couple of stations from line one to help continue to drive the cost out and in that automation process is where it kind of popped out. ***So the product never left the building.*** . . . And we noticed like I said, we noticed basically an eyelash of tolerance difference in the particular product, the components going to that line and ***that’s how we caught it.***

Analyst: ***Okay, so internally. That’s the key.***

DeSisto: ***Yeah, never saw the light of day.***

108. In addition, in response to an analyst’s question about “international sales growth in the quarter either year-on-year or relative to the fourth quarter of 2012,” Defendant Roberts stated: “[C]ompared to Q1 of 2012, which was probably much lighter in volume, it was probably more than triple what the number was back then and it was an uptick over Q4 of 2012. They – ***Ypsomed has done a great job of accelerating demand.***”

109. On May 8, 2013, Insulet filed its quarterly report with the SEC on Form 10-Q, which was signed by Defendants DeSisto and Roberts. In multiple places in the Form 10-Q, the Company represented that its patient base was expanding:

Our total revenue was \$57.4 million and \$47.8 million for the three months ended March 31, 2013 and 2012, respectively. ***The increase in the three month period***

is due to continued adoption of the OmniPod System by patients in the United States and internationally, as well as expansion of sales of other diabetes supplies to our existing patient base.

* * *

Cost of revenue was \$32.2 million and \$27.5 million for the three months ended March 31, 2013 and 2012, respectively. The increase in cost of revenue is due to higher sales volumes *as our patient base continues to increase*.

110. The Form 10-Q also stated: *“We believe our current manufacturing capacity is sufficient to meet our expected 2013 demand for OmniPods.”*

111. The statements set forth in ¶¶104-110 were, however, materially false and misleading, and omitted material facts, as follows:

a. Contrary to Defendants’ statements above, and as reflected in the 2015 FDA Warning Letter, the OmniPod Eros units being produced had a high degree of defects in violation of cGMP and Insulet’s own manufacturing standards, including pods with defective needle mechanisms, leakage problems, and faulty alarm systems as described in ¶¶34-37 above. Those defects had not been “remedied,” and even though they had been identified by Insulet’s “QA” process the defective product was still knowingly shipped to distributors and patients by Defendants;

b. Defendants failed to disclose that the OmniPod Eros was plagued with the foregoing serious, undisclosed manufacturing and quality control problems, such that the Company’s efforts to increase inventory supplies to support its roll-out efforts could only be effectuated by (a) materially lowering its QA standards and shipping defective product lots to its patients and distributors and thereby (b) negatively impacted the Company’s ability to increase and maintain the growth of its patient base and of its OmniPod Eros sales levels to both existing and new patients; and

c. Insulet’s statements concerning its international sales growth were

materially misleading because (a) Defendants failed to disclose that international growth was driven in significant part by Ypsomed's decision to build up a stockpile of Eros inventory at a rate well beyond what it needed to meet then-existing demand because of its serious concerns about Insulet's ability to provide adequate supplies of reliable product, and because (b) Defendants failed to disclose that Ypsomed's artificially inflated demand for Eros product was the product of Ypsomed's concerns about the extent of Insulet's manufacturing and related quality control problems, which Defendants had not publicly disclosed.

B. False and Misleading Statements and Omissions in Connection with the Announcement of Insulet's Second Quarter 2013 Results

112. On August 7, 2013, Insulet announced its financial results for the second quarter of 2013 and held an earnings conference call. During the call, Defendants again reassured investors that the Company had had an "outstanding quarter" and that Insulet's increased manufacturing capacity meant that the Company would have sufficient inventory to keep the Eros roll-out on track.

113. Defendant DeSisto went out of his way to assure investors that Insulet had not experienced any significant manufacturing problems while ramping up its production. As DeSisto commented:

As we accelerated the production, we have had to overcome some minor hiccups over the last few months. Some of these normal cost challenges have been resolved within a matter of hours. Yet, with the inventory levels low, the team remains keenly focused on assuring that we are producing at a rate to satisfy our growing demand. . . .

* * *

. . . Charlie [Liamos] and these guys, like I said, we are now producing more of the new product than we've ever produced on a given day of the old product. . . . So there's always – you look at all these kind of *normal little interruptions* that happen every day all across the world in every manufacturing company. *It's not a big deal.*

114. Defendant DeSisto also assured analysts that the Company was experiencing huge demand for the Eros and no negative feedback about the product during the roll-out process. As DeSisto stated:

I would tell you if you – the two biggest complaints [from patients] that we are having at the moment, which is pretty simple, is “I want it and I want it now” and “I don’t care what the insurance says [about my eligibility to be upgraded]”. . . .

So, I would tell you – I’m not sure what we would do differently. I’m still trying to work through that. *But I think the only complaint that we’ve heard is our customer service lines are being jammed solid* [with patients wanting to transition].”

Similarly, in the context of a question about the relative failure rates of the old pods to the new Eros pods, Defendant Roberts did not disclose the significant product defect rates that Insulet was experiencing, and instead simply commented that: “I think it’s pretty early days [to assess failure rates], while adding “[s]o from customers who are transitioning to the new pod, sometimes they think they’ve had a couple of failures but once we’ve spoken to them, it’s really just kind of that change in training, and we work them through that and they’re good to go.”

115. In addition, Defendant DeSisto advised that, due to large cuts in Medicare reimbursement rates for diabetes testing supplies that Medicare had recently announced, Insulet’s wholly owned Neighborhood Diabetes subsidiary would stop selling those supplies altogether – and Defendant Roberts further advised (in response to an analyst question) that, as a result, the remaining contribution of its low-margin Neighborhood Diabetes subsidiary to Insulet’s revenue would decline from roughly \$12 million to roughly \$7 million per quarter (or from roughly \$48 million to roughly \$28 million annually).

116. On August 8, 2013, Insulet filed its quarterly report with the SEC on Form 10-Q, which was signed by Defendants DeSisto and Roberts. In multiple places in the Form 10-Q, the Company represented that its patient base was expanding:

Our total revenue was \$60.1 million and \$117.4 million for the three and six months ended June 30, 2013 compared to \$51.0 million and \$98.8 million for the same periods in 2012. ***The increase in the three and six month period is due to continued adoption of the OmniPod System by patients in the United States and internationally***, as well as expansion of sales of other diabetes supplies to our existing patient base.

* * *

Cost of revenue was \$33.3 million and \$65.5 million for the three and six months ended June 30, 2013 compared to \$28.7 million and \$56.2 million for the same periods in 2012. ***The increase in cost of revenue reflects the higher sales volumes as our patient base continues to increase.***

117. The Form 10-Q also stated: ***“We believe our current manufacturing capacity is sufficient to meet our expected 2013 demand for OmniPods.”***

118. The statements set forth in ¶¶112-117 were materially false and misleading, and omitted to disclose material facts, as follows:

a. Contrary to Defendants’ statements above, and as reflected in the 2015 FDA Warning Letter, the OmniPod Eros units being produced had a high degree of defects in violation of cGMP and Insulet’s own manufacturing standards, including pods with defective needle mechanisms, leakage problems, and faulty alarm systems as described in ¶¶34-37 above. Those defects had not been “remedied,” and even though they had been identified by Insulet’s “QA” process the defective product was still knowingly shipped to distributors and patients by Defendants;

b. Defendants failed to disclose that the OmniPod Eros was plagued with the foregoing serious, undisclosed manufacturing and quality control problems, such that the Company’s efforts to increase inventory supplies to support its roll-out efforts could only be effectuated by (a) materially lowering its QA standards and shipping defective product lots to its patients and distributors and thereby (b) negatively impacted the Company’s ability to increase and maintain the growth of its patient base and of its OmniPod Eros sales levels to both existing

and new patients;

c. Insulet's statements concerning its international sales growth were materially misleading because (a) Defendants failed to disclose that international growth was driven in significant part by Ypsomed's decision to build up a stockpile of Eros inventory at a rate well beyond what it needed to meet then-existing demand because of its serious concerns about Insulet's ability to provide adequate supplies of reliable product, and because (b) Defendants failed to disclose that Ypsomed's artificially inflated demand for Eros product was the product of Ypsomed's concerns about the extent of Insulet's manufacturing and related quality control problems, which Defendants had not publicly disclosed; and

d. Defendants failed to disclose the extent to which Insulet needed to rely on its low-margin Neighborhood Diabetes subsidiary to support the Company's reported revenue growth.

C. Defendants' False and Misleading Statements and Omissions on August 15, 2013 at the Canaccord Genuity Growth Conference

119. On August 15, 2013, Defendant DeSisto participated in the Canaccord Genuity Growth Conference. At this conference, while making no mention of Insulet's quality control problems, DeSisto stated as follows:

But the real key of the whole thing is the ability to manufacture this. This is a class II medical device, and if you really step back and think about what it is, you are making a device that delivers one of the most – by the FDA's categorization, one of the most dangerous drugs that you can possibly deliver, which is insulin, and *you have to do it in a safe, efficacious manner.*

He again reassured investors that the Company was on track in all respects:

In terms of where we are, you can see the growth rate for the company. *We are on track I think we are pretty much spot on where we said we'd be through the first six months of this year.* We're pretty excited about it. . . . Once again, very clearly, if you look at it, we have a pretty predictable model. Kind of put in perspective for everyone, our handhelds we sell for between \$500 and \$600. It's probably – our average sell is probably about \$27 every three days in terms of pods. It becomes very, very predictable for us.

120. Defendant DeSisto also touted OmniPod Eros sales growth through its European distributor: “Ypsomed is probably four, five months ahead of us in terms of when they had the product and transitioned it, and *they’re still growing rapidly – very rapidly.*”

121. The statements set forth in ¶¶119-120 were materially false and misleading, and omitted to disclose material facts, as follows:

a. Contrary to Defendants’ statements above, and as reflected in the 2015 FDA Warning Letter, the OmniPod Eros units being produced had a high degree of defects in violation of cGMP and Insulet’s own manufacturing standards, including pods with defective needle mechanisms, leakage problems, and faulty alarm systems as described in ¶¶34-37 above. Those defects had not been “remedied,” and even though they had been identified by Insulet’s “QA” process the defective product was still knowingly shipped to distributors and patients by Defendants;

b. Defendants failed to disclose that the OmniPod Eros was plagued with the foregoing serious, undisclosed manufacturing and quality control problems, such that the Company’s efforts to increase inventory supplies to support its roll-out efforts could only be effectuated by (a) materially lowering its QA standards and shipping defective product lots to its patients and distributors and thereby (b) negatively impacted the Company’s ability to increase and maintain the growth of its patient base and of its OmniPod Eros sales levels to both existing and new patients;

c. Insulet’s statements concerning its international sales growth were materially misleading because (a) Defendants failed to disclose that international growth was driven in significant part by Ypsomed’s decision to build up a stockpile of Eros inventory at a rate well beyond what it needed to meet then-existing demand because of its serious concerns about Insulet’s ability to provide adequate supplies of reliable product, and because (b) Defendants failed

to disclose that Ypsomed's artificially inflated demand for Eros product was the product of Ypsomed's concerns about the extent of Insulet's manufacturing and related quality control problems, which Defendants had not publicly disclosed; and

d. Defendants failed to disclose the extent to which Insulet needed to rely on its low-margin Neighborhood Diabetes subsidiary to support the Company's reported revenue growth.

D. False and Misleading Statements and Omissions In Connection With the Announcement of Insulet's Third Quarter 2013 Results

122. On November 7, 2013, Insulet announced its financial results for the third quarter of 2013 and held an earnings conference call. During the call, Defendant DeSisto highlighted the new patient starts for Insulet's new product: "[T]he new smaller OmniPod [Eros] continued to receive an *extremely enthusiastic response* in the marketplace. Demand for the OmniPod continues *to exceed our expectations with new patient starts, more than 40% higher* than a year ago with no signs of this growth slowing in Q4." Later in the call, he represented that "*[n]ew patient starts remain extremely strong* and we continue to see more than 70% of our customers to be first-time pumpers."

123. Defendant Roberts also touted Insulet's new patient starts, stating that "*[n]ew customer additions continue at a rate in excess of 40% year-over-year since launch*, and we expect to continue to achieve these levels in Q4." When an analyst asked Defendants to "confirm for the third quarter . . . your new adds," Roberts answered, "Definitely up over Q2's numbers. Again, like I said, *north of 40% year-over-year increase* from where we were in Q3." Later in the call, Roberts declared that "we have seen no signs whatsoever of patient starts slowing down."

124. Defendants also emphasized patients were clamoring to get transitioned as soon as possible, and that the only significant issues in effectuating that transition had been dealing with

the many patients who wanted to change over to the Eros at the same time (rather than in a more orderly “staggered” fashion). As Defendant DeSisto stated:

In summary, we had exceptionally strong performance in the third quarter. The transition of basically the entire customer base in such a condensed time period was nothing short of moving a mountain. ***We’re pleased to have that hurdle behind us.***

* * *

. . . .[W]hen we kind of laid it out this year, the quarter we worried about was the quarter we were going to go through this transition. And it was, I guess it was every bit as painful as we imagined, but we’re pretty happy with how it turned out. We think we’re in a real good spot and we really are now focused on go-forward.

And Defendant Roberts similarly stated as follows:

Finally, as Duane noted, we remain very positive about our prospects for 2013 and beyond. The new OmniPod continues to generate excitement in the industry. And with the existing customer base transition behind us, we’re solely focused on growing the business. . . .

However, defendant Roberts gave no indication of any continuing problems relating to the Eros roll-out (and referred only to the Company having put the “customer service bumps and bruises” involved in transitioning so many people, in a short period, behind it), and echoed DeSisto’s comments to the effect that “the patient base ***is very happy with the product and things are going great.***”

125. Further, Defendant DeSisto stated that “[i]nternational demand of the new OmniPod also continues to be strong. Ypsomed noted earlier this week that since the beginning of the year the diabetes revenue has increased by more than 100% as compared to the prior year.”

126. On November 7, 2013, Insulet filed its quarterly report with the SEC on Form 10-Q, which was signed by Defendants DeSisto and Roberts. In multiple places in the Form 10-Q, the Company represented that its patient base was expanding:

Our total revenue was \$61.1 million and \$178.6 million for the three and nine months ended September 30, 2013, respectively, compared to \$54.8 million and \$153.5 million for the same periods in 2012. ***The increase in the three and nine***

month periods is due to continued adoption of the OmniPod System by patients in the United States and internationally.

* * *

Cost of revenue was \$33.7 million and \$99.2 million for the three and nine months ended September 30, 2013, respectively, compared to \$30.4 million and \$86.5 million for the same periods in 2012. *The increase in cost of revenue reflects the higher sales volumes as our patient base continues to increase.*

* * *

The decrease in inventories and increase in accounts payable, accrued expenses and other current liabilities are largely related to the scale up of our manufacturing operations as we transition our customer base to our new OmniPod System. . . . The increase in accounts receivable largely relates to the timing of shipments to customers and *overall expansion of our customer base.*

127. The filing also stated: *“We believe our current manufacturing capacity is sufficient to meet our expected 2013 demand for OmniPods.”*

128. The statements set forth in ¶¶122-127, were materially false and misleading and omitted to disclose material facts, as follows:

a. Contrary to Defendants’ statements above, and as reflected in the 2015 FDA Warning Letter, the OmniPod Eros units being produced had a high degree of defects in violation of cGMP and Insulet’s own manufacturing standards, including pods with defective needle mechanisms, leakage problems, and faulty alarm systems as described in ¶¶34-37 above. Those defects had not been “remedied,” and even though they had been identified by Insulet’s “QA” process the defective product was still knowingly shipped to distributors and patients by Defendants;

b. Defendants failed to disclose that the OmniPod Eros was plagued with the foregoing serious, undisclosed manufacturing and quality control problems, such that the Company’s efforts to increase inventory supplies to support its roll-out efforts could only be effectuated by (a) materially lowering its QA standards and shipping defective product lots to its

patients and distributors and thereby (b) negatively impacted the Company's ability to increase and maintain the growth of its patient base and of its OmniPod Eros sales levels to both existing and new patients;

c. Insulet's statements concerning its international sales growth were materially misleading because (a) Defendants failed to disclose that international growth was driven in significant part by Ypsomed's decision to build up a stockpile of Eros inventory at a rate well beyond what it needed to meet then-existing demand because of its serious concerns about Insulet's ability to provide adequate supplies of reliable product, and because (b) Defendants failed to disclose that Ypsomed's artificially inflated demand for Eros product was the product of Ypsomed's concerns about the extent of Insulet's manufacturing and related quality control problems, which Defendants had not publicly disclosed; and

d. Defendants failed to disclose the extent to which Insulet needed to rely on its low-margin Neighborhood Diabetes subsidiary to support the Company's reported revenue growth.

E. False and Misleading Statements and Omissions in Connection with the Announcement of Insulet's Fourth Quarter 2013 and Fiscal Year 2013 Results

129. On February 27, 2014, Insulet announced its financial results for the fourth quarter of 2013 and fiscal year 2013. In a press release issued that day, which Insulet filed with the SEC on a Form 8-K signed by Defendant DeSisto, the Company represented that "[t]he increase in revenue is a result of continued strong patient adoption of the OmniPod insulin pump in the United States and international markets during the fourth quarter 2013."

130. Also on February 27, 2014, Insulet held an earnings conference call. During the call, Defendant DeSisto vaunted the Company's new patient starts: "We finished the year with *new patient additions growing at a rate north of 40% year-over-year* as our easy to use design

appealed to customers[.]” Later in the call, in response to an analyst’s question, Defendant Roberts confirmed that new patient starts grew at least 40% in the fourth quarter of 2013 and 40% for the full year as well. When one analyst sought further clarification on Insulet’s new patient start numbers, Defendant Roberts obfuscated:

Analyst: Just regarding your guidance for new adds growing over 25% this year, just to make sure the math is ballpark, ***are you implying the new adds will grow from about 20,000 last year to north of 25,000 this year?***

Roberts: Mimi, I’m just going to leave the metric as is. I’ll let you guys do the actual amounts for everybody’s models. But we’ve mentioned that we’re over 60,000 customers now and the expectation is 25% net patient adds or 25% patient adds in 2014.

Analyst: ***And what percentage of the 60,000 is in the US?***

Roberts: ***We’re not going to break it up specifically***, but again we’re over 60,000 patients now.

131. With respect to manufacturing matters, Defendant DeSisto stated as follows:

With manufacturing operations on solid footing as we enter 2014, we now have the opportunity to increase our efforts on the many products we have in our pipeline. . . .

* * *

I also want to thank Charlie [Liamos] for all of his efforts over the past three years in the role of COO. ***Charlie was kind enough to step in full time to manage the manufacturing transition to the new OmniPod and was instrumental in getting us to the solid ground that we are [on] today.*** . . .

In summary, I think it’s obvious why we’re so excited about the success of 2013 and the opportunity we see for 2014. We navigated a new product launch, a major scale-up in manufacturing and a customer base transition while continuing to also move forward on projects and initiatives that will carry us into the future of diabetes management and drug delivery. . . .

* * *

. . . 2013 was a tremendous year in Insulet history. ***We navigated through all aspects of the new OmniPod launch*** and are now full speed ahead towards an exciting 2014.

Moreover, rather than disclose the extensive product defect issues that had been identified in new Eros pods, Defendant DeSisto stated: “in terms of the quality of product, I think [it] continues to improve out in the field. Part of that was education. It’s a new product. So in that regard we’re seeing improvement in all the numbers that we track.”

132. In addition, both defendants touted international customer demand for the OmniPod Eros, particularly in Europe. According to Defendant DeSisto, “Ypsomed in Europe has seen exceptional growth in key markets such as Germany, the UK and the Netherlands.” Later in the call, he added, “So, if you look at the way the program is with Ypsomed, there are certain minimums that they are required to meet and that hasn’t been a problem for them.” Similarly, Defendant Roberts represented that “[Ypsomed was] adding patients at a very rapid rate, and [] doubled their business in 2013.”

133. On February 28, 2014, Insulet filed its fiscal year 2013 annual report with the SEC on Form 10-K, which was signed by, among others, Defendants DeSisto, Roberts, and Liamos. In multiple places in the Form 10-K, the Company represented that its patient base was expanding:

Our total revenue was \$247.1 million for the year ended December 31, 2013, as compared to \$211.4 million for the year ended December 31, 2012. ***The increase in revenue is mainly due to the continued adoption of the OmniPod System by patients in the United States and internationally.***

* * *

The decrease in inventories and increase in accounts payable, accrued expenses and other current liabilities are largely related to the scale up of our manufacturing operations as we transitioned our customer base to our new OmniPod System. The decrease in deferred revenue related to the recognition of revenue billed in prior periods as we met the revenue recognition criteria. The increase in accounts receivable largely related to the timing of shipments to customers ***and overall expansion of our customer base.***

134. The Form 10-K also represented the following:

We believe our current manufacturing capacity is sufficient to meet our expected 2014 demand for OmniPods.

* * *

Generally, all outside vendors produce the components to our specifications and in many instances to our designs, and they are audited periodically by our Quality Assurance Department to ensure conformity with the specifications, policies and procedures for our devices. ***Our Quality Assurance Department also inspects and tests our devices at various steps in the manufacturing cycle to facilitate compliance with our devices' stringent specifications.*** We have received approval of our quality systems standards from DEKRA Certification B. V., Arnhem, The Netherlands, an accredited Notified Body for CE Marking and the International Standards Organization ("ISO"). Certain processes utilized in the manufacture and test of our devices have been verified and validated as required by the FDA and other regulatory bodies. As a medical device manufacturer and distributor, our manufacturing facilities and the facilities of our suppliers and sterilizer are subject to periodic inspection by the FDA, KEMA and certain corresponding state agencies.

135. The statements set forth in ¶¶129-134 were materially false and misleading and omitted to disclose material facts, as follows:

a. Contrary to Defendants' statements above, and as reflected in the 2015 FDA Warning Letter, the OmniPod Eros units being produced had a high degree of defects in violation of cGMP and Insulet's own manufacturing standards, including pods with defective needle mechanisms, leakage problems, and faulty alarm systems as described in ¶¶34-37 above. Those defects had not been "remedied," and even though they had been identified by Insulet's "QA" process the defective product was still knowingly shipped to distributors and patients by Defendants;

b. Defendants failed to disclose that the OmniPod Eros was plagued with the foregoing serious, undisclosed manufacturing and quality control problems, such that the Company's efforts to increase inventory supplies to support its roll-out efforts could only be effectuated by (a) materially lowering its QA standards and shipping defective product lots to its patients and distributors and thereby (b) negatively impacted the Company's ability to increase and maintain the growth of its patient base and of its OmniPod Eros sales levels to both existing and new patients;

c. Insulet's statements concerning its international sales growth were materially misleading because (a) Defendants failed to disclose that international growth was driven in significant part by Ypsomed's decision to build up a stockpile of Eros inventory at a rate well beyond what it needed to meet then-existing demand because of its serious concerns about Insulet's ability to provide adequate supplies of reliable product, and because (b) Defendants failed to disclose that Ypsomed's artificially inflated demand for Eros product was the product of Ypsomed's concerns about the extent of Insulet's manufacturing and related quality control problems, which Defendants had not publicly disclosed;

d. Defendants failed to disclose the extent to which Insulet needed to rely on its low-margin Neighborhood Diabetes subsidiary to support the Company's reported revenue growth; and

e. Defendants' statement that Insulet had "navigated through all aspects of the new OmniPod launch" was materially false and misleading, as the manufacturing issues that resulting in inventory and growth problems were ongoing and had not been successfully navigated.

F. False and Misleading Statements and Omissions in Connection with the Announcement of Insulet's First Quarter 2014 Results

136. On May 7, 2014, Insulet announced its financial results for the first quarter of 2014 and held an earnings conference call. During the call, Defendants boasted of Insulet's new patient starts. While Defendant DeSisto acknowledged that "new patient starts in the first quarter slowed to a rate of about 20% year over year," he added that "*new-patient starts [so far in the second quarter] are running more than 40% higher than at the same point in the first quarter.*" Similarly, Defendant Roberts stated that "*[n]ew patient starts so far this quarter being up over 40% from where we were at this point mid-February*" and that "*new-patient starts were up a little over 20%*" compared to the first quarter of the previous year.

137. Further, Defendant DeSisto represented that “we have made significant progress regarding the consistency of our manufacturing process for the new OmniPod. Our daily production has become much more predictable, and our tolerance is better defined.” He then elaborated that “[i]nventory levels have increased significantly as compared to the last half of 2013. *Quality levels have improved, and scrap costs, which remained higher than planned in the first quarter, have started to decrease.*”

138. Prompted by an analyst, Defendant Roberts confirmed that the higher scrap costs were “*only in the manufacturing process.*” The analyst followed up by asking, “[W]hat went wrong? Was there some new issue or a continuation that you didn’t get the yield improvements you had expected? What exactly happened?” In response, Roberts continued to minimize Insulet’s manufacturing and quality control problems:

Yeah, I wouldn’t say anything went wrong per se. I think it’s just kind of normal course of running the lines and ultimately as you go through the process there were a few components where a product would come in that maybe was a little bit more on the edge of a tolerance or so, and we saw a higher output of scrap than we were hoping to see. And that’s now allowed us to kind of revise the tolerance a little bit with the supplier. But there’s some costs that you have to eat as part of that. I think there’s a piece of it that just goes to the fact of we did experience the Chinese New Year effect, if you will, which is a lot of people leave. And then you have a new group of folks that come in and have to be trained. And while Flextronics did, I think, a nice job of trying to get ahead of that, there’s always a training component that tends to lead to a little bit more incremental scrap, as well as those lines kind of restart themselves. But I wouldn’t point to anything specific thing that anything went wrong in the quarter. To achieve 2.6 million Pods, I’d actually argue a lot went right.

139. On May 7, 2014, Insulet filed its quarterly report with the SEC on Form 10-Q, which was signed by Defendants DeSisto and Roberts. In multiple places in the Form 10-Q, the Company represented that its patient base was expanding:

Our total revenue was \$69.2 million and \$57.4 million for the three months ended March 31, 2014 and 2013, respectively. *The \$11.8 million increase is largely due to continued adoption of the OmniPod System by patients in the United States and internationally.*

* * *

Cost of revenue was \$36.4 million and \$32.2 million for the three months ended March 31, 2014 and 2013, respectively. ***The \$4.2 million increase is due to higher sales volumes in the United States and internationally.***

* * *

The increase in accounts receivable largely relates to the timing of shipments to customers and ***overall expansion of our customer base***. The increase in inventories is largely related to the scale up of our manufacturing operations as ***we continue to expand our customer base***.

140. The Form 10-Q also stated: ***“We believe our current manufacturing capacity is sufficient to meet our expected 2014 demand for OmniPods.”***

141. The statements set forth in ¶¶136-140 were materially false and misleading, and omitted to disclose material facts, as follows:

a. Contrary to Defendants’ statements above, and as reflected in the 2015 FDA Warning Letter, the OmniPod Eros units being produced had a high degree of defects in violation of cGMP and Insulet’s own manufacturing standards, including pods with defective needle mechanisms, leakage problems, and faulty alarm systems as described in ¶¶34-37 above. Those defects had not been “remedied,” and even though they had been identified by Insulet’s “QA” process the defective product was still knowingly shipped to distributors and patients by Defendants;

b. Defendants failed to disclose that the OmniPod Eros was plagued with the foregoing serious, undisclosed manufacturing and quality control problems, such that the Company’s efforts to increase inventory supplies to support its roll-out efforts could only be effectuated by (a) materially lowering its QA standards and shipping defective product lots to its patients and distributors and thereby (b) negatively impacted the Company’s ability to increase and maintain the growth of its patient base and of its OmniPod Eros sales levels to both existing and new patients;

c. Insulet's statements concerning its international sales growth were materially misleading because (a) Defendants failed to disclose that international growth was driven in significant part by Ypsomed's decision to build up a stockpile of Eros inventory at a rate well beyond what it needed to meet then-existing demand because of its serious concerns about Insulet's ability to provide adequate supplies of reliable product, and because (b) Defendants failed to disclose that Ypsomed's artificially inflated demand for Eros product was the product of Ypsomed's concerns about the extent of Insulet's manufacturing and related quality control problems, which Defendants had not publicly disclosed;

d. Defendants failed to disclose the extent to which Insulet needed to rely on its low-margin Neighborhood Diabetes subsidiary to support the Company's reported revenue growth; and

e. To conceal the US decline, beginning in 2014, Defendants switched new patient starts from being a US metric to a global one, without telling investors that they were doing so. In other words, Defendants artificially inflated the market's understanding of US patient growth by combining domestic and OUS new patients.

G. Defendants' False and Misleading Statements and Omissions on May 15, 2015 at the Bank of America Merrill Lynch Healthcare Conference

142. On May 15, 2015, Defendant Roberts participated in the Bank of America Merrill Lynch Healthcare Conference. In his opening remarks, he touted Insulet's new patient starts:

[W]e've said last week and certainly believe that 2014, we're going to show 25% plus *year-over-year patient starts*. Our first quarter is always historically our slower one. *And we were 20% in the first quarter*. We did discuss we're seeing sequential increase in Q2 versus Q1. What does that imply? Well, it really implies kind of closing in hopefully on the 30% year-over-year patient start number in Q2, which would keep us in line as we move forward to the rest of the year to hit north of that 25% mark.

He later explained that "[n]ew patient starts are critical though because ultimately that's the compounding for the future periods, as they continue to add to the base, we're able to drive more

and more new customers. So again, this first bullet wasn't updated, but we grew 35% year-over-year in the first quarter for the core OmniPod business.”

143. The statements set forth in ¶142 were materially false and misleading, and omitted material facts, as follows:

a. Defendants failed to disclose that the OmniPod Eros was plagued with the foregoing serious, undisclosed manufacturing and quality control problems, such that the Company's efforts to increase inventory supplies to support its roll-out efforts could only be effectuated by (a) materially lowering its QA standards and shipping defective product lots to its patients and distributors and thereby (b) negatively impacted the Company's ability to increase and maintain the growth of its patient base and of its OmniPod Eros sales levels to both existing and new patients;

b. Defendants failed to disclose the extent to which Insulet needed to rely on its low-margin Neighborhood Diabetes subsidiary to support the Company's reported revenue growth; and

c. To conceal the US decline, beginning in 2014, Defendants switched new patient starts from being a US metric to a global one, without telling investors that they were doing so. In other words, Defendants artificially inflated the market's understanding of US patient growth by combining domestic and OUS new patients.

H. False and Misleading Statements and Omissions in Connection with the Announcement of Insulet's Second Quarter 2014 Results

144. On August 7, 2014, Insulet announced its financial results for the second quarter of 2014 and held an earnings conference call. During the call, Defendant DeSisto told investors that “we enter third quarter *with our largest customer pipeline since the launch of the new OmniPod,*” and that *new patient starts “increased by approximately 20% year-over-year.”* Notwithstanding this strong growth, DeSisto indicated that growth would have been even stronger except that new

patient starts were “impacted in the second quarter by a unilateral change made by a significant managed care plan to their reimbursement policies.” DeSisto further noted that “[w]e are currently backlogged in new patient starts until [that] issue is resolved.”

145. Defendant DeSisto also touted Insulet’s manufacturing quality: “Turning to our manufacturing operations, for the third straight quarter we manufactured approximately 2.5 million OmniPods, providing the level of stability and predictability we haven’t had in our history. At a consistent level of 40,000 OmniPods per day, we have been able to improve quality and reduce scrap costs, resulting in expanded gross margins.” When one analyst asked whether the Company had “any manufacturing issues or concerns,” DeSisto downplayed any such concerns, representing that the Company was “continu[ing] to make really good progress” in increasing its capacity and touting the “consistency” of Insulet’s production.

146. On August 7, 2014, Insulet filed its quarterly report with the SEC on Form 10-Q, which was signed by Defendants DeSisto and Roberts. In multiple places in the Form 10-Q, the Company represented that its patient base was expanding:

Our total revenue was \$72.0 million and \$141.2 million for the three and six month periods ended June 30, 2014, respectively, compared to \$60.1 million and \$117.4 million for the same periods in 2013. ***The \$11.9 million and \$23.7 million respective increases are largely due to continued adoption of the OmniPod System by patients in the United States and internationally.***

* * *

Cost of revenue was \$36.2 million and \$72.6 million for the three and six months ended June 30, 2014, respectively, compared to \$33.3 million and \$65.5 million for the same periods in 2013. ***The \$3.0 million and \$7.1 million respective increases are due to higher sales volumes in the United States and internationally.***

* * *

The increase in accounts receivable largely relates to the timing of shipments to customers and ***overall expansion of our customer base.***

147. The Form 10-Q also stated: *“We believe our current manufacturing capacity is sufficient to meet our expected 2014 demand for OmniPods.”*

148. The statements set forth in ¶¶144-147 were materially false and misleading, and omitted to disclose materials facts, as follows:

a. Contrary to Defendants’ statements above, and as reflected in the 2015 FDA Warning Letter, the OmniPod Eros units being produced had a high degree of defects in violation of cGMP and Insulet’s own manufacturing standards, including pods with defective needle mechanisms, leakage problems, and faulty alarm systems as described in ¶¶34-37 above. Those defects had not been “remedied,” and even though they had been identified by Insulet’s “QA” process the defective product was still knowingly shipped to distributors and patients by Defendants;

b. Defendants failed to disclose that the OmniPod Eros was plagued with the foregoing serious, undisclosed manufacturing and quality control problems, such that the Company’s efforts to increase inventory supplies to support its roll-out efforts could only be effectuated by (a) materially lowering its QA standards and shipping defective product lots to its patients and distributors and thereby (b) negatively impacted the Company’s ability to increase and maintain the growth of its patient base and of its OmniPod Eros sales levels to both existing and new patients;

c. Insulet’s statements concerning its international sales growth were materially misleading because (a) Defendants failed to disclose that international growth was driven in significant part by Ypsomed’s decision to build up a stockpile of Eros inventory at a rate well beyond what it needed to meet then-existing demand because of its serious concerns about Insulet’s ability to provide adequate supplies of reliable product, and because (b) Defendants failed to disclose that Ypsomed’s artificially inflated demand for Eros product was the product of

Ypsomed's concerns about the extent of Insulet's manufacturing and related quality control problems, which Defendants had not publicly disclosed;

d. Defendants failed to disclose the extent to which Insulet needed to rely on its low-margin Neighborhood Diabetes subsidiary to support the Company's reported revenue growth; and

e. To conceal the US decline, beginning in 2014, Defendants switched new patient starts from being a US metric to a global one, without telling investors that they were doing so. In other words, Defendants artificially inflated the market's understanding of US patient growth by combining domestic and OUS new patients.

I. False and Misleading Statements and Omissions in Connection with the Announcement of Insulet's Third Quarter 2014 Results

149. On November 5, 2014, Insulet announced its financial results for the third quarter of 2014 and held an earnings conference call. During the call, Defendant Roberts fielded questions from analysts seeking clarification on new patient starts, a metric that was conspicuously not mentioned during Sullivan's and Roberts's opening remarks. First, an analyst asked, "can you talk a little bit about the new patient add trajectory in Q3 and what's implied in Q4? Was it plus/minus 20%?" Roberts answered, among other things, that:

Overall, we saw probably somewhere about a 5% to 10% sequential increase in new patient starts from Q2 to Q3. Still on the trajectory *I would tell you of kind of somewhere in the 15% to 20%* range overall new patient starts year-over-year. And the trajectory still seems very solid here as we're a month and a few days into the fourth quarter.

Then another analyst posed a question about patient starts, and Roberts obfuscated:

Analyst: So I guess maybe we could start with the new patient additions. And again, your comments, they definitely seem a little bit different than kind of the comments last quarter where I think expectations were around 20% new patient growth and doesn't sound like you gave sort of a new number. Yet the revenue guidance is coming down. And I guess what I'm trying to get at is there's obviously – there was a backlog of patients related to [payor issue]. Is the expectation

that most of those start to flow in here in the fourth quarter? And even though they may not be big on the revenue side, they are going to be noticeable on the new patient additions?

Roberts: I'm not sure I completely followed that. But we're – again where we're heading, just so we stay clear here is, on a year-over-year basis we've talked about that *we're looking effectively for 20% year-over-year patient growth* – new patient starts, and I think everything has been trending close to that number or probably a little lower than that at the moment. But again, if you look at the specific issue around the payer, that's been the one that's been driving it. On a quarter-over-quarter basis, Q2 to Q3, we've – I mentioned a couple minutes ago that we basically driving between kind of 5% and 10% sequential growth. So those are the two pieces.

150. On November 5, 2014, Insulet filed its quarterly report with the SEC on Form 10-Q, which was signed by newly installed CEO Sullivan and Defendant Roberts. In multiple places in the Form 10-Q, the Company represented that its patient base was expanding:

Our total revenue was \$75.0 million and \$216.2 million for the three and nine month periods ended September 30, 2014, respectively, compared to \$61.1 million and \$178.6 million for the same periods in 2013. *The \$13.9 million and \$37.6 million respective increases are largely due to continued adoption of the OmniPod System by patients in the United States and internationally.*

* * *

The increase in accounts receivable largely relates to the timing of shipments to customers and *overall expansion of our customer base.*

151. The Form 10-Q also stated: *“We believe our current manufacturing capacity is sufficient to meet our expected 2014 demand for OmniPods.”*

152. The statements set forth in ¶¶149-151 were materially false and misleading, and omitted to disclose materials facts, as follows:

a. Contrary to Defendants' statements above, and as reflected in the 2015 FDA Warning Letter, the OmniPod Eros units being produced had a high degree of defects in violation of cGMP and Insulet's own manufacturing standards, including pods with defective needle mechanisms, leakage problems, and faulty alarm systems as described in ¶¶34-37 above. Those

defects had not been “remedied,” and even though they had been identified by Insulet’s “QA” process the defective product was still knowingly shipped to distributors and patients by Defendants;

b. Defendants failed to disclose that the OmniPod Eros was plagued with the foregoing serious, undisclosed manufacturing and quality control problems, such that the Company’s efforts to increase inventory supplies to support its roll-out efforts could only be effectuated by (a) materially lowering its QA standards and shipping defective product lots to its patients and distributors and thereby (b) negatively impacted the Company’s ability to increase and maintain the growth of its patient base and of its OmniPod Eros sales levels to both existing and new patients;

c. Insulet’s statements concerning its international sales growth were materially misleading because (a) Defendants failed to disclose that international growth was driven in significant part by Ypsomed’s decision to build up a stockpile of Eros inventory at a rate well beyond what it needed to meet then-existing demand because of its serious concerns about Insulet’s ability to provide adequate supplies of reliable product, and because (b) Defendants failed to disclose that Ypsomed’s artificially inflated demand for Eros product was the product of Ypsomed’s concerns about the extent of Insulet’s manufacturing and related quality control problems, which Defendants had not publicly disclosed;

d. Defendants failed to disclose the extent to which Insulet needed to rely on its low-margin Neighborhood Diabetes subsidiary to support the Company’s reported revenue growth; and

e. To conceal the US decline, beginning in 2014, Defendants switched new patient starts from being a US metric to a global one, without telling investors that they were doing

so. In other words, Defendants artificially inflated the market's understanding of US patient growth by combining domestic and OUS new patients.

J. False and Misleading Statements and Omissions in Connection with the Announcement of Insulet's Fourth Quarter 2014 and Fiscal Year 2014 Results

153. On February 26, 2015, Insulet filed its fiscal year 2014 annual report with the SEC on Form 10-K, which was signed by, among others, Defendants Dorval and Lamos. In multiple places in the Form 10-K, the Company represented that its patient base was expanding:

Our total revenue was \$288.7 million for the year ended December 31, 2014, as compared to \$247.1 million for the year ended December 31, 2013. *The increase in revenue is mainly due to the continued adoption of the OmniPod System by patients in the United States and internationally.*

* * *

The increase in accounts receivable largely relates to the timing of shipments to customers and *overall expansion of our customer base.*

154. The Form 10-K also represented the following:

We believe our manufacturing capacity is sufficient to meet our expected 2015 demand for OmniPods.

* * *

Generally, all outside vendors produce the components to our specifications and in many instances to our designs, and they are audited periodically by our Quality Assurance Department to ensure conformity with the specifications, policies and procedures for our devices. *Our Quality Assurance Department also inspects and tests our devices at various steps in the manufacturing cycle to facilitate compliance with our devices' stringent specifications.* ... Certain processes utilized in the manufacture and test of our devices have been verified and validated as required by the FDA and other regulatory bodies. As a medical device manufacturer and distributor, our manufacturing facilities and the facilities of our suppliers and sterilizer are subject to periodic inspection by the FDA, KEMA and certain corresponding state agencies.

155. The statements set forth in ¶¶153-154 were materially false and misleading for the following reasons:

- a. Contrary to Defendants' statements above, and as reflected in the 2015 FDA

Warning Letter, the OmniPod Eros units being produced had a high degree of defects in violation of cGMP and Insulet's own manufacturing standards, including pods with defective needle mechanisms, leakage problems, and faulty alarm systems as described in ¶¶34-37 above. Those defects had not been "remedied," and even though they had been identified by Insulet's "QA" process the defective product was still knowingly shipped to distributors and patients by Defendants;

b. Defendants failed to disclose that the OmniPod Eros was plagued with the foregoing serious, undisclosed manufacturing and quality control problems, such that the Company's efforts to increase inventory supplies to support its roll-out efforts could only be effectuated by (a) materially lowering its QA standards and shipping defective product lots to its patients and distributors and thereby (b) negatively impacted the Company's ability to increase and maintain the growth of its patient base and of its OmniPod Eros sales levels to both existing and new patients; and

c. Insulet's statements concerning its international sales growth were materially misleading because (a) Defendants failed to disclose that international growth was driven in significant part by Ypsomed's decision to build up a stockpile of Eros inventory at a rate well beyond what it needed to meet then-existing demand because of its serious concerns about Insulet's ability to provide adequate supplies of reliable product, and because (b) Defendants failed to disclose that Ypsomed's artificially inflated demand for Eros product was the product of Ypsomed's concerns about the extent of Insulet's manufacturing and related quality control problems, which Defendants had not publicly disclosed.

LOSS CAUSATION

156. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and omissions, and engaged in a scheme to deceive the market. This course

of wrongful conduct operated as a fraud or deceit on the Class and caused the price of Insulet common stock to be artificially inflated. But for Defendants' misrepresentations and omissions, Lead Plaintiffs and the other members of the Class would not have purchased Insulet common stock, or would not have purchased such shares at artificially inflated prices. Later, when Defendants' prior misrepresentations, omissions and fraudulent conduct were disclosed to the market, including on January 7, 2015, January 15, 2015, February 26, 2015, March 30, 2015 and April 30, 2015, the price of Insulet common stock fell significantly as the prior artificial price inflation was dissipated. As a result of their purchases of Insulet common stock during the Class Period, Lead Plaintiffs and other members of the Class suffered economic loss, i.e. damages, under the Exchange Act. The timing and magnitude of the decline in the prices of the Company's common stock negates any inference that the economic losses and damages suffered by Lead Plaintiffs and the other members of the Class were caused by changed market conditions, macroeconomic factors, or Company-specific facts unrelated to Defendants' fraudulent conduct.

157. For example, after the close of the financial markets on January 7, 2015, Insulet preannounced that its revenue for the fourth quarter ended December 31, 2014 would be \$71 million to \$73 million (substantially lower than the Company's prior guidance and well below the expectations of securities analysts), as well as a wholesale change of the Company's senior management. As discussed at ¶¶73-74 above, the Company disclosed to analysts that several of its distributors, including Ypsomed, were engaging in aggressive efforts to reduce inventory. Analysts attributed a material portion of the lower revenue performance to reduced demand by distributors, who they believed had begun to cut back on purchases of OmniPod Eros product.

158. In response to these disclosures, Insulet's stock price dropped from \$44.53 per share at the close of the market on January 7, 2015 to \$40.52 per share at the close on January 8, 2015, a decline of approximately 9%, on unusually heavy trading volume of 3.5 million shares

(compared to an average daily volume of approximately 330,000 shares traded during the 12 months prior to the beginning of the Class Period).

159. The January 8, 2015 price decline was the result of the nature and extent of Defendants' fraud being partially revealed to investors and the market. *Inter alia*, the Company's disclosures of January 7 were a partial disclosure of the extent to which, contrary to the Company's prior positive misrepresentations, demand for the Company's OmniPod Eros product had declined, particularly in the United States (which in turn, as alleged herein, was a result of the production problems, quality control issues and the continuing impact of the botched 2013 Eros roll-out), and to the internal turmoil, operational and manufacturing problems at Insulet.

160. During an "offline" session following Insulet CEO Patrick Sullivan's transcribed remarks at the JP Morgan Health Care Conference January 14, 2015, the Company made additional partial corrective disclosures, including (a) Insulet CEO Sullivan's disclosure that US new patients starts were down 9% in 2014; (b) his revelation that new patient starts had begun to slow in the US in early 2014, but that this had effectively been masked by a large stocking order placed by Ypsomed; (c) his confirmation of "some destocking of distributors ... on the US side" in the prior quarter; and (d) his announcement that Insulet expected its financial performance for the first quarter of 2015 to be "flat" sequentially over the fourth quarter of 2014. These disclosures were not revealed until the publication of reports by securities analysts reached the market on the morning of January 15, 2015, before the opening of trading. Indeed, as a JP Morgan analyst report that day reported, "[these] disclosures indicate that the US OmniPod underlying business was in worse condition than prior management comments led us to believe, and the mishandling of the Eros launch was more damaging than widely assumed" – and that "1Q14 US new patient growth [was] flat to up low single digits." As the JP Morgan report added, "Our read is that early in 2014

management switched “new patient starts” from being a US metric to a global one.... *The Street was never told of this switch.*”

161. In response to these disclosures, the price of Insulet’s common stock again fell sharply, from \$38.50 per share at the close on January 14, 2015 to \$31.86 per share at the close on January 15, 2015 – or approximately 17%, on exceptionally heavy trading volume of roughly 7.364 million shares.

162. The January 15, 2015 price decline was the result of the nature and extent of Defendants’ fraud being partially revealed to investors and the market. *Inter alia*, the disclosures on January 14 and 15 were a partial disclosure of the extent to which, contrary to the Company’s prior positive statements, demand for the Company’s OmniPod Eros product had declined, particularly in the United States (which in turn, as alleged herein, was a result of the production problems, quality control issues and the continuing impact of the botched 2013 Eros roll-out), and that the Company had actively helped mask the true conditions at the company by manipulating its reporting of the key “new patient starts” metric.

163. After the close of trading on February 26, 2015, Insulet announced earnings for the fourth quarter of 2014. On the earnings conference call the following day, the Company disclosed that in 2014, OmniPod generated \$173 million in the US and \$50 million internationally and that approximately 75% of its 75,000 patients as of the end of 2014 were in the US.

164. In response to the Company’s February 26, 2015 disclosures, the price of Insulet’s stock declined from its February 26, 2015 closing price of \$32.91 per share to close at \$31.73 per share on February 27, 2015 – a decline of \$1.18 per share, or approximately 4%, on unusually high trading volume of over 2.7 million shares traded.

165. The February 27, 2015 price decline was the result of the nature and extent of Defendants’ fraud being partially revealed to investors and the market. *Inter alia*, the Company’s

disclosures of February 26, 2015 were a partial disclosure of the extent to which, contrary to the Company's prior positive statements, demand for the Company's OmniPod Eros product had declined, particularly in the United States (which in turn, as alleged herein, was a result of the production problems, quality control issues and the continuing impact of the botched 2013 Eros roll-out).

166. After the close of the market on March 30, 2015, Insulet abruptly announced that the Company's CFO Defendant Dorval was resigning. In response, Insulet's stock price declined from \$34.28 at the close on March 30, 2015 to \$33.35 at the close on March 31, 2015. The March 30, 2015 announcement was a further partial disclosure of fraud as the market and investing public construed CFO Dorval's abrupt departure as evidence that the problems at the Company (including its misleading reporting of key metrics such as new patient starts) were even more serious and pervasive than had been previously disclosed.

167. After the close of the markets on April 30, 2015, the Company announced its financial results for its first quarter of 2015. In those disclosures, the Company disclosed, inter alia, (a) a 4% decline in revenue from its US OmniPod business and total revenue of just \$61 million, and (b) that most of this decline was attributable to Ypsomed's continuing actions to reduce inventory in the absence of greater demand for OmniPod's Eros product.

168. In response to the Company's April 30, 2015 disclosures, the price of Insulet's stock declined from its April 30, 2015 closing price of \$29.85 per share to close at \$26.97 per share on May 1, 2015 – a decline of \$2.88 per share, or approximately 10%, on unusually high trading volume of almost 5 million shares traded.

169. The May 1, 2015 price decline was a direct result of further disclosures of the nature and extent of Defendants' fraud to investors and the market, including the extent to which, contrary to the Company's prior positive statements, demand for the Company's OmniPod Eros product

had declined, particularly in the United States (which in turn, as alleged herein, was a result of the production problems, quality control issues and the continuing impact of the botched 2013 Eros roll-out), and that the Company had actively helped mask the true conditions at the company by manipulating its reporting of the key “new patient starts” metric. These disclosures also confirmed the extent to which demand for the Eros product had leveled off in Europe.

SUMMARY OF SCIENTER ALLEGATIONS

170. The Defendants acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued by them were materially false and/or misleading; knew that such statements would be disseminated to the investing public; and knowingly and substantially participated in the issuance and dissemination of the public documents and statements. As detailed above and summarized by the scienter allegations set forth below, Defendants’ intent to deceive and/or reckless disregard for the truth may be strongly inferred from the following facts and circumstances set forth herein.

171. First, the fact that the fraud concerned the Company’s core product and key business area, and was the focus of analysts’ and investors’ attention, is strong evidence of scienter. Insulet’s revenue stream from sales of its OmniPod Eros products are the admitted core of the Company’s business. For example, in its Form 10-K for the year-ended December 31, 2014, filed on February 26, 2014, Defendants stated: “We currently rely on sales of the OmniPod System to generate most [of] our revenue.” Moreover, according to a January 15, 2015 Oppenheimer analyst report, US and International OmniPod sales represented \$63.3 million, or 81%, of Insulet’s \$75 million in total revenue during the third quarter of 2014. The Individual Defendants knew or were reckless in not knowing throughout the Class Period that statements they made concerning new patient start metrics and destocking of excess Insulet inventory by the Company’s main international distributor were false and misleading. Indeed, Defendants DeSisto, Roberts, Dorval,

and Liamos were aware of sales and orders for the core drivers of revenue at the Company – notably the new patients and the EROS OmniPods – and would have been keenly aware of anything affecting the Company's business with one of its main distributors. The fact that the fraudulent scheme affected the Company's primary product and core business area supports a strong inference of Defendants' scienter.

172. Second, the Individual Defendants knowingly signed off on OmniPod Eros product that was defective so that the product could be shipped for sale to patients. According to a former senior quality engineer at Insulet who was responsible for corrective actions, preventative actions and dealing with non-conforming product, and as confirmed by Insulet's former senior officer responsible for manufacturing operations, Defendants Liamos and DeSisto would routinely override Insulet's Head of Quality Control, and sign off on product with "Severity A" failures, such as needle mechanism and leaking pod issues, so that the product could be shipped for sale to patients. As Insulet's former senior quality engineer stated, *there was "never a case that they scrapped a non-conforming product, no matter the quality level."* According to Insulet's former senior quality engineer, whose job responsibilities included clearing lots that were flagged as defective, "there was never a lot rejected," because if Insulet did not ship the product, the Company might fail.

173. Third, the fact that the Defendants personally addressed Insulet's quality control problems with the OmniPod further supports scienter. As Insulet's former regional sales manager for more than four years through the first quarter of 2014 stated, Defendant Liamos would personally travel to Insulet's production plant in China (where the Eros was manufactured) in an effort to fix the quality problems.

174. Fourth, the fact that the Company's quality and manufacturing problems with the OmniPod were well known within the Company is further evidence of Defendants' scienter. As

Insulet's former senior quality engineer who was responsible for corrective actions, preventative actions and dealing with non-conforming product stated, discussions about the push to ship defective product lots would arise at the end of each quarter when management would need to get defective lots "released in a timely manner" so that Insulet could "hit their numbers." Such discussions were "common knowledge" at Insulet and the need for this end of quarter push was "discussed openly" at the Company. Moreover, as Insulet's former senior quality engineer stated, Defendant Lamos "was the biggest push" at Insulet.

175. Fifth, the volume of complaints that Insulet received about the OmniPod Eros system further supports a strong inference of Defendants' scienter. As multiple former employees of Insulet confirmed, Insulet received many complaints concerning the quality problems with the OmniPod. For example, as, a regional sales manager for Insulet from 2011 until late 2013 explained, poor quality problems with the Eros lasted throughout the Class Period and continued at least through her/his departure in late 2013, and such problems were significant and "well documented on email" at Insulet. Insulet's former regional sales manager from January 2010 through March 2014 similarly explained that "2013 was a year of complaints and issues," and so many customers demanded to speak to more senior management about defects in their pods that Insulet's Chief Commercial Officer, Peter Devlin, among other senior executives, would end up talking to irate patients.

176. Sixth, the Individual Defendants repeatedly made detailed statements based on purported personal knowledge about the manufacturing, production and quality control process associated with and revenue derived from the OmniPod, the success of the transition to the OmniPod Eros, and particularly, the number of "new patient starts," which were a critical metric used by analysts and investors to evaluate the Company's financial performance. For example, on Insulet's earnings conference calls for the first, second, and third quarters of 2014, Defendant

DeSisto stated that Insulet had added approximately 20% new patients over the prior year, and that new patient starts had increased at a rate of approximately 20% year-over-year. Defendants DeSisto and Robert also repeatedly made representations concerning the “QA” process and indicated that manufacturing problems had been resolved and that no defective products left Insulet’s possession. On January 15, 2014, Insulet CEO Sullivan admitted that instead of experiencing new patient starts in the US, Insulet’s new patient starts had actually declined by 9% in 2014. Sullivan further revealed that the Company had effectively concealed these materially adverse facts by (a) changing the way it had reported OmniPod new patient starts and (b) using certain large “stocking orders” by Ypsomed in Europe to mask disappointing sales figures in the critical, higher margin US market.

177. Seventh, in their Certifications Pursuant to Sections 302 and 906 of the Sarbanes-Oxley Act of 2002, submitted with the Company’s 2014 and 2015 annual reports on Forms 10-K, Defendants DeSisto and Roberts represented that (i) they had reviewed the Company’s respective filings; (ii) the reports did “not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made ... not misleading”; and (iii) the “information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the [Company].” These types of public comments – through which the Individual Defendants held themselves out as knowledgeable on these subjects – further support a strong inference of scienter.

178. Eighth, while in possession of material non-public information regarding the quality and manufacturing issues with Insulet’s OmniPod Eros, including its true new patient starts metrics and its ability to continue selling and shipping inventory to its main international distributor Ypsomed, Defendants Lianos and DeSisto sold substantial amounts of Insulet common stock at artificially inflated prices, reaping enormous proceeds. The prices at which Defendants

Liamos and DeSisto sold their stock far exceeded the closing price of Insulet stock after the truth emerged about the Company's new patient starts metric and declining revenue from its US OmniPod business (*i.e.*, \$26.97 per share on April 30, 2015).

179. In total, during the Class Period, Defendant Liamos sold more than 282,000 shares of Insulet common stock for proceeds of more than \$10 million. Moreover, Liamos's sales during the Class Period far exceeded both his pre-Class Period sales. Specifically, in a control period before the Class Period, from May 13, 2011 until May 5, 2013,² Liamos did not sell a single share of Insulet common stock.

180. Moreover, all of Liamos's sales occurred shortly after Defendants made false statements about Insulet's launch of the OmniPod system, at times when Insulet stock traded at artificially inflated prices. For example, in Insulet's Form 10-K for the year-ended December 31, 2013, filed on February 28, 2014 and signed by Defendant Liamos, Defendants represented that Insulet's "increase in revenue is mainly due to the continued adoption of the OmniPod System by patients in the United States and internationally." In the same Form 10-K, Defendants stated that their "customer base" had experienced "overall expansion." Less than a week later, on March 3, 2014, Defendant Liamos sold 10,000 shares of Insulet common stock, followed by an additional 32,000 shares during the remainder of the Class Period.

181. The table below shows Defendant Liamos's sales of Insulet common stock during the Class Period:

Defendant Liamos's Insider Stock Sales During the Class Period			
Date	Number of Share	Share Price (Approximate)	Total Proceeds (Net of any Commissions)
11/15/2013	28,400.00	\$35.53	\$1,008,929.88
11/15/2013	7,800.00	\$36.39	\$283,836.54

² The "control period" before the Class Period consists of 723 days, which is the length of the Class Period.

Defendant Liamos's Insider Stock Sales During the Class Period			
Date	Number of Share	Share Price (Approximate)	Total Proceeds (Net of any Commissions)
11/15/2013	4,600.00	\$36.86	\$169,550.02
11/18/2013	32,076.00	\$35.27	\$1,131,474.48
11/18/2013	7,124.00	\$35.72	\$254,496.35
12/2/2013	62,208.00	\$36.26	\$2,255,780.28
12/3/2013	1,600.00	\$36.00	\$57,596.00
1/2/2014	46,300.00	\$35.94	\$1,663,832.17
1/3/2014	39,700.00	\$36.12	\$1,433,801.23
2/3/2014	11,037.00	\$42.93	\$473,849.31
3/3/2014	10,000.00	\$45.85	\$458,465.00
9/10/2014	4,000.00	\$35.17	\$140,664.00
10/1/2014	4,000.00	\$36.58	\$146,320.00
11/3/2014	4,000.00	\$42.95	\$171,800.00
12/1/2014	4,000.00	\$45.67	\$182,680.00
1/2/2015	4,000.00	\$46.08	\$184,320.00
2/12/2015	4,000.00	\$32.00	\$128,000.00
3/2/2015	4,000.00	\$32.00	\$128,012.00
4/1/2015	4,000.00	\$33.16	\$132,640.00
Total	282,845.00		\$10,406,047.26

182. In total, during the Class Period, Defendant DeSisto sold more than 264,000 shares of Insulet stock for proceeds of nearly \$10 million, which was more than 20 times DeSisto's base salary for 2014. Moreover, all of DeSisto's sales occurred shortly after Defendants made false statements about Insulet's launch of the OmniPod system, at times when Insulet stock traded at artificially inflated prices. For example, on May 7, 2013, Defendant DeSisto told investors: "[Insulet] transitioned all [of our] new customer starts to the new OmniPod, *and the initial feedback has been excellent.*" On the same day, DeSisto represented that Insulet was seeing increased demand in Europe, given that "Ypsomed continues to accelerate the rate of patient additions." Less than one month later, on June 3, 2013, DeSisto sold 20,000 shares of Insulet common stock, followed by an additional 240,000 shares during the remainder of the Class Period.

183. The table below shows Defendant DeSisto's sales of Insulet stock during the Class Period:

Defendant DeSisto's Insider Stock Sales During the Class Period			
Date	Number of Shares	Share Price (Approximate)	Total Proceeds (Net of any Commissions)
6/3/2013	20,000.00	\$29.76	\$595,100.00
7/1/2013	20,000.00	\$31.51	\$630,296.00
8/1/2013	20,000.00	\$31.85	\$636,916.00
9/3/2013	20,000.00	\$33.38	\$667,616.00
10/1/2013	5,527.00	\$36.33	\$200,805.86
12/2/2013	18,500.00	\$36.58	\$676,818.80
1/2/2014	20,000.00	\$36.07	\$721,374.00
2/3/2014	20,000.00	\$42.95	\$859,090.00
3/3/2014	20,000.00	\$45.80	\$916,098.00
4/1/2014	20,000.00	\$47.68	\$953,660.00
6/2/2014	20,000.00	\$34.75	\$695,086.00
7/1/2014	20,000.00	\$40.52	\$810,336.00
8/1/2014	20,000.00	\$34.23	\$684,672.00
9/2/2014	20,000.00	\$36.30	\$725,998.00
Total	264,027.00		\$9,773,866.66

184. Last, as noted above, several senior executives were terminated or abruptly resigned as negative information about the Company was being disclosed. For example, right on the heels of the Company's January 7, 2015 announcement that it missed its guidance for the fourth quarter of 2014, the Company announced that it was replacing its Chief Commercial Officer, Vice President of Sales, Vice President of Marketing, Vice President of Managed Care, Vice President of Customer Care, and Vice President of International. In addition, on March 30, 2015, Defendant Dorval abruptly announced she was resigning as CFO only four months after replacing Defendant Roberts (who had also resigned). Notably, this announcement also came just one month prior to the Company's disclosure on April 30, 2015 that the destocking issues it had earlier denied were ongoing were actually still plaguing the Company such that it caused Insulet to miss its guidance for the first quarter of 2015. The unusually high number of senior executives resigning, coupled

with their timing and the surrounding circumstances, is powerful evidence of scienter. Indeed, the timing of Defendant Dorval's abrupt resignation strongly supports the inference that she knew about the Company's misleading reporting practices, or that she was recklessly disregarding them, and resigned rather than be held accountable for the fraud that occurred on her watch as Insulet's CFO.

CLASS ACTION ALLEGATIONS

185. Lead Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased the common stock of Insulet during the Class Period (the "Class"). Excluded from the Class are Defendants and their families, the directors and officers of Insulet and its affiliates, and the immediate family members, successors and/or assigns of any of the foregoing excluded persons or entities.

186. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. As of April 28, 2015, there were approximately 56.75 million shares of Insulet common stock outstanding, owned by hundreds or thousands of investors.

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

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

- F. Whether Defendants' conduct caused the members of the Class to sustain damages; and
- G. The extent of damage sustained by Class members and the appropriate measure of damages.

188. Lead Plaintiffs' claims are typical of those of the Class as both Lead Plaintiffs and the members of the Class were similarly affected by and suffered damages as a result of Defendants' common course of wrongful conduct in violation of the federal securities laws, as alleged herein.

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

190. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Furthermore, as the damages suffered by individual class members may be small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

INAPPLICABILITY OF STATUTORY SAFE HARBOR

191. Insulet's "Safe Harbor" warnings accompanying its purportedly forward-looking statements issued during the Class Period were ineffective to shield those statements from liability. Indeed, those warnings were themselves misleading because they presented as potential risks conditions that already existed or were known to be imminent when the warnings were made.

192. Defendants are also liable for any false or misleading forward-looking statements pleaded herein because, at the time each such statement was made, the speaker knew the statement was false or misleading and the statement was authorized and/or approved by an executive officer of Insulet who knew that the statement was false. None of the historic or present tense statements

made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to, or stated to be dependent on, those historic or present tense statements when made.

PRESUMPTION OF RELIANCE

193. At all relevant times, the market for Insulet's common stock was an efficient market for the following reasons, among others:

- A. Insulet common stock met the requirements for listing, and was listed and actively traded on NASDAQ, a highly efficient and automated market;
- B. As a regulated issuer, Insulet filed periodic public reports with the SEC and NASDAQ;
- C. During the Class Period, the average weekly trading volume of Insulet's common stock was greater than 2% of the outstanding shares, justifying a strong presumption that the market for Insulet shares was efficient;
- D. Insulet regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;
- E. Insulet was followed by several securities analysts employed by major brokerage firm(s) who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firm(s). Each of these reports was publicly available and entered the public marketplace;
- F. There was a cause and effect relationship between unexpected corporate events or financial releases and movements in Insulet's stock price; and
- G. Insulet was eligible to register its stock pursuant to a Form S-3 registration statement.

194. As a result of the foregoing, the market for Insulet common stock promptly digested current information regarding Insulet from all publicly available sources and reflected such information in the price of Insulet common stock. Under these circumstances, all purchasers of

Insulet common stock during the Class Period suffered similar injury through their purchase of Insulet common stock at artificially inflated prices and the presumption of reliance applies.

195. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding problems with the OmniPod Eros launch and Insulet's declining growth—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 Company's OmniPod business, as set forth above, that requirement is satisfied here.

COUNT I

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

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

197. During the Class Period, Defendants carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Lead Plaintiffs and other Class members, as alleged herein; and (ii) cause Lead Plaintiffs and other members of the Class to purchase Insulet common stock at artificially inflated prices.

198. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock in an effort

to maintain artificially high market prices for Insulet common stock in violation of §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

199. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the Company's financial well-being, operations, and prospects.

200. During the Class Period, Defendants made the false statements specified above, which they knew or recklessly disregarded to be false or misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

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

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

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

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

COUNT II

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs pray for judgment as follows:

- A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;
- B. Awarding compensatory damages in favor of Lead Plaintiffs and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- C. Awarding Lead Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and
- D. Awarding such legal, equitable, injunctive or other further relief as the Court may deem just and proper.

JURY DEMAND

Lead Plaintiffs demand a trial by jury.

DATED: June 1, 2016

/s/ Glen DeValerio

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CERTIFICATE OF SERVICE

I, Glen DeValerio, hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on June 1, 2016.

/s/ Glen DeValerio _____
Glen DeValerio