
Insulet 4Q16 - Record-high US, International OmniPod for third straight Q; Dash PDM launch by end of year; OmniPod Horizon system completes two closed-loop studies - February 27, 2017

Executive Highlights

- Insulet [reported](#) a strong 4Q16, with record-high US OmniPod sales (\$63 million) up 17% YOY and record-high international sales (\$21 million) rising 35% YOY. Both were all-time highs for the third straight quarter - impressive momentum. Total 4Q16 revenue of \$104 million exceeded guidance (\$99-\$102 million) and grew 24% YOY. Full-year revenue also exceeded guidance, growing 39% YOY to \$367 million.
- At the end of 2016, Insulet's estimated worldwide OmniPod installed base was ~105,000-110,000 "active users," reflecting ~26% growth vs. ~85,000 users at the end of 2015. 60%-65% of these patients are in the US, while an estimated 35-40% are outside the US.
- The new Bluetooth-enabled OmniPod Dash PDM and pod is still expected to launch later this year, though it will be a "limited market release" that goes into 1Q18. Two feasibility studies of the OmniPod Horizon Automated Glucose Control System are now complete, totaling over 50 adults and children (down to age six years). A launch is still expected in late 2019, consistent with the [Investor Day](#) presentation.

Insulet [reported](#) 4Q16 financial results today in a confident call led by CEO Patrick Sullivan. The company continues to see solid sales momentum - record-high OmniPod sales for the third straight quarter - a testament to the differentiated product, loyal installed base, and continued growth from MDI. Following the [November Investor Day](#), management said it remains on the ambitious track to deliver \$1 billion in sales and 65%+ margins by 2021. See the top financial and pipeline highlights below.

Financial Highlights

1. US OmniPod sales of \$63 million grew 17% YOY and hit an all-time high for the third straight quarter. Sales increased a strong 6% sequentially from the previous record-high last quarter (3Q16), and the YOY comparison was the hardest Insulet has had in the past year. Full-year US OmniPod sales in 2016 totaled \$230 million, up 21% and breaking the \$200 million mark for the first time. 1Q17 US OmniPod revenue is expected to grow 12% YOY (\$56.5-\$57.5 million).
2. International OmniPod sales of \$21 million increased a robust 35% YOY and 9% sequentially, also a record-high for the third straight quarter. Like the US, this marked Insulet's toughest YOY comparison in the past year, as sales grew 16% YOY in 4Q15. 2016 International OmniPod sales totaled \$72 million, up 78% YOY and showing a nice sequential uptick throughout the year
3. At the end of 2016, Insulet's estimated worldwide OmniPod installed base was ~105,000-110,000 "active users," a ~26% gain vs. ~85,000 users at the end of 2015. Approximately 60%-65% of these patients are in the US (~67,000, +15% over 2015), while an estimated 35-40% are outside the US (~40,000, +50% over 2015). The worldwide base is expected to grow 20% in 2017, while the US installed base is again expected to increase by ~15%.
4. Total 4Q16 revenue of \$104 million exceeded guidance (\$99-\$102 million) and grew 24% YOY. The OmniPod business supplied ~74% of 4Q16 growth, the highest point in over a year. Full year 2016 revenue grew 39% YOY to \$367 million, exceeding guidance (\$362-\$365 million).

5. 2017 sales are expected to grow a more modest 17% to \$420-\$440 million. This includes expected 14% growth in the US OmniPod business (\$257-\$265 million), 36% growth in the international OmniPod business (\$94-\$101 million), and 10% growth in drug delivery (\$69-\$74 million). All three are a downtick from 2016's growth.

6. The MiniMed 670G has caused a slight "distraction" for Insulet, not a "disruption": it lengthened some patients' decision-making process, resulting in a slower conversion rate from lead to new patient shipment. In key commercial wins, Insulet expanded its US sales team by 20% at the start of this year. Impressively, more than 30,000 OmniPod users are on Insulet-provided Glooko (almost half of the US installed base), and the average Glooko office has seen a five-fold increase (!) in OmniPod prescriptions post implementation.

7. Gross margin in 4Q16 rose to 59%, up impressively from 50% in 4Q15 and flat from 3Q16. Management guided for gross margins "approaching" 60% in 2017. Insulet still expects to be sustainably EBIT positive in 2018

8. Under the leadership of SVP Mr. Charles Alpuche, Insulet manufactured ~65% more pods in 2016 vs. 2015, with 20% fewer headcount and a 50% reduction in scrap. This resulted in 15% savings per pod.

Pipeline Highlights

9. The new Bluetooth-enabled OmniPod Dash PDM (locked down Android phone, first shown [in November](#)) is still expected to launch later this year, though management shared for the first time it will be a "limited market release" that goes into 1Q18. As expected, the new PDM will "debut" at ADA.

10. Insulet has now completed two feasibility studies of the OmniPod Horizon Automated Glucose Control System, totaling over 50 adults and children (down to age six years). A launch is still expected in late 2019, consistent with the [Investor Day](#) presentation. Dr. Bruce Buckingham shared the first data in 24 adults [at ATTD ten days ago](#), and more data is expected in podium and poster presentations at ADA.

11. The U500 and U200 OmniPods with Lilly are "on track," presumably with the [Investor Day](#) timelines: launches expected in 1H19 and late 2019-early 2020, respectively. The U500 formative human factors work and [clinical trial enrollment](#) (n=417) are complete; no FDA submission timing was shared, though the 417-patient trial is expected to finish this May. U-200 technical and clinical trial design work are "well underway" (the same language used in 2Q16).

12. On Abbott's FreeStyle Libre: "We've got a great partnership with Abbott and like the Libre product. There is a lot of overlap of our customers in Europe, who are experiencing dramatically reduced burden and a great customer experience. I think that's a nice opportunity. We have ongoing discussions about our pipelines, but there is nothing specific to comment on in terms of a Libre integration."

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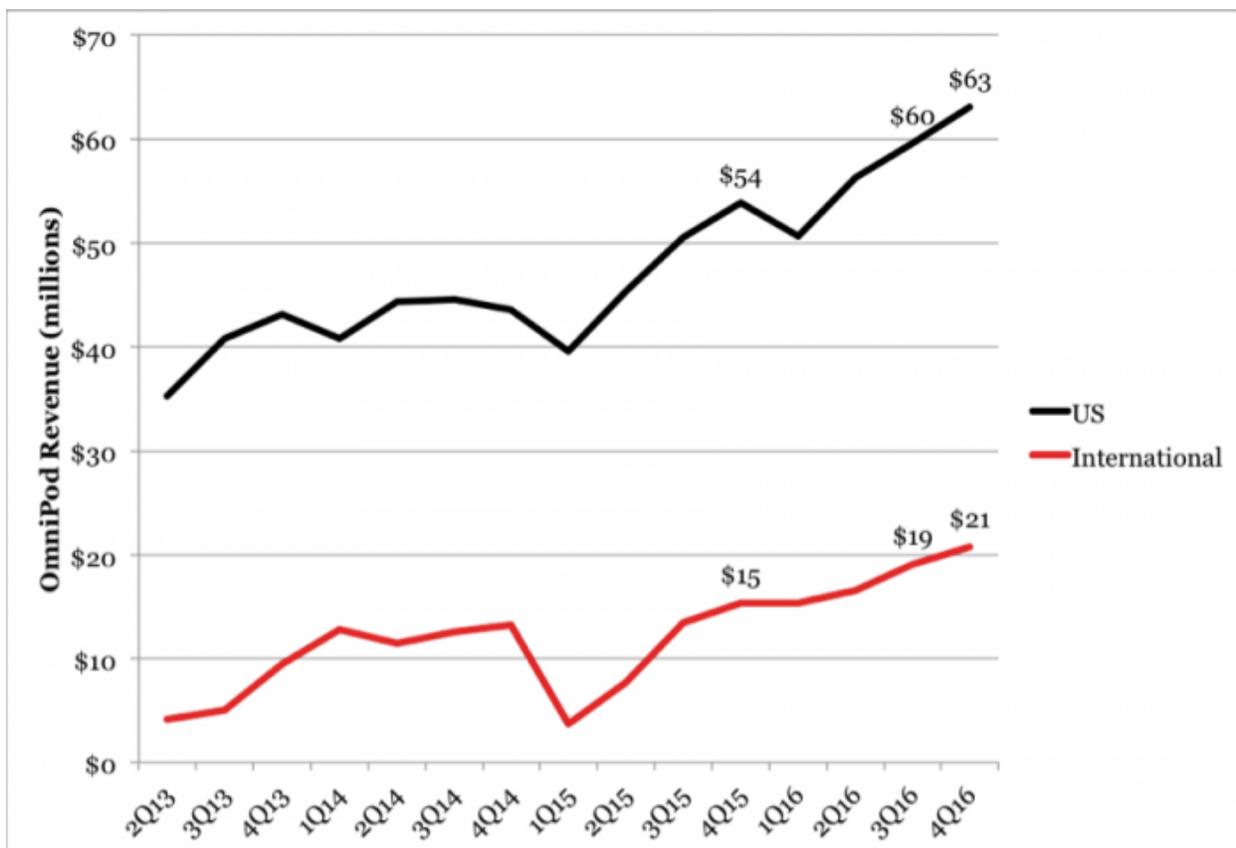
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Pipeline Summary

Financial Highlights

Quarterly US and International OmniPod Sales (2Q13-4Q16)



1. US OmniPod sales of \$63 million grew 17% year-over-year (YOY) and hit an all-time high for the third straight quarter. Sales increased a strong 6% sequentially from the previous record-high last quarter (3Q16) - encouraging momentum for the business in a very competitive US pump environment. Sales slightly exceeded guidance (\$61-\$62 million), a trend we've come to expect from this team. The YOY comparison was the hardest Insulet has had in the past year, as US sales grew a strong 24% in 4Q15. Full-year US OmniPod sales in 2016 totaled \$230 million, up 21% and breaking the \$200 million mark for the first time.

- **1Q17 US OmniPod revenue is expected to be in the range of \$56.5-\$57.5 million, representing slightly slower 12% YOY growth on a tougher comparison to 28% YOY growth in 1Q16.** This represents a 9% sequential decline from 4Q16, typical of first quarter seasonality. Management also said it factored "competitive dynamics" into this guidance (i.e., the upcoming MiniMed 670G launch); more on that below.

2. International OmniPod sales of \$21 million increased a robust 35% YOY and 9% sequentially, also a record-high for the third straight quarter. Like the US, this marked Insulet's toughest YOY comparison in the past year, as sales grew 16% YOY in 4Q15. Sales hit the top-end of the guidance (\$20-\$21 million), and management said growth came from deeper expansion into existing markets and new markets like France. 2016 International Omnipod sales totaled \$72 million, up 78% YOY and showing a nice sequential uptick throughout the year. Insulet is talking to Ypsomed about resigning the agreement, and we'll be interested to see what happens here - obviously this partnership is going well from a sales perspective, though Ypsomed now has it's own tubed pump with very similar "ease-of-use" and "simplicity" marketing to the OmniPod.

- **1Q17 International OmniPod revenue is expected to be in the range of \$23-\$24 million, representing strong 53% YOY growth at the midpoint.** This will come on a difficult comparison to a tripling in sales in 1Q16; clearly, management is very optimistic about the international runway.

3. At the end of 2016, Insulet's estimated worldwide OmniPod installed base was ~105,000-110,000 "active users," a ~26% gain vs. ~85,000 users at the end of 2015.

Approximately 60-65% of these patients are in the US (~67,000, +15% over 2015), while an estimated 35-40% are outside the US (~40,000, +50% over 2015). Insulet easily exceeded guidance for 20% worldwide installed base growth in 2016, though it fell short of doing so in the US (as previously expected). This was not discussed at length, but management shared that the pipeline is at record levels right now, though the sales cycle is taking longer (see below).

- **In 2017, management expects the global installed base to rise 20% (adding ~20,000 patients), while the US installed base is again expected to increase by ~15% (adding ~10,000 patients).** This obviously implies faster growth outside the US, similar to 2016 base growth and revenue performance. We think this is prudent, given the uncertainty with the 670G and Tandem potentially launching two products (G5 integration and predictive low glucose suspend).

4. Total 4Q16 revenue of \$104 million exceeded guidance (\$99-\$102 million) and grew 24% YOY. The OmniPod business supplied ~74% of 4Q16 growth, the highest point in over a year. The US and International OmniPod business were pretty evenly split on the growth contribution front - 47% of the quarter's growth from the US vs. 28% international. Drug Delivery revenue hit an all-time high at \$19.6 million, increasing 34% YOY, 22% sequentially, and supplying 25% of the quarter's growth (its lowest in the past two years). However, the Amgen OmniPod Neulasta product is seeing very strong adoption, now up to 50% of all Neulasta doses in the US - this was right on par with [Investor Day](#) expectations and an impressive rise from 44%-45% in the [3Q16](#) call. Insulet also renewed the supply agreement with Amgen during the quarter; terms were not disclosed.

- **Full Year 2016 revenue of \$367 million exceeded guidance for \$362-\$365 million, growing an impressive 39% YOY.** The OmniPod business drove 70% of 2016 growth (39% in the US, 31% outside the US), while drug delivery contributed the remaining 30%. As a reminder, this excludes the Neighborhood Diabetes business, which was **divested to Liberty Medical for \$5 million in cash in February 2016 (less than 10% of what Insulet paid for the acquisition in 2011, but a smart move).**

5. For 2017, management expects revenue in the range of \$420-\$440 million, growing a far more modest 17% vs. 2016 at the mid-point. This guidance includes expected 14% growth in the US OmniPod business (\$257-\$265 million), 36% expected growth in the international OmniPod business (\$94-\$101 million), and 10% growth in the drug delivery business (\$69-\$74 million). We'd note that all three are more conservative than 2016 growth rates: 21% (US OmniPod), 78% (International OmniPod), and 92% (Drug Delivery). Management did a good job of sharing excitement about all three business lines on the call, though it's clear expectations are lower for 2017 - probably a combination of competitive dynamics and harder year-over-year comparisons in 2017 vs. 2016. There is no expectation for Medicare coverage in 2017. Talks are ongoing with CMS, but have slowed due to the change in administration.

6. The MiniMed 670G has caused a slight "distraction" for Insulet, not a "disruption": it lengthened some patients' decision-making process, resulting in a slower conversion rate from lead to new patient shipment. "Leads were incredibly robust, and remain at record rates in Q1. What we didn't appreciate was the delay in conversion from a lead to a new patient shipment." As stated at [JPM](#), management emphasized that in any given quarter, only ~10% of US revenue comes from new patient starts - a small fraction relative to the recurring revenue from the installed base. This means the revenue impact of new users is relatively small, a good sign as Insulet rides out the noise from the 670G approval. President Shacey Petrovic emphasized that Insulet's #1 competitor is MDI, and its goal is to grow the market, not to steal share from other pump companies ("70%-80%, if not more, of our patients come from MDI"). That is exactly the kind of thinking the insulin delivery field needs.

- **Insulet expanded its US sales team by 20% at start of 2017, both in areas where OmniPod has strong market access and some previously uncovered areas** - the number of reps was not specified, but we assume it's around 20-30. Reps will emphasize the pod's quality of

life impact and reduction of burden/diabetes distress, points we heard repeatedly on this call following some of the [publications last year](#).

- **Impressively, more than 30,000 OmniPod users are on Insulet-provided Glooko (almost half of the US installed base), and the average Glooko office has seen a five-fold increase (!) in OmniPod prescriptions post implementation.** Whoa, talk about a serious revenue driver. The 30,000 patients on Glooko is up from 22,000 as of 3Q16, meaningful 36% growth in a short period of time. It was brilliant of Insulet to offer this free to all of its users, and clearly that investment seems to have been worth it. We'll be interested to see what real-world data comes out of this partnership and how it contributes to payer coverage.
- **Notably, Insulet added 15 million covered lives through Medicaid and managed Medicaid plans in 2016, a trend it plans to accelerate in 2017.** In Q&A, Ms. Petrovic estimates Medicare/Medicaid combined lock Insulet out of 30% of the market, with another 10% locked out from regional payers. CEO Patrick Sullivan "remain[s] confident" that Medicare coverage will happen, it's just a matter of when."

7. Gross margin in 4Q16 rose to 59%, up impressively from 50% in 4Q15 and flat from 3Q16. Management guided for gross margins "approaching" 60% in 2017. Similar to the past few calls, management was "extremely pleased with the tremendous progress in margin expansion," maintaining the [Investor Day](#) goal for 65%+ gross margins by 2021. The gains have come from improvements in manufacturing, supply chain (move to ocean freight), and product quality. [In November](#), SVP of Global Manufacturing & Operations Charles Alpuche gave a compelling presentation on this front and definitely inspired serious confidence.

- **Insulet still expects to be sustainably EBIT positive in 2018.** Cash increased from \$283 million at the end of 3Q16 to \$299 million at the end of 4Q16 - the company clearly has plenty on hand to invest in the business, most importantly in the new highly automated US manufacturing plant (see below). As a reminder, Insulet [raised](#) net cash of \$180 million in 3Q16 from a private placement of 1.25% convertible senior notes.

8. Under the leadership of Mr. Alpuche, Insulet manufactured ~65% more pods in 2016 vs. 2015, with 20% fewer headcount and a 50% reduction in scrap. This resulted in 15% savings per pod. Manufacturing is the name of the game in patch pumps, and this topline improvement in volume with better quality and lower costs is impressive. We wonder how the price of BD's upcoming type 2 patch pump (late 2018 launch) will compare to Insulet's U200 and U500 pods.

- **As expected following the [Investor Day](#), Insulet has purchased a facility in Acton, MA to build a highly automated US manufacturing plant. This remains on schedule to come online in 2019.** One US line will be capable of producing "up to 70%" of the total capacity of four lines in China, with up to 90% fewer headcount. The new plant will give Insulet (i) redundancy beyond its single plant in China; (ii) similar overall production costs (China wage rate inflation is actually outpacing the US by nearly 3x, and combined with freight costs, is a similar price to US manufacturing); and (iii) much lower supply chain response time (from 25 days to 17 total). Cash on hand following the 3Q16 raise will fund the plant's construction.
- **Insulet also renewed its contract manufacturing agreement with Flextronics in China;** this was not further discussed on the call.

Pipeline Highlights

9. The new Bluetooth-enabled OmniPod Dash PDM (locked down Android phone, first shown [in November](#)) is still expected to launch later this year, though management shared for the first time it will be a "limited market release" that goes into 1Q18. As expected, the new PDM will "debut" at ADA. We're glad to see a slow rollout is planned, given the challenging second-gen OmniPod launch under the old management team, plus the [more recent example](#) of Medtronic/BD's MiniMed Pro-set limited launch. Management said the "majority" of the development work is complete, Insulet has already had a pre-submission meeting with the FDA, and human factors work has started. We assume a submission will

need to come around mid-year or early 3Q16 to get this out to early users by end of year. Management emphasized Dash will be "very differentiated" and offer the "best user experience and interaction" on the market today. [Read our Investor Day coverage](#) for a deeper dive.

- **Insulet is still finalizing details around the commercial strategy, but said this rollout is "not hugely problematic" from a revenue perspective.** As a reminder, the entire installed base will need to transition over to the new Bluetooth-enabled PDM and pod, as Dash is not backwards compatible with the current OmniPod. However, Insulet is not reliant on the installed base switching to Dash immediately, since revenue in any quarter is highly pod-driven (unlike tubed pump companies). Said management, "We have lots of flexibility in how to launch this product." Android phones are pretty cheap, so we hope this will be offered free to OmniPod users or perhaps for a nominal fee.

10. Insulet has now completed two feasibility studies of the OmniPod Horizon Automated Glucose Control System, totaling over 50 adults and children (down to age six years). A launch is still expected in late 2019, consistent with the [Investor Day](#) presentation. Dr. Bruce Buckingham shared the first data in 24 adults [at ATTD ten days ago](#), and more data is expected in podium and poster presentations at ADA. Thus far it looks good in controlled inpatient settings, with outstanding control overnight (90% time-in-range) and strong hypoglycemia reduction (90% reduction); Dr. Buckingham noted room to improve around mealtimes, which is the case for all AID systems in development. Management shared lots of excitement for this program, highlighting "excellent glucose control" and "tremendous promise" to reduce the burden of managing diabetes - with new Medical Director Dr. Trang Ly at the helm, we expect a major focus on usability, particularly in pediatrics.

- **In Q&A, Ms. Petrovic emphasized plans to launch with a pediatric indication ("we're totally committed"),** given Insulet's strong uptake in this population. The FDA has encouraged Insulet to go for an indication down to age two, far lower than the 670G's current indication down to age 14 years. Though most type 1s are adults, we believe automated insulin delivery may offer some of the biggest quality of life and glycemic control benefits in pediatrics and adolescents, who have more glucose unpredictability, higher A1c levels (especially in teens), and greater family fear/exhaustion.

11. The U500 and U200 OmniPods with Lilly are "on track," presumably with the [Investor Day](#) timelines: launches expected in 1H19 and late 2019-early 2020, respectively. Both products will use the same pod and leverage the new Dash PDM platform, but with different software. The U500 formative human factors work and [clinical trial enrollment](#) (n=417) are complete; no FDA submission timing was shared, though the 417-patient trial is expected to finish this May. Perhaps we'll see data as a late-breaker at ADA or EASD. U-200 technical and clinical trial design work are "well underway" (the same language used in 2Q16). The U200 product was first announced a year ago at [JPM 2016](#), and we hope it goes faster than the U500 OmniPod.

12. Noted management in response to a question on partnering with Abbott's FreeStyle Libre: "We've got a great partnership with Abbott and like the Libre product. There is a lot of overlap of our customers in Europe, who are experiencing dramatically reduced burden and a great customer experience. I think that's a nice opportunity. We have ongoing discussions about our pipelines, but there is nothing specific to comment on in terms of a Libre integration." This was also asked at the Investor Day [in November](#), with Dash PDM/FreeStyle Libre integration (via NFC and LibreLink on Android) positioned "as a potential expansion." This could be a nice form factor, allowing patients to wear a pod and Libre or Dexcom sensor, and use the dedicated Dash Android PDM to engage with either device. This will not be the case upon Dash's launch, however, as it would presumably require a PMA submission.

- **As a reminder, the Dash PDM pulls out the integrated Abbott BGM, opting to pair with undisclosed BGM(s) wirelessly via Bluetooth.** Abbott is the only one of the Big Four that does not have a Bluetooth-enabled BGM; Roche has Accu-Chek Connect and Guide, Ascensia has the Contour Next One and Plus One, and LifeScan has the OneTouch Verio Flex. We're not sure if Insulet will partner with one or multiple Bluetooth-enabled meters.

Pipeline Summary

Pipeline Product	Timeline
OmniPod Dash Platform: locked down Android hone, Bluetooth-enabled pod, mobile app for secondary display, Dexcom G5 app integration on phone	Launched expected by end of 2017 (limited release running into 1Q18). "Debut" at ADA 2017.
OmniPod Horizon Automated Glucose Control system <i>OmniPod with built-in Bluetooth and control algorithm, Dexcom G5 or G6 CGM, Dash PDM</i>	Launch in late 2019. Two in-clinic feasibility studies completed in adults and pediatrics. First data presented at ATTD 2017; more data at ADA 2017.
Lilly U500 OmniPod PDM	Expected to launch in 1H19. Study underway , slated to wrap up in May 2017.
Lilly U200 OmniPod PDM	Expected to launch in late 2019-early 2020.
Drug Delivery - Amgen Neulasta Delivery Kit (oncology) - Ferring (infertility) - Capricor (heart failure) - Other partnerships (obesity, pulmonary hypertension, oncology, and Parkinson's medications)	- Launched - Launched - Supplying for phase 2 trial - No specifics shared

--by Adam Brown and Kelly Close