



MEMORANDUM

Insulet 2Q15 - Revenue rises 5% carried by drug delivery business; US OmniPod flat YOY; Next-gen PDM filing delayed a few months; Focus on Medicare, Medicaid, and the AP - August 12, 2015

Executive Highlights

- Total revenue in 2Q15 reached a record high \$75.6 million, a 5% year-over-year (YOY) increase and a strong 24% sequential increase from a weak 1Q15. The drug delivery business supplied 99% of the quarter's growth.
- US OmniPod sales reached a record high (barely!) \$44.7 million, growing a modest 0.7% YOY and 14% sequentially. Notably, new patient starts grew ~20% YOY, which seemed unusual given the flat revenue. International OmniPod sales of \$7.7 million declined 33% on a very tough comparison to 174% YOY growth in 2Q14. Sales rose an encouraging \$4 million (108%) sequentially, but the first half international revenues are still down enormously (over 50%) versus the first half of 2014.
- FDA filing of the next-gen PDM is delayed a few months from the previous goal to file by the end of this year. Management still expects a 2016 launch.

Insulet held its 2Q15 conference call this afternoon following the very unexpected "preliminary" results press release on July 29; we've updated this report to reflect management's commentary during the call and subsequent Q&A. The financials are unchanged from our initial coverage, though CEO Patrick Sullivan and new CFO Michael Levitz did provide more color on the business and expectations for 2Q15. Chief Commercial Officer Shacey Petrovic and President of Drug Delivery Daniel Levangie joined for Q&A. We're not sure, still, exactly the reason for the delay.

Despite lots of incisive investor questions on the still-weak US business, higher-than-expected operating expenses, and lower margins, management remained highly confident that it is laying a foundation for long-term growth. Overall, the company's performance rebounded somewhat from a very weak [1Q15](#), though there is still significant uncertainty, particularly in the US OmniPod business; 2H15 will provide a more definitive read on the business and the new management team's vision. We were glad to see higher R&D spending - we think more data will help Insulet.

Financial and Business Highlights

1. Total revenue in 2Q15 reached a record high \$75.6 million, a 5% year-over-year (YOY) increase and a 24% sequential increase from a weak 1Q15. This performance came in far ahead of management's guidance of \$67-70 million (a 3-7% YOY decline), which seemed at the time (and was) conservative guidance. The drug delivery business supplied 99% of the quarter's growth. Management continues to expect a ramp in the US and International OmniPod businesses in 2H15, rising to low-teens and mid teens YOY growth (respectively) in Q4.

2. US OmniPod sales reached a record high \$44.7 million, growing 0.7% YOY and 14% sequentially. Notably, new patient starts grew ~20% YOY, reaching the third highest for a quarter in the company's history (behind 2Q and 3Q13). Still, this marks three straight quarters of sub-1% YOY sales growth, which is very uncharacteristic and doesn't bode well. The flat performance was in line with management's expectations, though we expressed surprise on the first report that revenue and new starts would have such different growth rates and analysts echoed the surprise today.

3. International OmniPod sales of \$7.7 million declined 33% on a very tough comparison to 174% YOY growth in 2Q14. Sales rose 108% sequentially, though this was to be expected given a \$4 million shortfall in Ypsomed sales in 1Q15. Will sales rebound as expected in 2H15, particularly given the expected fall launch of Ypsomed's own pump? Overall, international sales for the first half of 2015 vs. the first half of 2014 are down 53%.

4. Insulet has implemented higher OmniPod manufacturing acceptance criteria following an FDA warning letter received in June. The FDA has deemed the company's corrective actions adequate, and management said that product quality is now at the highest level in the company's history. We'd love to get more details on what in particular needed bolstering - we have heard over time concerns on precision of insulin delivery.

5. In a clear sign of the team's focus on future innovation and awareness, R&D expense nearly doubled YOY in 2Q15 (\$12.1 million vs. \$6.7 million in 2Q14), while sales and marketing expenses rose 47% to \$21.8 million.

6. Notably, Insulet is pursuing multiple parallel paths to secure Medicare/Medicaid coverage of the OmniPod. This would be a major positive for Insulet. The company said it has had several very productive meetings with CMS to date. CEO Patrick Sullivan call Medicare/Medicaid coverage his "highest priority" on the access front and we were thrilled to hear this from a patient perspective..

7. Today, Insulet announced the appointment of Michael Spears as VP, Regulatory, Quality and Clinical Affairs, the ninth (!) member of the [new senior management team](#).

R&D Pipeline Highlights

8. FDA submission of Insulet's next-gen PDM is now delayed "a few months" from the previous timing to file by the end of 2015. The company still anticipates a 2016 launch of the touchscreen, Bluetooth enabled handheld.

9. Notably, management now hopes to fast track an artificial pancreas device. There were no other specifics or timing details, but it's clear that Insulet is committed to automated insulin delivery. We're not sure if Insulet's handheld will immediately launch with Dexcom G5 integration, or if that will require a later update or regulatory filing. This was also very positive to hear from a patient perspective. We think Insulet would work especially well for dual-hormone devices.

10. The [data integration with Glooko](#) (launched [last week](#)) and the U500 insulin-compatible OmniPod with Lilly were not mentioned on the call. Glooko now has OmniPod downloading instructions [on its compatibility page](#) - we haven't tried it yet but have heard (from n=1) that it's a bit of a hassle. Still - a start! As of the [1Q15 call](#), a clinical trial of the Lilly-partnered U500 OmniPod remained on track to start in 2015 - historically we've heard very good things from researchers on this front..

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Financial and Business Highlights

1. Total revenue in 2Q15 reached a record high \$75.6 million, a 5% year-over-year (YOY) increase and a very strong 24% sequential increase from 1Q15. This performance came in far ahead of management's guidance of \$67-70 million (a 3-7% YOY decline), suggesting (i) the forecast was very conservative; (ii) the drug delivery business far outperformed expectations (it supplied 99% of the quarter's growth); and/or (iii) the new commercial team may be gaining traction sooner than expected (though the flat US sales do not suggest this is the case). The sequential gain was also encouraging to see, though the comparison was very easy, as weak 1Q15 revenue declined 12% YOY and 16% sequentially.

- **The OmniPod business had another weak quarter** - US revenue of \$44.7 million was basically flat, growing just 0.7%, while international revenue declined 33% to \$7.7 million. More on these two segments below. Sales in the Neighborhood Diabetes business rose 5% to \$15.7 million, though were essentially flat from \$15.0 million in 2Q14.
- **The drug delivery business had a very strong showing, supplying 99% of the quarter's growth on sales of \$7.5 million (rising 7x from \$1.1 million in 2Q14).** Management called the results "terrific" and sees this business as a "significant growth driver" going forward. Indeed, management increased the full-year drug delivery revenue guidance from \$15-\$20 million to \$23-\$27 million. We didn't see that as a major increase given year over year growth but were glad to see the direction it headed.

	2Q14	3Q14	4Q14	1Q15	2Q15
Worldwide Sales (millions)	\$72.0	\$75.0	\$72.5	\$61.2	\$75.6
Year-on-Year (YOY) Growth	20%	23%	6%	-11%	5%
Sequential Growth	4%	4%	-3%	-16%	24%

- **Management reiterated the full-year 2015 revenue guidance: \$305 million-\$320 million (growth of 6%-11% YOY from 2014 sales of \$289 million).** The full-year guidance for drug delivery has now increased to \$23-\$27 million from the previous \$15-\$20 expectation; management did not say it, but given no change in the overall guidance, it sounds like some conservatism is expected related to the OmniPod business. Still, Insulet is 44% of the way to the full-year guidance's midpoint, and assuming the commercial team comes up to speed in the US, hitting the midpoint seems fairly likely (especially given the business' seasonality and typical strength at year-end). In 3Q15, Insulet expects revenue in the range of \$82-\$85 million, representing a year-over-year increase of ~11% at the midpoint of the range.
- **Today's call offered more granularity on growth expectations for the business segments, continuing to predict a ramp in the US and International OmniPod businesses in 2H15.** Remarks made it clear that inventory de-stocking is now finished in both the US and internationally, so growth should start to ramp in the coming quarters. We'd note that the upcoming US OmniPod comparisons are very easy - 9% YOY growth in 3Q14 and 1% growth in 4Q14, so mid/upper single digit growth in 3Q15 and low teens growth in 4Q15 seems very achievable, particularly as the new commercial team gains steam.

	3Q15 Guidance	4Q15 Guidance
US OmniPod	Mid/upper single-digit growth	Low teens growth
International OmniPod	Mid/upper teen growth	Mid teens growth
Neighborhood Diabetes	\$15 million	\$15 million
Drug Delivery	\$5-\$7 million (vs. \$2.3 million in 3Q14)	\$6-\$8 million (vs. \$0.8 million in 4Q14)

2. US OmniPod sales reached a record high \$44.7 million, growing just 0.7% YOY and 14% sequentially. Notably, new patient starts grew ~20% YOY, reaching the third highest for a quarter in the company's history (behind 2Q and 3Q13). Insulet also saw more than a 20% increase in new pediatric patient starts during the quarter, representing an all-time record. The sequential performance was an encouraging sign, particularly because US new patient starts in 1Q15 represented an all-time record high for any first quarter in the company's history. Even still, three straight quarters of sub-1% YOY growth is very uncharacteristic for Insulet, and the company has plenty to prove in the back half of the

year. The flat performance was in line with management's guidance, given a new US commercial team and new marketing activities that will need time to bear fruit. Additionally, the comparison to 2Q14's 26% YOY growth was fairly challenging. Overall, it's clearly a mixed picture right now, and 3Q15 should provide much more clarity.

- **Management was "very pleased" with the new US patient starts, though we reiterate our initial surprise to see it differ so dramatically from the weak 0.7% YOY revenue growth.** Analysts tried hard during Q&A to find explanatory variables (e.g., changes in pricing, changes in utilization or attrition), but none were clear explanatory variables. Management did note that the sales force expansion helped drive this new patient growth number, which does bring up a question of sustainability going into the back half of the year. Still, CEO Patrick Sullivan was "excited by the early returns from the US team" and believes the momentum will grow in 2H15.

	2Q14	3Q14	4Q14	1Q15	2Q15
US OmniPod Sales (millions)	\$44.4	\$44.6	\$43.6	\$39.2	\$44.7
Year-on-Year (YOY) Growth	26%	9%	1%	-4%	0.7%
Sequential Growth	9%	1%	-2%	-10%	14%

- **The second-half of 2015 will see the launch of Medtronic's MiniMed Connect (remote monitoring of pump/CGM data) and potentially Tandem's t:slim G4, which could impact Insulet's growth.** Certainly, it's possible that the January launch of the Animas Vibe at least partially contributed to the US slowdown in 1H15 (it grew 32% in 1H15, per [J&J's 2Q15 update](#)). Of course, it's hard to pull this apart from other contributing factors, such as the management changeover.

3. International OmniPod sales of \$7.7 million declined 33% on a very tough comparison to 174% YOY growth in 2Q14. Sales rose an encouraging 108% sequentially, though this was to be expected given the \$4 million shortfall in Ypsomed sales in 1Q15 (due to inventory de-stocking). Management reiterated comments from the [1Q15 call](#), which shared an Ypsomed forecast for 40%+ growth in the OmniPod patient installed base in 2015. Remarks made it clear that the inventory reduction is complete and the international OmniPod business is expected to see mid/upper teen growth in 2H15.

- **It will be fascinating to see if the international OmniPod trajectory changes if Ypsomed's in-house prefilled, touchscreen, durable pump launches in fall 2015, as expected.** Our [June conversation](#) with Ypsomed management suggested that the YpsoPump will be targeted to markets in which the OmniPod lacks sufficient reimbursement. Ypsomed believes the more complete pump portfolio (OmniPod patch pump and durable YpsoPump) will reach more customers and help increase the company's geographic footprint over just the OmniPod alone. Overall, this is a hard one to definitively call until the YpsoPump launches and we see the real numbers.

	2Q14	3Q14	4Q14	1Q15	2Q15
International OmniPod Sales (millions)	\$11.5	\$12.6	\$13.3	\$3.7	\$7.7
Year-on-Year (YOY) Growth	174%	147%	40%	-71%	-33%
Sequential Growth	-10%	10%	6%	72%	108%

4. Insulet has implemented higher OmniPod manufacturing acceptance criteria following an FDA warning letter received in June. The FDA has deemed the company's corrective actions adequate, and management said that product quality is now at the highest level in the company's history. We don't have specifics here on what has improved or what was below standard. As we

reported [previously](#), the warning letter related to FDA observations in a March 2015 inspection of Insulet's Billerica, Massachusetts facility. Apparently, the company released certain lots of OmniPods in mid-2013 and 1H14 that did not conform to final manufacturing acceptance criteria. Insulet responded to the FDA within the prescribed timing, and to be extra cautious, has taken corrective actions beyond what is required: 12 lots of OmniPods are being proactively replaced in the US and seven lots are being replaced in Europe. Management believes the vast majority of product is no longer in the field. Overall, it's excellent to see the new management team taking quality so seriously, given the widely publicized quality challenges following the launch of the second-gen pod.

- **The higher quality bar for acceptable OmniPods did result in a one-time \$2.5 million charge (!) from incremental scrap and warranty costs.** Otherwise, the news is not expected to have an adverse impact on business operations going forward. That is a bigger charge than we would have expected, though assessment on this front is far out of our area of expertise.

5. In a clear sign of the team's focus on future innovation and product awareness, R&D expense nearly doubled YOY in 2Q15 (\$12.1 million vs. \$6.7 million in 2Q14), while sales and marketing expenses rose 47% to \$21.8 million. Analysts were taken by surprise by the overall rise in operating expenses, though management repeatedly made it clear that there are "very exciting opportunities for investment" in both the OmniPod and drug delivery businesses. We were glad to hear the next-gen PDM and artificial pancreas projects mentioned several times in responses to these questions. Management said it is currently conducting a multi-year strategic planning process, and the outcome will be shared with the investment community in the future.

- **Consolidated gross margin declined to 45% from 50% in 2Q14, largely attributed to the aforementioned quality initiatives - we'd like to better understand what is changing on COGS.** The revenue mix between US OmniPod, International OmniPod, and the drug delivery business also impacts margins from quarter-to-quarter - we would've thought the international products would have a lower margin than those sold in the US. **Notably, in Q&A, management characterized the Street's expectations as too high for gross margins of 53%-54% for the rest of 2014 and 55% for 2015.** Longer-term, the goal remains 60% gross margins, but CFO Michael Levitz thinks it will take "some time" to get there.
- **On the positive side, net loss improved markedly to \$15.4 million from \$29.1 million in 2Q14.** The new team seems more focused on growing topline revenue than profitability near-term, though remarks definitely expressed excitement on prospects for future margin expansion. Presumably investors are ready to see this.

6. Notably, Insulet is pursuing multiple parallel paths to secure Medicare/Medicaid coverage of the OmniPod. The company has had several very productive meetings with CMS to date. Insulet is also meeting with legislative and advocacy groups. Given the bureaucratic challenges here, we assume this would not happen near-term. Still, it was notable to hear CEO Patrick Sullivan call Medicare/Medicaid coverage his "highest priority" on the access front.

7. Today, Insulet announced the appointment of Michael Spears as VP, Regulatory, Quality and Clinical Affairs, the ninth member of the [new senior management team](#). Mr. Spears will report directly to CEO Patrick Sullivan. This sends a clear signal that the new team takes product quality very seriously, which is excellent to see.

- **During 2Q15, Insulet COO Patrick Ryan and longtime and highly respected General Counsel R. Anthony Diehl [resigned](#),** completing a full changeover of the executive management team under new CEO Patrick Sullivan (who [began in September](#)). The announcement simultaneously announced the promotion of Mark Licari to VP of Global Manufacturing and Operations; he recently joined the company as VP of Manufacturing Operations/R&D for the Drug Delivery business - clearly an important role, given how much upside that business has over time. Mr. Licari has an impressive 30+ years of experience in manufacturing/operations, including time at Roche and HP Medical. In the new position, he will report directly to CEO Patrick Sullivan like the

rest of the recently hired team. [Insulet has flattened the organization and will not hire a replacement COO; senior VPs will now oversee the specific key areas like manufacturing, operations, regulatory/quality, etc.] To replace Mr. Diehl on the legal front, David Colleran will assume the role of Vice President and General Counsel; he most recently served in the same position at Covidien (now acquired by Medtronic).

- **Insulet also appointed Dr. Jessica Hopfield to its Board of Directors on July 28, which now includes eight members.** Dr. Hopfield currently serves as Vice Chair of Joslin's Board of Directors; as an independent director of rEVO Biologics (a biotech focused on rare diseases); and as an independent consultant to start-up technology firms. She was previously a partner at McKinsey & Company, focused on the Global Pharmaceuticals and Medical Products practice from 1995 to 2009. Her combined healthcare experience should be a valuable asset as Insulet transitions to a new era.

Pipeline Highlights

8. FDA submission of Insulet's next-gen PDM is now delayed "a few months" from the previous timing to file by the end of 2015. The company still anticipates a 2016 launch of the touchscreen, Bluetooth enabled handheld. Assuming a submission takes place in early 2016, launch within the year is definitely possible; we'd note it's not a sure thing, given the substantial regulatory delays with the second-gen OmniPod PDM. This partially stemmed from human factors confirmation screens, and we assume learnings from that experience will be leveraged this time around.

- **Management said the later PDM timing stems from three factors:** (i) the "new" focus on higher quality; (ii) to incorporate feedback received at ADA on the prototype device (see below); and (iii) a desire to be very thoughtful and careful about the design, given the ultimate goal to develop artificial pancreas applications. These seem very reasonable to us - better to wait a few months and get it perfect than to disappoint patients' very high expectations. We're very happy to hear the third reason stated so explicitly.
- **The OmniPod booth at ADA had a tiny table demoing the new touchscreen, Bluetooth-enabled PDM.** It was very much positioned as a "prototype" in "market research" phase. The overall design is a definite upgrade from the current device: a ~25% larger screen area, an ~33% reduction in thickness, a touchscreen interface, a rechargeable battery (lasting four days on a 1-2 hr charge), Bluetooth capabilities, and plans to build an OmniPod app that interacts with apps from Dexcom and Glooko. It retains the integrated Abbott FreeStyle Lite BGM. It definitely achieves the more-consumer-electronic, less-medical-device look that Insulet is going for. Still, there is room for improvement. The resistive touchscreen technology itself was definitely underwhelming, as it requires a fairly hard press/swipe and is far less responsive than capacitive touchscreens on modern smartphones or Tandem's t:slim. There were a few very odd user interface choices as well (e.g., the extended bolus checkbox is way too close to the carb entry form). We assume the additional few months will allow the team to polish the user interface.
- **Insulin delivery innovation is increasingly crucial as the market becomes much more competitive.** Near-term launches will come from Tandem (t:slim G4 in 2H15), Medtronic (MiniMed Connect in Fall 2015, MiniMed 640G potentially in 2016), and J&J (Finesse bolus-only patch device in 2016) will offer important competition. Looking beyond into ~2017-2018, JDRF's Dr. Aaron Kowalski believes several automated insulin delivery systems will launch, likely led by Medtronic's MiniMed 670G.

9. Management now hopes to fast track an artificial pancreas device. There were no other specifics or timing details, but it's clear that Insulet is committed to automated insulin delivery, which was always a question mark under the previous management team. As a reminder, the [1Q15 call](#) officially announced that an artificial pancreas project was in the pipeline, with early work on the algorithm evaluation and customer requirements. Insulet actually held a symposium on the artificial pancreas at ADA; this was not publicized at all and took place *during* the update-filled JDRF artificial pancreas symposium, which made it impossible for our team to attend. Still, we are elated to see more focus on this

from Insulet and wonder what the team is thinking on the automation front (e.g., predictive low glucose suspend? hybrid closed loop? Something else?).

- **We're not sure if Insulet's handheld will immediately launch with Dexcom G5 integration, or if that will require a later update or regulatory filing.** As a reminder, this partnership was rekindled [one year ago at ADA 2014](#), allowing Insulet/Dexcom patients to view their pump and CGM data on *both* their smartphone (within a modified version of the base Dexcom Gen 5 app) and right on the Insulet PDM screen itself (the Gen 5 transmitter will pair with two Bluetooth devices).
- **Dexcom [continues to expect](#) Gen 5 approval and launch by the end of 2015, so a CGM-integrated OmniPod PDM launch in 2016 is technically possible.** Still, we wonder if the initial launch of the PDM could integrate pump and CGM data only via the Dexcom and/or an Insulet app, and a subsequent update might bring the Dexcom CGM data right onto the OmniPod PDM screen. A big question mark is whether sending Gen 5 data to the OmniPod PDM makes it a PMA device; it might not, since the Gen 5 transmitter can pair with two devices (e.g., receiver and iPhone; iPhone and OmniPod). If patients can also get Gen 5 data on a dedicated Dexcom receiver or the FDA-approved Dexcom Gen 5 app, does that allow Insulet to avoid a PMA filing for a G5-integrated OmniPod handheld? We're not sure.
- **There was no update on the CGM-integrated OmniPod, suggesting this R&D project is not moving forward.** We had always thought this was a long shot, and believe a partnership with Dexcom makes more strategic sense for Insulet. The one-device-on-the-body is compelling, but not enough given the R&D risk of investing too heavily in this project. Certainly, Dexcom is moving lightning fast on the pipeline front.

10. The [data integration with Glooko](#) (launched [last week](#)) and the U500 insulin-compatible OmniPod with Lilly were not mentioned on the call. Glooko now has OmniPod downloading instructions [on its compatibility page](#) - downloads are currently only available on Android phones, and patients plug a Micro-to-Mini USB cable and download the PDM to the Glooko app. It sounds fairly easy, though we have not been able to try it yet. As a reminder, Glooko's patient-facing app/adaptor is \$59.95 per year; the product is also available through providers (\$300 per month - new details based on Glooko's [pricing page!](#)) and payers/health systems ([pricing](#) unknown).

- **As of the [1Q15 call](#), a clinical trial of the Lilly-partnered U500 OmniPod remained on track to start in 2015**, and meetings with certain investigators were scheduled for the summer. We're not sure where this pipeline project is at, though it has not moved very quickly since it was initially announced in the [1Q13](#) call more than two years ago.

Pipeline Summary

Pipeline Product	Timeline
Next-gen Bluetooth-enabled PDM	Prototype on display at ADA 2015 . FDA 510(k) filing in ~early 2016, with expected 2016 launch
Data Integration with Glooko Data Integration with Tidepool	Launched Currently in a private beta; nearing launch
PDM integration with Dexcom Gen 5 app and transmitter	Timing unknown (i.e., either with the new PDM launch or after it)
Updated OmniPod PDM for use with Lilly's Humulin U500 insulin	Clinical study to begin in 2015; investigator meetings this summer
Artificial Pancreas	Currently evaluating algorithms and customer needs.

<p>OmniPod with integrated CGM [single on-body device]</p>	<p>No updates since 4Q14, when development was ongoing and the first in-human trial was expected in early/mid-2015.</p>
<p>Drug Delivery</p> <ul style="list-style-type: none"> ▪ Amgen (oncology) ▪ Ferring (infertility) ▪ Capricor (heart failure) ▪ Other partnerships (obesity, pulmonary hypertension, oncology, and Parkinson's medications) 	<ul style="list-style-type: none"> - Launched - Launched - Supplying for phase 2 trial - No specifics shared

-- by Adam Brown and Kelly Close