Closer Look

MEMORANDUM

Insulet 1Q14 - OmniPod revenue grows over 35% on international demand; FDA sends feedback on LifeScan Verio-integrated PDM - May 7, 2014

Executive Highlights

- Total revenue in 1Q14 reached $69 million (a 21% year-over-year increase), driven by 35%+ year-over-year (YOY) growth in the core OmniPod business (~$59 million).
- The FDA has sent feedback on the 510(k) filing of a LifeScan OneTouch Verio integrated OmniPod PDM, and LifeScan is currently evaluating how to respond.

This afternoon, Insulet CEO Mr. Duane DeSisto led the company's 1Q14 financial update. Overall, OmniPod sales grew very strongly (35%+) in the US and abroad as Insulet continues to expand the insulin pump market. Whew! At the same time, Insulet's operating leverage continues to improve. The company is expanding manufacturing capacity, boosting sales resources, and investing in an increasingly robust R&D pipeline. It's a long way from the days in which the second gen pod kept getting delayed. We remember that, but it seems ages ago. Below, we bring you our top 10 business and R&D highlights from the call, followed by a pipeline summary and Q&A.

1. Total revenue in 1Q14 reached $69 million (a 21% year-over-year increase), driven by 35%+ year-over-year (YOY) growth in the core OmniPod business (~$59 million). New patient starts rose 20% in 1Q14 vs. 1Q13, and in 2Q14 thus far, new patient starts have risen a striking 40% vs. the same period in 1Q14.

2. International sales were extremely strong, as expected; Ypsomed's Diabetes Direct business increased 117% YOY, driven primarily by sales of the OmniPod, unsurprising in light of last year's Ypsomed report and Ypsomed's most recent report from this morning - we'll be reporting on this soon. Notably, the patch pump now has greater than 10% market share in the Netherlands, UK, and Switzerland.

3. Since the launch of the new OmniPod, over 35% of total prescribers are new doctors, up from "over 30%" in 4Q13. Importantly, 70% of these new prescribers have come back to write additional prescriptions. We think a lot of the reason for this is the "plug and play" element of the product.

4. Insulet has added 15 "key account managers" to its commercial sales force, and management said it expected another 5-10 in the next 30-45 days. In the two territories where Insulet tried this strategy, the company saw a 20-25% uptick in new patients - wow! They are being helped by the fact that many doctors who wouldn't prescribe the first gen Omnipod, especially the size, really appreciate the second gen and can persuade many more patients.

5. In 1Q14, Insulet produced a record 2.6 million pods, a 4% increase over production in 4Q13.

6. Still, all the growth costs a lot. Insulet recorded a $1.9 million operating loss in 1Q14, a 70% improvement from 1Q13's $6.2 million operating loss. Management expects to return to operating profitability in 2Q14 (it was first seen in 4Q13) as revenues increase and gross margins improve. During the 4Q13 call, management had expected to be operating profitable in every quarter in 2014.

7. Finally, the FDA has sent feedback on the 510(k) filing of a LifeScan OneTouch Verio integrated OmniPod PDM. LifeScan is currently evaluating how to respond to FDA's questions related to the Verio strips. Apparently, LifeScan will be held accountable to the new FDA draft guidance.

8. An FDA 510(k) submission of the special PDM designed for use with Lilly's U500 insulin is still expected in late 2014.

9. An insertion study for the CGM-integrated OmniPod was recently completed; early indications are that the various approaches around cannula insertion are viable options - no specifics were shared. Management believes this product is a "gamechanger in the type 1 diabetes market."

10. Insulet remains on track to have the more modern, next-gen PDM developed in time for ADA 2015.

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FINANCIAL AND BUSINESS HIGHLIGHTS

1. Total revenue in 1Q14 reached $69 million (a 21% year-over-year increase), driven by 35%+ year-over-year (YOY) growth in the core OmniPod business (~$59 million). Both figures came on a challenging comparison, as revenue grew 20% and 24% (respectively) in 1Q13. In prepared remarks, management emphasized that growth was driven by higher than expected international revenue from Ypsomed (see below) - this is lower margin of course, but great to see the product growing so much overseas, where there is so much more penetration potential. First quarter revenue of $69 million was achieved directly at the midpoint of management's previously issued 1Q14 guidance: $67-$71 million. Growth in 1Q14 occurred despite a more than $4 million reduction in Neighborhood Diabetes testing supply revenue due to CMS competitive bidding program. It's hard to say what Insulet would look like without this business in terms of cost and leverage. Adjusting for the impact of competitive bidding, YOY revenue growth was near 30%, so Neighborhood had quite a negative impact. Sequentially, total revenue grew 1% from 4Q13 (better than other pump company's hit harder by seasonality), a slight improvement over the 1% sequential decline seen between 4Q12 and 1Q13 one year ago.

- **New patient starts rose 20% in 1Q14 compared to 1Q13.** Notably, through the second quarter thus far, new patient starts have risen 40% vs. the same period in the first quarter of this year. Combined with the sales force expansion, this trajectory should put Insulet well on its way to achieving strong growth in 2Q and in the rest of the year.
- **Management reiterated the previously issued guidance for 2014** - total revenue to fall in the range of $295-$315 million (19%-27% YOY growth). For the second quarter of 2014, Insulet expects that revenue will be in the range of $70-$74 million (16-23% YOY growth; 1-7% sequential growth). In Q&A, an investor called the 2Q guidance "modest" - management tempered expectations, noting that international revenue will likely be lower and the newly expanded sales force will take some time to get up to speed.

	1Q13	**2Q13**	**3Q13**	**4Q13**	**2013**	**1Q14**
Worldwide OmniPod Revenue (millions)*	$44	$48	$56	~$58	**~$206**	~$59
Year-Over-Year Growth	24%	25%	30%	~30%†	**~27%**	35%+

Sequential Growth	-2.7%	11%	16%	4.6%	-	~1%

*OmniPod Revenue is extrapolated based on previous performance and the growth rate given during the financial call.
†Management's said that OmniPod revenue grew "more than 35%" year-over-year vs. 1Q13.

2. International sales were very strong, as we have come to expect from strong reports by Ypsomed (link) - Ypsomed's Diabetes Direct business increased 117% YOY, driven primarily by sales of the OmniPod. The OmniPod now has greater than 10% market share in the Netherlands, UK, and Switzerland. Meanwhile, Ypsomed has "aggressive growth" plans for the OmniPod in Germany, the Nordics, and Italy. Insulet management continues to expect the international business to more than double in 2014. By our math, non-US sales now account for ~10% of the OmniPod business. The international business through Ypsomed does have lower gross margins, though management noted that most of the gross margin turns right into operating margins given that Ypsomed takes care of all the marketing, etc. - that makes international sales the most profitable piece of Insulet's business today despite the lower gross margins. Ypsomed reported its half-year results earlier today and we'll be back with a report on this for readers next week.

3. Since the launch of the new OmniPod, over 35% of total prescribers are doctors new to Insulet, up from "over 30%" in 4Q13. Importantly, 70% of these new prescribers have returned to write additional prescriptions. The call shared several other important metrics: (i) over 70% of Insulet's new patient adds have never used a pump before (consistent with 4Q13); (ii) the company's fastest growing segment is patients <18 years age; (iii) 25% of the installed base uses CGM; and (iv) 3-5% of Insulet's installed base is type 2 - we believe there is a great deal of potential here. As background, Insulet's installed base is currently over 60,000 patients.

- **Management estimates that pump penetration in type 1 diabetes in the US is ~25-26% (400,000-450,000 pumpers out of 1.7 million type 1s).** This gives Insulet a 13-15% US market share. CFO Brian Roberts noted that when he started at Insulet five years ago, pump penetration was more like 22% on a base of 1.5 million patients. Most companies seem to use a slightly different type 1 base, but Insulet's seems reasonable, particularly given stronger recent growth in type 1 patients. Mr. Roberts also reiterated that Insulet's growth has been primarily from MDI patients, which has grown the market despite much more modest gains from competitors.

4. Insulet has added 15 "key account managers" to its commercial sales force, and another 5-10 are expected in the next 30-45 days. Notably, in the two territories where Insulet tried this strategy, the company saw a 20-25% uptick in new patients. With the new additions, the commercial team is now around 125 people, and will grow to 130-135 soon. The goal of these "key account managers" is to be a third person on the team in high performing territories - they will focus on the set of practices where Insulet has existing relationships. This will free up bandwidth for existing territory mangers to get to more practices and ultimately grow Insulet's prescriber base. Management believes some impact will be seen in 2Q, but the benchmark of productivity will really come in the third quarter. Said management, "We're pretty excited about what we've seen so far." The only reason Insulet didn't expand earlier was to ensure that the manufacturing side of the business was stabilized.

- **The key account managers have already "helped immensely" related to questions about Abbott's recall of the FreeStyle test strip.** Management noted in Q&A that this recall was quite confusing ("clear as mud") and resulted in a lot of questions over a 3-4 week period. However, the recall did not impact Insulet's business or new customers. As a reminder, the recall was first announced in February when Abbott discovered that certain FreeStyle strips (expiration date before August 2015) could result in erroneously low blood glucose results. Patients on the OmniPod were advised to contact Abbott to receive 400 replacement FreeStyle test strips at no charge. On April 23, Abbott posted an FAQ page for OmniPod users here (we assume to clear up confusion). We were glad to see the latter, though it was unfortunate that it took two months to post.

5. In 1Q14, Insulet produced a record 2.6 million pods, a slight 4% increase over production in 4Q13. The increase was achieved despite a two-week shutdown at Flextronics for Chinese New Year. Management noted that daily production (40,000 pods per day!) is now much more predictable, quality levels have improved, and scrap costs have started to decrease. A fourth manufacturing line is progressing as planned, and all equipment will be in place by 3Q14 (consistent with the 2H14 timeline given in the 4Q13 call). Management highlighted that building lines four and five will be straightforward ("cookie cutter"). After that, Insulet will look at other facilities under the Flextronics umbrella (e.g., Switzerland, Malaysia) so manufacturing is not all located in one place.

6. Insulet recorded a $1.9 million operating loss in 1Q14, a 70% improvement from 1Q13's $6.2 million operating loss. This was a slight step back from 4Q13, where Insulet had an operating profit of $0.2 million. At the time, management had expected to be operating profitable in every quarter in 2014. Insulet expects to return to operating profitability in 2Q14 as revenues increase and gross margins improve. The lower-than-expected gross margin in 1Q14 was a focus of Q&A:

- **Consolidated gross margin of 47% was flat sequentially -** management attributed the result to lower margins from higher-than-expected international revenue, impact from the transition of the customer base, and higher than planned scrap costs (not a concern going forward). The 47% gross margin still did represent a 350 basis point increase vs. 1Q13. Cost per OmniPod is expected to decrease throughout the year, and management is confident that consolidated gross margin will reach 50% in Q2 and 54-55% by year-end. US-based margins are expected to reach the low-to-mid 60s in the coming quarters.

R&D PIPELINE HIGHLIGHTS

7. Insulet and LifeScan have already received FDA feedback regarding the 510(k) filing in February of a LifeScan OneTouch Verio integrated OmniPod PDM. Questions related to the handheld (Insulet's responsibility) are straightforward and Insulet is ready to turn those in. However, questions related to the strips (LifeScan's responsibility) are more complicated in light of the new FDA draft guidance - according to Insulet, LifeScan is "going to be held accountable" to the new guidance. This was surprising to hear given that the guidance has not been finalized. LifeScan is "starting to wrestle" with those questions now and Insulet is waiting to hear back. We do understand that LifeScan has some positive options.

- **In light of the challenge of upgrading patients to the second-gen pod, Insulet does not plan to upgrade existing patients to the LifeScan PDM for free.** Said CEO Duane DeSisto, "I've done one upgrade for free, and it was the most painful experience of my life." Once the new LifeScan PDM is approved, new customers will most likely get it once they initially start on the OmniPod. For existing customers on the Abbott PDM, Insulet plans to have some kind of upgrade path available, likely at a more neutral price. For patients whose formulary has cheaper LifeScan strips, it may be worth it to move. We think from a pump sales perspective, having a pump where patients can use two different strip brands is a major advantage, particularly given formularies that are becoming more and more dictatorial.
    - **Given this commentary, it will be interesting to see if Insulet wants the option for patients to use of one of two major strip brands or whether it will let the Abbott agreement expire and to switch completely over to LifeScan.** The deal structures would be interesting to see. As background, Insulet extended its agreement with Abbott in 3Q13 to integrate FreeStyle blood glucose monitoring technology into the OmniPod PDM handheld. That agreement is non-excusive and will last through 2014. Certainly, two partners gives patients more freedom to chose what strip they want to use, though it undoubtedly creates additional complexity for Insulet (making two PDMs, dealing with two partners, etc.). On the other hand, being able to say it offers patients choice is quite powerful. Back in the day, we would have assumed that Abbott would fight to keep the deal; now, with Flash Glucose Monitoring, we are not sure how much Abbott

would fight to keep the deal. The deal would, of course, be very valuable for J&J's LifeScan business.

8. Regarding the special PDM designed for use with Lilly's U500 insulin, an FDA 510(k) submission is still expected in late 2014. The project is progressing on schedule and Insulet finished the first round of human factors testing, which we imagine was a decent amount of work. Meanwhile, Lilly is working with regulators to update the insulin labeling for use with the OmniPod. In light of the second-gen pod delays at FDA, management smartly shied away from giving an expected launch timeline for the U500 OmniPod ("If you remember, the Eros pod was 'around the corner' for two years. I vowed that I would never go down that path again. We can tell you the piece under our control, and we'll see what the Agency says").

- **Today, ~3-5% of Insulet's installed base has type 2 diabetes.** In the 4Q13 call, management reiterated that this U500 OmniPod has an estimated marketing potential of two million highly insulin resistant type 2 patients (>100 units of insulin per day). This number, of course, will only grow dramatically as type 2 diabetes continues to expand so aggressively.

9. An insertion study for the CGM-integrated OmniPod was recently completed. The company is compiling the data, but early indications are that the various approaches around cannula insertion are viable options. Management was frank in noting that the commercial path to this product "is a long one." Still, CEO Mr. Duane DeSisto believes the single on-body device will be a "gamechanger in the type 1 diabetes market." Management also reminded listeners of important news from the 4Q13 call - Insulet has found a viable solution to the pod-CGM sterilization challenges that led to delays in 2013.

- **The call shared new color on the business and margin advantages of a CGM-integrated OmniPod.** Most importantly, CFO Brian Roberts noted that there is a "lot of commonality in components" between the CGM sensor and the OmniPod, and thus, "there is an awful lot of leverage to be gained" (e.g., insertion, battery power). Reimbursement of the two products individually is ~$9-$10 per day in revenue, which over use of a three-day pod equates to $54-$60. Insulet expects it could add a sensor into the pod for ~$8, which brings the total cost of the CGM-integrated pod into the mid-teens range, but with much higher revenue potential.
- **Management also emphasized that the OmniPod is uniquely positioned to combine CGM and insulin delivery**, since the pod's battery and insertion are both located on the on-body device. As a sidenote, Medtronic and BD are also working on combined CGM-insulin delivery products, though there is no formal timing on either device.

10. Insulet remains on track to have the more modern, next-gen PDM developed in time for ADA 2015. We assume this means a final(ish) version will be shown at that time, though we would not look for it to be approved by the FDA in a year's time. As a reminder, this project was first announced in the 4Q13 call, which called for FDA submission of the new PDM in 2015. Insulet expects to offer additional details on the new PDM in the coming quarters. We wonder what features the company will prioritize in the handheld - connectivity (like Cellnovo), touchscreen (like Tandem), an updated user interface (like Medtronic's upcoming MiniMed 640G), waterproof (like Animas), etc. Certainly, the trend is towards devices that are more like consumer electronics, so at minimum, we expect the PDM's "cool factor" to rise in this iteration.

PIPELINE SUMMARY

Pipeline Product	Timeline
New OmniPod PDM with integrated LifeScan OneTouch Verio BGM	FDA 510(k) filed in February 2014; LifeScan currently evaluating feedback from the FDA related to the strips.
Updated OmniPod PDM for use with Lilly's Humulin U500 insulin	FDA 510(k) submission expected in late 2014

OmniPod with integrated CGM [single on-body device]	Sterilization issues appear resolved. Compiling data from insertion study. Update expected in 2H14 following IP filing.
"More modern" PDM	On track to be developed in time for ADA 2015; FDA submission expected in 2015
Drug delivery device for Amgen oncology medications	Anticipate approval in late 2014, with launch soon after. Will leverage existing manufacturing with minimal impact on expenses. Expected to have ~2x the per-pod revenue and majority of margin should fall to the bottom line.
Drug delivery device for Ferring Pharma infertility drugs	No recent update.
Additional partnerships for drug delivery with obesity, pulmonary hypertension, oncology, and Parkinson's medications	No formal agreements announced.

QUESTIONS AND ANSWERS

Q: I had one question about how we should think about your commentary you've made thus far in the second quarter as well as the additions you've made to your sales team, relative to your guidance? It is good guidance, but it is modest growth deceleration vs. the guidance for the first quarter, and the first quarter is a seasonally weak quarter. Looking at the guidance, it is about 16-23% growth, and I'm just trying to put that into the context of the first quarter being seasonally weak. You had incremental sales force hitting the ground in April, and you've given positive commentary on the new patient starts. Are you just being overly conservative? If so, why?

A: It is a combination of a couple different things. First, we mentioned a couple of times that international revenues were a little stronger than we had planned in the first quarter. Our expectation is that those will probably level off a little bit in the second quarter. It is just a little bit of timing for when Ypsomed was taking shipments, and, again, there was a little bit of catch-up related to the end of last year that, you'll recall, we planned around the shutdown for the Chinese New Year in January. That is a little bit of the timing difference. At the midpoint of our guidance, it would be around 20%. That's effectively where we were in the first quarter, and hopefully there's certainly some upside from there.

I do note that we're putting in 20 new resources in field, literally within last month or so. It takes them a little bit of time to get up to speed and hit the ground running, but they're doing a great job so far. I think, all in, we're very confident and bullish about where the year's tracking. So far this quarter new patients starts are up over 40% from where we were at this point mid-February. I think this is a big plus for us, and now we're going to see where the rest of the quarter delivers - both around the US and internationally.

Q: It looks like you're getting very solid gross margin on the OmniPod itself, but there is obviously some dilution from Neighborhood Diabetes. You came in a little bit below what we were looking for. We might be missing something here, but could you talk about the cadence of the gross margin ramp as we move through the year? We don't want to get ahead of ourselves, given that there is dilution from Neighborhood Diabetes. How should we think about the consolidated gross margins as we move through the year?

A: There are a couple of things contributing to the overall gross margin in 1Q14. The first is the mix with international, because certainly international is at a much lower gross margin for us; however, frankly, most

of that margin turns right into operating margin, so it still remains the most profitable piece of our business today. Secondly, as you talked about, Neighborhood Diabetes has experienced some pricing erosion and testing supplies as contracts start to renew - certainly nowhere near as dramatic as what happened with competitive bidding, but there's certainly been a few margin points that have escaped. We're looking to beat 50% + here in the second quarter, and then I'd expect we could add a couple hundred basis points - call it 200 or 300 - per quarter in the back half to the year, each quarter. That would get us somewhere around 54% or 55% consolidated by the end of 2014.

Q: I believe you have some international backlog; you've talked about that a little bit. Have you burned that off abroad and what about the US? Do you have enough inventory that you've supplied all of that backlog to this point?

A: Consistent with what we've talked about for the past couple of quarters, that backlog was originally built up at the end of 3Q13. We talked about being effectively - using your words - burned off in the course of 4Q13 and 1Q14. We have achieved that. Mr. Pat Ryan, our new Chief Operations Officer, has done a great job getting up to speed. We produced more pods in the first quarter than we've ever done historically - that includes the effective two weeks that we were shutdown for the Chinese New Year as well as the typical ramp up time when everybody returns. We were really well positioned on inventory for the quarter. We build inventory a little bit, and we've worked off all of that backlog.

Q: There have been some comments regarding how strong your international business was. By my math, you've exceeded 10%, which makes it material. What percentage of total revenue is international?

A: We're not going to comment specifically on what the revenue number is, but it certainly picked up in 1Q14 a little bit from where we were in 4Q13, on an absolute dollar basis.

Q: If it's over 10%, it becomes material, and it should be in the 10Q?

A: That's a 10K requirement. It's an annual look at what the level of revenue will ultimately be.

Q: When do you expect the LifeScan approval? You've received questions back, and you're responding. How many rolls at the FDA do you think this will take before you get the product on the market?

A: We'll put the FDA comments into two buckets. The handheld bucket, the comments regarding our handheld, are pretty straight-forward. We're ready to turn those. There seem to be some new guidance in what's required for a strip, and LifeScan is now starting to wrestle with those. We're waiting to hear from them on when they think they can turn in that document. I would say, as we sit here, we are ready. On the handheld side, there were no surprises for us, but there does seemed to be renewed interest at the FDA regarding glucose monitoring - there's some draft guidance out there that I think LifeScan is going to be held accountable to. We're waiting for them, but it's all strip-based. I don't have a good answer for you, but we'll know a little more here soon. There's a meeting at the end of this week or the beginning of next week to try to wrestle that to the ground.

Q: As you're getting approvals towards the end of this year and filing with Amgen and Lilly, can you help us frame how we should think about these opportunities heading into 2015 and beyond? Could you walk us through how that might impact the different lines of the income statement?

A: It's probably a little premature for us to get too detailed into the thinking around 2015. At the moment, as we've discussed, the U-500 510(k) filing is planned for this calendar year. Our expectation certainly remains the same around the Amgen product - that is, toward the end of this calendar year we'll hopefully see an approval. We also just talked a little bit about the PDM. Within the 2014 framework, certainly I don't think any of those will really have a material - or any - impact on the 2014 numbers. However, as we get deeper into 2014, we can start to frame out what our thinking will be for 2015.

Q: Can you provide us where you exited the quarter in terms of how many sales representatives you had? How should we be thinking about representative productivity going through the rest of the year with the addition of key account managers?

A: For the commercial team, we sit at about 125 or so, give or take a couple. We're looking to add another five to ten in the course of the next, maybe 30-45 days. That would put us in the 130-135 range. It is consistent with what we said earlier that these are the third men and women on the team, so they come with experience. Typically, you're going to focus on a set of practices where we have an existing relationship. I certainly think that our hope is that after their initial training, they'll be able to get up to speed fairly quickly. The goal is now to provide the existing territory managers with more bandwidth to be able to gain additional new practices to increase the prescriber base in 2H14.

We tested this in two accounts. We think it's key to where we want to go, and the only reason we didn't do this earlier is that we wanted to make sure the production side of the business was stabilized. We feel good about this. We'll see it over the next little bit of the quarter and then the third quarter - 3Q14 should be where we do a good benchmark on how this is going to work for us. However, we're pretty excited about what we've seen so far.

Q: What magnitude of productivity gain you achieved in those couple of accounts? Or some of the early accounts where you've added it? It looks like it's about a 10% to 15% overlay so far.

A: In test accounts, we saw we had 20-25% uptick in the business.

Q: In new patients or total revenue?

A: In new patients. However, the great part of the model is that if we get you under the curb, it's like compound interest. It continues to come every quarter. What we've seen is a 20-25% increase very quickly in those accounts; however, more importantly, I think that just the increase in the headcount is helping us. It would be nice to say that every product is going to be perfect, but when we do have a hiccup, those relationships are helping us manage all of that that normally goes into this space. We just went through the whole recall with the Abbott FreeStyle strip, which really had nothing to do with us. However, having those people in those accounts helps immensely because some of those press releases were as clear as mud. Having those people on the ground was immense, and, ultimately, you build strong relations with people and then they last. It's more than just the quarter - it really strengthens the bond between practitioners and the company.

Q: Going back to the gross margin conversation, you discussed three things; one of what you mentioned were the scrap costs. Was that only in manufacturing or did any of that product that was scrapped make it out into the field?

A: It was only in manufacturing.

Q: What went wrong? Was there some new issue or a continuation hat didn't get the yield improvements you had expected?

A: I wouldn't say anything went wrong, exactly. It's a kind of normal course of running the lines and, ultimately, as you go through the process there are a few components where a product would come in more on the edge of tolerance, so we saw a higher output of scrap. That's now allowed us to revise the tolerance with the supplier. There's some cost that you have to eat as part of that. A piece of it, also, is that we experienced the Chinese New Year effect, if you will; a lot of people leave, and you have a new group of folks coming in and getting trained. While Flextronics did 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. However, I wouldn't point to anything specific that went wrong in the quarter. Actually, to achieve 2.6 million pods, a lot went right.

Q: What was the third component? You mentioned scrap, and a transition of existing patients, and gross margin. I missed that one as you were discussing it.

A: The third is on the other side, which is that we had a little bit higher international revenue than planned. That comes with a much lower gross margin profile and a mid-teen type of percent, which brings down the margin a little.

Q: Would you say those three were roughly equal hits to gross margin, or was it disproportionate?

A: They're probably roughly equal. The manufacturing side - the scrap plus transition costs - would have been a little bit more than the international revenue. However, they all balance out.

Q: if you're going to file 510(k) with the U5-00, and Lilly's working through its issues, is that an end-of-year 2015 launch, or could that come earlier?

A: Our hope is that we get filed in back half of the year, and then we'll go down the regulatory response. We'll wait and see. If you remember, the Eros pod was around the corner for two years; I vowed I would never again go down that path. We can tell you the piece under our control, and then we'll see what the agency does.

Q: When is the FDA going to approve combo CGM device?

A: [Laughter]

Q: You did a good job of getting up to one million pods a month, but if growth continues, and you're adding new products, you could need two million or three million in the next few years. Is there anything from capacity standpoint other than adding lines? Will you run out of real estate?

A: Adding lines four and five are cookie cutter. After that, it would probably be in the best interest of the company to, within the Flextronics umbrella, find a different facility. Or, with four or five lines we'd be spread over a few different areas within the same campus. We also need to consider the cost of these facilities; however, I think we would move.

The good news is that line three is the best line we've developed, in terms of productivity, in terms of minimizing the labor. So, we can replicate that. Flextronics was integral in that and in installing it. They've seen it from beginning to end. We're pretty excited that that's a fixed cost, and we understand that piece. Lines four and five are fairly cookie cutter. Once we get beyond that, I think it would be in our best interest to look for a different facility. The great part is that Flextronics is everywhere - from Switzerland to Mexico to Malaysia.

Q: Since the introduction of the next gen pod, the Eros, I would argue that you have a little bit of a new customer. You have new physicians prescribing to new patients that weren't in before. You have higher growth in international markets. Have you noted any change in usage - up or down - from what you have in your old generation?

A: That's an excellent observation because the answer is: You're spot on. We knew with the old generation product that there were barriers for physicians or institutions, particularly with our insulin on board calculator or the size of the OmniPod. We knew that there were places that we weren't going to be able to penetrate until we came out with the next-generation product. As a result of that, those were the first areas we went to with the next-generation product. We said, "Remember all reasons you gave us why you wouldn't let us in the door? Well, look what we have."

I would tell you from day one I always thought our product was the perfect product for any kind of active child. Define that of whatever age you want. My wife would define me as an active child, so that's 50 something and below. However, I think it's the perfect product for that, and once we shrunk the size and changed the insulin on board calculation, many HCPs flung open the door. I'm very excited about where the business is coming from.

If you're 13 to 18 years old, and your introduction to insulin pumping is our product, you're never going on one with a tube. You're just never going to do it, and you'll do whatever you can not to switch to MDI. We have the right audience, we got the right people, and I think we have a lot of the right doctors - that's the mix. I will tell you we're seeing the same thing internationally. People are standing up taking notice.

We are diligently working on our next-generation handheld, which I think is going to be pretty cool and pretty surprising once we get that. There is no such thing as a perfect product - you can always make it better - but I think that our new handheld and OmniPod combination is going to be really, really exciting and will be fun for everybody to market. We feel good about where we are and where we're going.

Q: Were the 40% new patients starts on a sequential basis? That wasn't year-over-year, correct?

A: Yes, 1Q14 patient starts were up a little over 20% year-over-year. The comment regarding new starts as north of 40% in 2Q14 thus far was in comparison to 1Q14.

Q: Did the FreeStyle recall impact your business at all?

A: Probably for a period of about three to four weeks we handled many questions. But I'd be pretty disingenuous if I said it impacted our business. There was no question we had about three or four weeks of disruption, and there were a lot of people calling it. However, it really didn't impact us getting new customers - it really impacted the existing customer base trying to wrestle to the ground what the right date was and which strips to use. The last thing you need is for people to be distracted by something, but I would say that's pretty much in our rearview mirror now. It was a three or four - or maybe two to three - week period where there was a great deal of confusion.

Q: What's the transition plan to the LifeScan PDM. Will you upgrade for free? Is it an automatic rollout? What will the rollout look like?

A: The free upgrade we did was the most painful experience of my life, so we're never doing anything for free again. You have heard it here, and you can write it. As long as I'm here, I'm never doing anything for free because it hurts too much. I would say that once the product's approved, we would just start transitioning to new customers, and we'll go from there.

We haven't solidified any plans except for the free part. Most likely, new customers will ultimately transition directly to the new LifeScan Verio PDM, and I'm sure we'll have some sort of upgrade program for existing customers who wish to get that PDM - likely very similar to what we did about four or five years ago when we moved from the PDM 100 to the PDM 200.

Q: Where do you see the existing penetration in type 1 overall? As you look forward and at the continued migration from MDI, and as you have the key account manager overlay, does that migration accelerate? Where do you think it can go?

A: Everybody has numbers that are approximates of this. We've always used about 1.7 million people in the US living with type 1 diabetes, and pump penetration is about 25% of that number, maybe a little bit more. That implies that there are about 400,000 to 450,000 pumps in the country right now. When I started with Insulet about five years ago, pump penetration was about 22%, and there were about 1.5 million people with type 1 diabetes. Certainly, the numbers have gone up over that period of time, and I think to influence credit a lot of that has been on the back of this company. As you've seen others out there in the market who talked about their numbers with relatively modest increases or remain relatively flat over time. Obviously, our growth has been primarily from the MDI patient base, and we've basically gone from zero to north of 60,000 in that period.

That's why we've talked about these new resources to commercial being so important - it gives us more reach and frequency to be able to get to these doctors. We know that's a tried and true way of how to grow business. There are certainly an awful number of people out there with whom we thinking insulin pumping makes an awful lot of sense. Our view is that Insulet can be driver of accelerating this market penetration by bringing more and more MDI people to pumping.

Q: As we look ahead to a CGM-enabled pod or a pod for drug delivery, what is your high-level view of where you expect to see that gross margin for those two specific products settling?

A: It's a little early to discuss the CGM-enabled pump. What's intriguing about the space is what makes us unique is the commonality of components between a CGM sensor and our pod. There is much to leverage by

effectively integrating sensor technology right into the product - insertion, battery power, all of the different pieces I think is unique in trying to bring these two pieces together.

If you look at reimbursement of the two products individually today, they average somewhere in the neighborhood of $9-$10 of revenue per day. If you look at that over a three-day period, you're looking at somewhere between $54-$60 of revenue. We've commented historically that we think that we could add the sensor to the pod and call it in the $8 range, which would allow us to be a mid-teen priced pod by that point with a higher revenue potential.

Specifically around the other drug delivery products, we've talked about one of the benefits in general of that space is that we think we can leverage a great deal of what we do on the diabetes product, and therefore, keep the costs basically the same, and be able to charge a higher revenue number, maybe in the 2x plus kind of range. The other big benefit there is there's not a lot of operating expenses. The majority of that margin should ultimately fall to the bottom line.

Q: Could you give a bit more detail on Amgen the supply agreement? Is Insulet exclusive in drug categories that you mentioned, like oncology? Or can you sign with another pharmaceutical partner?

A: Cancer is a pretty wide category. There is exclusivity, but it's pretty narrowly defined. We have plenty of opportunity in that area.

Q: Could you clarify about the 70% of additional orders coming back from new doctors? Does that mean regarding new prescribers within the last year through 2013, 70% have put a new prescription during the first quarter?

A: They were not all necessarily in the first quarter, but certainly since these doctors have come on. It includes new doctors who started a patient in the first quarter, so we're kind of penalizing our self a bit there in the sense that those doctors won't necessarily add their second patient in the same first period. However, 35% and more of our prescribing base are new physicians, and over 70% of those so far have placed additional orders since their initial.

Q: Those 30% who haven't come back you, some of it will just be taking more time since some of those are from the first quarter? Have you lost any prescribers for any reason?

A: I can't tell you definitively that every single doctor will prescribe again, but, on the whole, the feedback across the country and commercial teams has been extremely positive. Overall, we think the trends are in the right direction.

Q: In terms of the pump with U-500, if it's approved by mid-next year, will reimbursement be all in place, or is there anything that would delay that launch? Is there anything else that has to be done on either your or Lilly's side?

A: Far be it for me to speak for Lilly; however, today, U-500 insulin is approved. The OmniPod is approved. Today, if a doctor writes an OmniPod prescription for a patient with type 2 diabetes, the hurdles in terms of requirements that carrier may want to see is greater - however, they do reimburse it. I don't think there will need to be a new code. I don't think so because, like I said, both of these products are approved and if there is a need, the carriers will approve the product.

Also, keep in mind that today somewhere between 3-5% of our overall patient population are patients with type 2 diabetes, so they can get approval. We don't have visibility, however, we just follow the same process that we do with patients with type 1 diabetes. Typically you see there's some additional paperwork, but on a whole, people are getting approved.

Q: On the competitive front, Tandem mentioned last night that now half of their patients or new patients adds are new to pumping. Are new to pumping patients choosing t:slim? Or is Tandem drawing patients away from Animas and Medtronic?

A: There's one major competitor in this space, and we all know who that is. Competition occurs in mind share of the doctor's office. At a customer level, I use the analogy that we're selling a motorcycle, and everyone else

is selling a car. If you like motorcycles, we're going to get your business. If you want a car, there are two or three guys selling a car. Our focus is the big guy.

--by Adam Brown, Hannah Martin, and Kelly Close