
Ypsomed F1H18 - Omnipod sales of \$80 million, driving half of EBIT profit; Patch pump YpsoPod ambitiously expected 2020-2021, hope to fill gap from Insulet agreement termination - November 14, 2017

Executive Highlights

- **Omnipod sales totaled a strong 80 million CHF (\$80 million) in F1H18, driving a striking ~80% of Ypsomed's Diabetes Care growth and half of Ypsomed's EBIT profitability.** This is clearly going to leave a major hole in Ypsomed's business following upcoming [termination](#) of the Omnipod distribution agreement on June 30, 2018. Management expects continued strong Omnipod sales of CHF 85 million in the second half of FY18, good news for Insulet.
- **Overall Ypsomed sales hit a record-high CHF 213.4 million (\$213 million), increasing 15% YOY on a tough comparison to F1H17,** when revenue increased 18% YOY. Growth was driven by Diabetes Care sales, which climbed 25% YOY to CHF 141.9 million - Omnipod comprised a notable 56% of these sales. Delivery Systems revenue declined 2% YOY to CHF 62.7 million.
- **Ypsomed's own tubed YpsoPump is now available in six countries, with four more expected by year end. Ten additional countries are coming in 2018.** The pump has achieved a "very excellent, smooth" launch, though no revenue or user metrics were shared. The pump has launched continuous Bluetooth communication with the mylife mobile app, an important milestone.
- **Ypsomed expects FDA clearance for the YpsoPump in 2Q19.** This was not mentioned on the call, but was noted in the [slide deck](#).
- **YpsoPod, Ypsomed's Omnipod competitor patch pump, is ambitiously slated for a roll out in late 2020/early 2021.** Nearer term, BGM and CGM Bluetooth integration with the mylife App are expected in 2018, followed by a mylife Control App to remotely command the YpsoPump and a pivotal trial for a closed loop system with the YpsoPump in 2019.

Ypsomed [reported](#) F1H18 results on Thursday in a call led by CEO Mr. Simon Michel and CFO Mr. Niklaus Ramseier. Given Insulet's [termination](#) of the Omnipod distribution agreement with Ypsomed (starting July 1, 2018), the call focused primarily on how Ypsomed's own ambitious diabetes care pipeline will serve to fill the significant revenue gap and corresponding growth. Read on for our top highlights from the call - view the [press release](#), [slide deck](#), and [semiannual report](#) here.

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Financial Highlights

1. Ypsomed Record High Revenue of CHF 213.4 Million Driven by 25% YOY Diabetes Care Growth; Delivery Systems Revenue Declines 2% YOY

Overall Ypsomed sales hit a record-high CHF 213.4 million (\$213 million), increasing 15% YOY on a tough comparison to [F1H17](#), when revenue increased 18% YOY. Management noted that this performance was "clearly above our own expectations." Growth was driven by Diabetes Care sales, which climbed a strong 25% YOY to CHF 141.9 million on a tough comparison to [F1H17](#), when revenue increased 23% YOY. Omnipod sales of \$80 million CHF comprised a notable 56% of Diabetes Care revenue and drove ~80% of the segments growth in the half year. The [semiannual report](#) cited strong sales in both established and newly exploited markets, particularly France - of course, that's exactly where Omnipod has seen strong momentum recently, per [Insulet 3Q17](#). Delivery Systems revenue declined 2% YOY to CHF 62.7 million against a tough comparison to [F1H17](#), when sales climbed 12% YOY. The [semiannual report](#) noted GSK's removal of its GLP-1 product Tanzeum from the market as a key factor in softening sales. However, Ypsomed expects renewed growth in F2H17 given current order volumes.

- **Profitability (EBIT) declined 4% YOY to CHF 26.9 million, attributed to launch costs for the YpsoPump.** Of concern for Ypsomed, Insulet's Omnipod drove 52% of EBIT profitability in the half year (CHF 14 million).
- **On a positive note, management raised sales guidance, calling for FY18 growth of 18% YOY - up from the previous 15% YOY.** Ypsomed expects EBIT of around CHF 60 million in FY18, implying a slight sequential increase in profitability in the second half of FY18.

2. Termination of Omnipod Agreement -> CHF 160+ Million Revenue Reduction; "We Will Focus On Our Own Products"

Omnipod sales were a strong 80 million CHF (\$80 million) in F1H18, driving a striking ~80% of Ypsomed's Diabetes Care growth and half of Ypsomed's EBIT profitability. Though Ypsomed did not share Omnipod sales [one year ago](#), we estimate they grew ~40% YOY based on this call's provided share of growth (80% of Ypsomed Diabetes Care's YOY growth of 28.5 million CHF). Management expects continued strong Omnipod sales of CHF 85 million in the second half of FY18, good news for Insulet - there was obviously concern Ypsomed might shuttle patients to its own pump in the coming ~9 months, but the agreement incentives seem well designed to avoid this (see below).

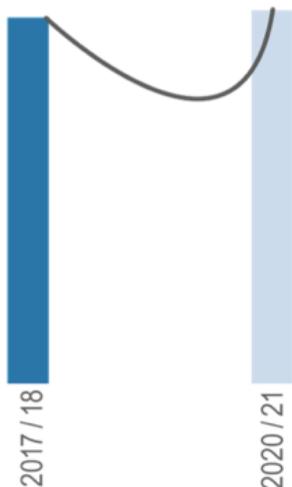
- **Throughout the call, management expressed confidence in Ypsomed's future despite the summer 2018 [termination](#) of the Insulet distribution agreement, claiming, "Omnipod simply did not have enough margin for both companies."** We heard similar comments on Insulet's 3Q17 call, where management called going direct in Europe a "tremendous opportunity," driving a ~50% revenue increase over what Insulet currently receives from Ypsomed.
- **The loss of Omnipod next year will reduce Ypsomed Diabetes Care revenue by at least CHF 160 million on an ongoing full-year basis - a very big hole to fill.** Management noted that there still remains a half-year of Omnipod sales in 2018, as well as the expected CHF 50 million milestone payment promised to Ypsomed. To align incentives, the final amount Insulet pays will

depend on the number of pods used in one year *after* Insulet assumes distribution in mid-2018 - very smart. The more Insulet pays, the bigger the market will have become. While Mr. Michel noted the termination came "one to two years too early," ultimately, he believes it was the right decision.

- **In this deal termination, Ypsomed loses more than Insulet near-term; it will be up to both companies to define the mid- and long-term impact.** For Insulet, the team will need to successfully take on a direct business in Europe, including all the sales and marketing and other functions Ypsomed takes on. This also means competing head-to-head with Ypsomed's own pump(s), a future launch of Medtronic's MiniMed 670G in Europe (no recent timing given), possible 2018 launch of Diabeloop's AID system, a possible EU entry for Tandem, and the Roche/Senseonics/TypeZero product. For Ypsomed, the team will need to successfully fill the revenue gap left from Insulet, scale the YpsoPump in an increasingly competitive EU pump market, and get the YpsoPod to market - no small feat.
- **As evident in the graph below (left panel), Mr. Michel foresees the major revenue dip occurring in 2019/20.** The following "very strong increase" will be driven by pens and the YpsoPump, with the pen business contributing 75% of both revenue and profitability. Mr. Michel believes "the future is bright," expecting profitability to increase "massively." It remains to be seen whether the YpsoPump, and eventually the YpsoPod (Ypsomed's own patch pump), will be able to fill the revenue gap left by Omnipod, although management believes the YpsoPump will prove "two to three times more profitable than the Omnipod."

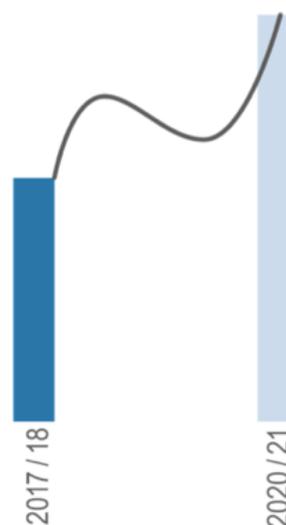
Outlook Ypsomed for 2020/21

Compensation of decrease in turnover due to loss of mylife™ Omnipod®



Development of turnover including special effect of the compensation payment by Insulet Corp.

With an increase in profitability



Development of the EBIT including special effect of the compensation payment by Insulet Corp.

- **The incentive scheme as part of the agreement termination seems to be working - Insulet reported record international 3Q17 Omnipod sales of \$33 million for the sixth straight quarter, increasing 70% YOY.** For context, Insulet's international sales were \$25 million in 1Q17 and \$27 million in 2Q17. It's hard to line up the timing with Ypsomed's FY18, but the ~80 million in Omnipod sales reported in this update is indeed ~50% higher than what Insulet reported over the same time period.

Focus on own manufactured products

- Ypsomed covers the entire value creation chain for the most important products in the mylife™ Diabetescare portfolio integrally. This will increase profitability considerably in the mid-term.
- Furthermore, we have the full flexibility in technical further development and digital integration to create a connected system.



- **Given [Animas' recent exit](#), the pump business is increasingly fragile - how many companies can the market support, both in the US and globally?** Ypsomed certainly faces stiff competition from more established players in the field, including several 2018 pivotal trials expected for automated insulin delivery - see our landscape here. Can Ypsomed execute successfully? While the durable YpsoPump won't be in direct competition with the tubeless Omnipod, Ypsomed may compete for the same patients, given the marketing and previous experience. Mr. Michel claimed he was "happy with the decision from J&J to close Animas," despite acknowledging that the majority of Animas customers will likely go to Medtronic. Still, Ypsomed will "fight hard to get a couple of these patients." It's unlikely Ypsomed will benefit significantly from the Animas exit, given Medtronic's [position](#) as the preferred transition partner, strong [welcome programs](#) from Insulet and Tandem, and no availability of YpsoPump in the US or Canada (where a big chunk of Animas users are).

Pipeline Highlights

3. YpsoPump Now Available in Six Countries, Four More by Year End; "Very Excellent, Smooth Launch"; Added Continuous Bluetooth Communication to Phone

The mylife touchscreen durable YpsoPump is currently available in six countries, with four more by year end and ten expected in 2018. So far, the YpsoPump has achieved a "very excellent, smooth launch," with positive feedback from both patients and providers. No user base or launch metrics were shared, so we assume it's still in the hundreds or perhaps low thousands (our speculation). The updated 1.5 version of the YpsoPump software has just begun roll out. In addition to the prefilled NovoRapid pump cartridge, users can now manually fill a cartridge with the insulin of their choice, allowing the YpsoPump to be used with every fast-acting insulin - great to see this launching on time. According to the [semiannual report](#), Ypsomed will offer more prefilled cartridges "in the next few years" - this could imply Lilly also has a prefilled pump cartridge coming for Humalog, though we're not sure. The pump has a quick half-hour training phase (management noted Medtronic's one-day training period for 670G) claiming that nurses love

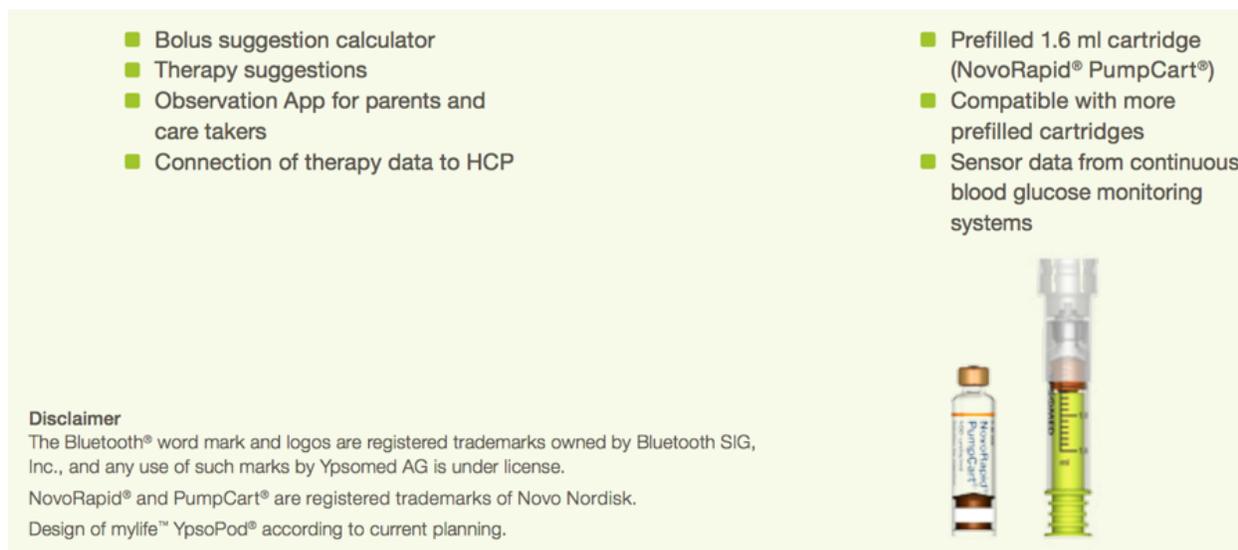
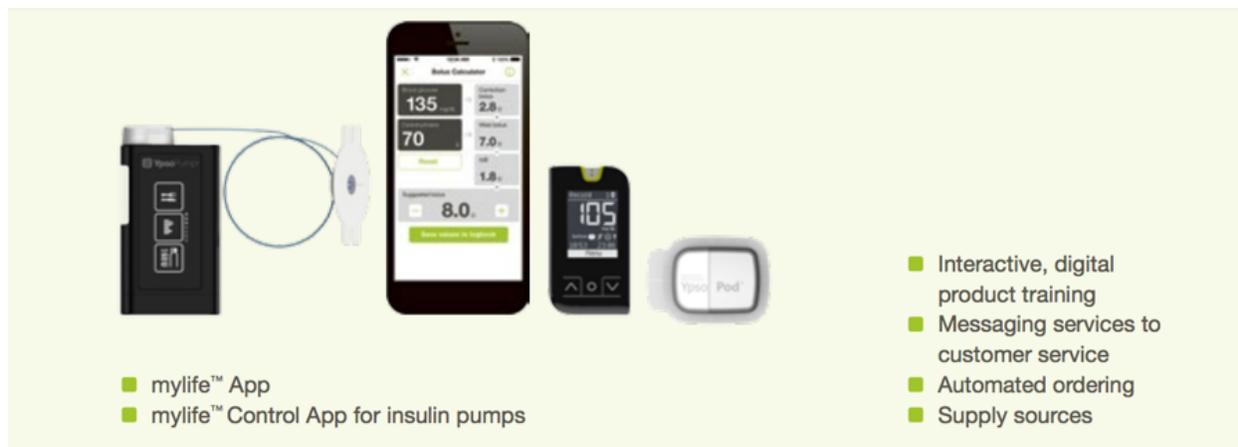
the device's reduced training burden. We do not believe continuous pump communication with the mylife smartphone app (via Bluetooth) has launched; this was previously expected in FY18, though the report showed this in the "product portfolio of the future." If it has launched, YpsoPump would be the first pump on the market to send data continuously to a user's smartphone (excluding the MiniMed Connect keychain uploader) - a terrific win for patients to check pump status without having to pull out the pump. This embedded Bluetooth should also integrate nicely into [JDRF's open protocol initiative](#), as well as DIY efforts.

- **While not mentioned during the call, the [slide deck](#) noted FDA clearance for YpsoPump is expected in 2Q19, with more details to be provided in 2018.** Though two years away, this feels quite ambitious to us, given the highly competitive pump market, the current absence of a CGM partner, and Ypsomed's lack of a clear automated insulin delivery pipeline. We believe a US launch in 2019 without automation would be quite a difficult marketing lift for Ypsomed.

4. BGM and CGM Data to Stream to Mylife App Via Bluetooth in 2018; Control App to Drive YpsoPump in 2019; YpsoPod Patch Pump to Launch Late 2020-Early 2021

In March-April of next year, Ypsomed plans to introduce the new mylife Unio Neva BGM, which will link to the mylife App via Bluetooth. Next steps include integrating CGM into the app in 2018 (management cited ongoing discussions with Dexcom and Abbott) and developing a mylife Control App to enable remote bolusing in 2019. Mr. Michel sees the Control App as critical to designing a closed loop system, which the company plans to test with the YpsoPump in a pivotal trial in 2019. Ypsomed is currently "evaluating several algorithms," although Mr. Michel noted that there are "not so many good ones." This timeline seems fairly doable assuming execution is strong, but things need to fall into place quite quickly - given how long it has taken the 670G to launch and other companies to get their design/pivotal timing lined up.

- **Management expects its own tubing-free patch pump, the YpsoPod, to launch in late 2020 to early 2021, pushing back the [previously expected](#) release date by about six months. The slide deck (see below) showed the first picture we've seen - the prototype is reportedly the same on-body size as the Omnipod.** Mr. Michel noted that the company recently learned a clinical trial will be required in Europe, so it's unclear whether the six-month delay will necessitate further extension. Even large companies like Roche (e.g., Solo MicroPump) have been challenged to launch a patch pump, so we'll be watching to see if Ypsomed can design one successfully, build it at a reasonable cost, and manufacture at scale with excellent quality. Most companies we've followed underestimate the challenges of doing this - it's taken Insulet about a decade! - so the bar is definitely high to do this in three years. Ypsomed told us it is fully aware of these challenges and has more than 30 years' experience in designing and manufacturing insulin delivery devices.
- **The [semiannual report](#) details several planned future additions for the mylife App:** bolus suggestions based on blood glucose data, active insulin, and consumed carbohydrates are listed first, followed by an Observation App to facilitate remote monitoring of children and loved ones. The report also mentions improved data sharing with physicians. No timing updates were provided, though given where pumps are going (Bluetooth-enabled, more functionality pushed to the phone), these are must-haves in our view.



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Design of mylife™ Ypsopod® according to current planning.



5. Ypsomed Orbit Infusion set to Be Included in Bigfoot Pivotal Trial in 2018; Scaling Up of Orbit Manufacturing

In a brief mention during the call, Ypsomed acknowledged that the Orbit 360-degree infusion set will be included in the [Bigfoot-Abbott pivotal trial](#) slated for 2018. At this stage, it's just a supply agreement for the pivotal, though Mr. Michel implied it's a bit more: "[Bigfoot] is extremely innovative, but they still have a long way to go. If they are successful by 2020-2021 we'll definitely be in the game with our infusion set." (That latter comment implied a commercial deal, which it is not.)

- **Like the Insulet deal, this could be perceived as another Ypsomed partnership that creates weird incentives** - Ypsomed's own closed-loop efforts and in-house pump(s) will directly compete with Bigfoot. That said, Ypsomed could obviously supply Bigfoot and then offer its own system, though it's hard to imagine Ypsomed could be highly successful in the pump market without a clear automated insulin delivery product. Will this supply deal mature into a commercial agreement? Will Bigfoot end up going with another supplier for the commercial product? Presumably Unomedical is the only other option for Bigfoot's set, since Medtronic is BD's exclusive worldwide partner.
- **Mr. Michel highlighted the Orbit infusion set as Ypsomed's "key element" for the Ypsopump proposition.** Notably, current production of the infusion set in Mexico will be transferred to a "highly automated production plant" in Switzerland with an annual capacity of two million units. Mr. Michel cited greater control over production as the main reason for the move. The

[slide deck](#) notes that the Switzerland plant will be running in 2017, while an additional plant in Germany capable of producing 10 million units annually is expected for 2019.

- **This is a critical partnership for Bigfoot, as it needs a custom infusion set for its pump.** According to the [Bigfoot press release](#), the modification concerns the "proprietary connector cap," just as Asante had when its pump was on the market. Bigfoot CEO Jeffrey Brewer shared with us that, "We are only using best-in-class components that support our vision for easy to use, simple to train, high-quality user experiences." Ypsomed's Orbit set has some incremental advantages, as noted in the [Bigfoot press release](#), including 360-degree rotation for tubing, a novel patch adhesive, and easy insertion. Mr. Brewer also highlighted Ypsomed's patient-centered design process, unique features in Bigfoot's pump that Ypsomed is designing for, and Orbit's common design for steel and teflon versions. For more on Mr. Brewer's thoughts, read our interview with him [here](#).

6. SmartPilot, YpsoMate 2.25, and YpsoDose Still in Development

Ypsomed's [semiannual report](#) highlighted the company's **SmartPilot, an attachable device equipped with sensors that clips onto the YpsoMate autoinjector**. The SmartPilot wirelessly connects to an app, records the handling steps of the user, and provides step by step instructions along with audible and visual feedback when an injection is successfully completed or if the user makes a mistake. The app includes a reminder feature, and dose data can be sent to providers via the cloud. SmartPilot is intended for use in clinical studies and is compatible with the YpsoMate platforms for both 1 ml and 2.25 ml syringes. It's unclear when the SmartPilot is expected to launch, but we're fans of the tool and think it has the potential to be a huge asset for the GLP-1 class, in particular. YpsoMate 2.25 (large-volume auto-injector) and YpsoDose (prefilled, large-volume patch injector) are also in development, as noted in the company's slide deck, although no details on timing were shared.

SmartPilot™ allows patient-oriented study designs

- Less effort for patients increases their motivation to participate.
- The reminder function and step-by-step instructions lead to fewer study drop-outs and operating errors.
- Less administrative effort and better data quality through electronic data capture.
- Insights into patient behaviour enable possible improvements in therapy.



Current developments



-- by Maeve Serino, Adam Brown, and Kelly Close