



## SIMON MICHEL

### CHIEF EXECUTIVE OFFICER, YPSOMED

In this exclusive in-depth interview with ONdrugDelivery Magazine, Simon Michel, Ypsomed Chief Executive Officer, talks about his vision for how the connected world of drug delivery devices will evolve, and Ypsomed's central role within it. Mr Michel comes across as a CEO tackling this topic not at a distance, but one who is fully involved, has a true grasp of how connectivity can improve healthcare, has a detailed knowledge from the level of the broadest, biggest global issues to be considered, right down to the detailed technical level. This top-to-bottom understanding gives him a clear vision of the route through, the steps the industry needs to take, to make it happen.

**Q** Ypsomed reported its 2015/16 annual results in May with continued growth of 10%. How was this achieved?

**A** Ypsomed's results across both of its divisions, the retail arm, mylife Diabetescare, and on the YDS (Ypsomed Delivery Systems) business-to-business side, were strong and in terms of revenue their contribution is now roughly equal, fifty-fifty. Business has actually been picking up in both areas and the top-line growth of 10% is going to accelerate in the coming years. We calculate, with an annual growth of 12-15% year-on-year as a realistic forecast, revenue of CHF500 million (£363 million) in 2019.

---

"The power must come from the smart phone or other device that sends the power to the pen and the pen then sends back data. In other words, we have to work with NFC but its range at present is only a couple of centimetres. We need NFC that works at a range of 2-5 metres, and this standard doesn't exist yet."

---

On the B2C (business-to-customer) diabetes side, it is the insulin pump market that is growing faster than expected. For example in countries like the UK, and others in Europe, children are put directly onto a pump, they are no longer given a pen, and with the OmniPod Patch Pump we have a great product in our hands. On the B2B (business-to-business) side which develops the pens and autoinjectors, there are strong global trends such as the increasing incidence of diabetes, the emergence of biosimilars and the increasing numbers of drugs coming through that have to be injected. We are in these areas and we are a market leader.

**Q** Would it be correct to say that this growth has been through increasing revenue streams rather than through acquisitions and the like? It seems to be a strategy that works.

**A** Yes. This is pure organic growth, and it will stay purely organic growth for the foreseeable future. We have done our homework. When you look back in our history, we were at one time the sole provider of insulin pens to Sanofi and today, we are talking with dozens of pharma companies and Sanofi is still a very good client for SoloStar pen components.

**Q** Ypsomed's platform strategy for delivery systems is paying off. What is the focus moving forward?

**A** Ypsomed has really changed the rules. I would even say we have changed the rules in the market. Ten years ago we introduced the first real pen platform concept. Before that, companies like Ypsomed sold projects so, for example, if a customer came to us, we would sit down together, our engineers would begin to draw first concepts of a pen and four years later there was a product ready for clinic. Today this has changed dramatically. It's no longer four years – it takes a matter of months. So we have accelerated these timelines massively by developing platforms, by engineering them, by patent protecting them and, this is key, we also industrialise them.

If a pharma company comes to us today we have injector platforms ready, fully industrialised – you can really buy them off the shelf. The adaptations required for the autoinjectors and disposable pens are relatively minor compared to ten years ago. Worldwide we are conducting over 50 projects in parallel and this is not the ceiling. This world is changing so rapidly now.

**Q** How does being active in the diabetes care business support activities for the delivery systems business?

**A** That, of course, presents a really good opportunity. We currently serve around 30,000 OmniPod patients and we are adding around 800 per month.

At Disetronic, Ypsomed's predecessor company (now part of Roche) my father

(Willy Michel) invented the first insulin pump, next to Alfred Mann, 30 years ago. They were head-to-head, competing. Al Mann sold his pumps to Medtronic and we sold ours to Roche Diabetes Care. There's a lot of history here and contact with patients. We have kept this direct contact over the years.

We now have 15 sales subsidiaries and 350 reps in the field, daily contact with patients and a hotline with 40 people manning it. It's a very strong patient interaction on the B2C side, and this interaction has clear benefits on the B2B side too. We do focus groups, we test new concepts with patients. There is really a strong crossover internally between the B2C and B2B sides of our business, around knowledge building and really knowing the patient.

There is also of course strong interaction and constant communication between the two sides of the business "on the ground". Here at Ypsomed in Burgdorf, we are 500 people, including 150 engineers, 100 people in product management, and the B2B and B2C teams are located very close to one another within the building.

**Q** How do you see connected devices making an impact in the market for self-injection systems?

**A** Let me give you an example of how connectivity is already changing the world. For two or three years now, my sons have been using the Oral B 6000 toothbrush, which is Bluetooth integrated and I can check their usage on my mobile phone via the app. As soon as you think about this example, you quickly realise that there are many, many even more intelligent ways to use connectivity technology. You realise that autoinjectors must be smart.

Personally, my affinity and familiarity with telecommunications and data is very high. In a previous role I worked in this sector while we were introducing 3G mobile networks in Switzerland.

I would just be a bit careful on the expectations in the market. When I look at the history of devices, the 1980s was the decade of the re-usable pens, the 1990s was the decade of disposable pens and the focus was definitely on the function back then. Then in the 2000s, the focus was on cost and we saw the first large-volume, fully automated 50, 70 and 100 million-unit pen lines as we operate today. This decade is the decade of usability. We have been talking about usability

for more than ten years but in reality these devices are hitting the market now. So thinking about smart devices and connectivity, I would talk about the next decade; the 2020s will be the decade of adherence and smart devices. These things take time. The industry is extremely slow moving, especially in the world of combination products. You cannot quickly change a disposable product just like that.

We also have to look at the standard on the tech side. At the moment we are extremely limited. We talk about low energy Bluetooth and NFC (near field communication) but low energy Bluetooth in most cases is too expensive at the moment to put into a disposable device so we talk about re-usable solutions.

The industry focus is on disposable pens but there is very limited room in the budget to put in Bluetooth connectivity and power source – it's over one dollar per device.

Also, it's not really acceptable that a disposable pen has its own electrical power. The power must come from the smart phone or other device that sends the power to the pen and the pen then sends back data. In other words, we have to work with NFC but its range at present is only a couple of centimetres.

The normal distance between a person and their mobile phone is in the 1.5-metre range. It is usually either on their body in a pocket or worn, or nearby on a desk or table. NFC on an autoinjector, as it is now with such a short range, is an intermediate solution. It gives added value for some therapies if you can really train the user to hold the autoinjector to the phone for data transfer but this is an active process, not passive.

So, on the one hand, we have to wait for the tech to emerge for communication. On the other hand, companies like Ypsomed have work to do on solutions to record the information on disposable devices: how much was injected, at what speed, at what time. This is an electronic and mechanical engineering job.

I would like to touch on another topic which we believe is a kind of dilemma in the industry, which we still have to solve, the different parties have to find their roles. There is no

doubt about it, pens and autoinjectors must become smart in order to enhance adherence. There, we are all clear. But if you look in the industry, who is going to build the infrastructure (Figure 2)? Payers for example, have very little motivation to invest here because most payers (not all but most) really have a quarterly financial focus and there is very little incentive for programmes to look at the health status of patients ten years down the road. Also there are no global insurance companies. Most of them are local focusing on one or a few countries, so they have limited interest in investing in global cloud solutions.

Then looking at pharma, big pharma, in the whole of their history, they have avoided owning patient data. Now suddenly they are faced with a need to change this, to build up knowledge bases and interact with patients. Pharma companies are not yet sure they want to do it, they don't have cloud teams – IT teams to talk about integrating the cloud into customer care, for example, do not exist. There are existing third-party cloud providers out there but at the moment they are very much patient focused – they are not yet payer or pharma focused. Finally, looking at doctors, there is still reluctance in the medical professional community to go online and transmit patient data via the cloud. The question is: will the device manufacturers be the ones who will jump into this role of building the infrastructure?

At the moment, Ypsomed is analysing intensively whether we should offer OEM cloud services, a pay-per-user cloud service where a pharma company can hook up, it's fully secure, we transfer the data from all our autoinjectors, via the mobile phones of the patients, into the cloud and the data will land where pharma can use it.



**Figure 1: Leveraging Ypsomed, the two-step autoinjector platform, Ypsomed Smart features NFC-based connectivity and built-in low-cost sensors to identify use status.**

This might be for Phase IV study data, or for routing to doctors to inform them whether the patient has taken a shot or not. This is a real dilemma – the industry still does not know yet who will be in the cloud-provider role. We are quite sure that the device manufacturers have to play a part.

**Q** Which device types and geographical areas have the greatest potential for connectivity?

**A** Geographically, this is global, the whole world. But to be more specific, the number one area in terms of potential is the US because they have the biggest budgets around for drug and device development. You can even think about business models that are offered by newcomers, who want to offer integrated solutions in the field of diabetes and they can do it because there is money around. There is venture capital around for new companies and there is also money around in the system to pay for cloud solutions and connected services.

In terms of which types reach the market as connected devices first, I believe it's a head-to-head race between the first insulin pen and the first autoinjector.

At the moment, Ypsomed is working in both areas in but remember, as I mentioned just now, there will be intermediate solutions and the industry will still have to wait for the ultimate architecture for the way it works. It is still not there because the communication technology needed is the missing piece. Security is another hurdle which governments, healthcare systems and pharma are confronted with.

**Q** You announced a new wearable injector YpsoDose in your annual report. Will this device also be connected?

**A** In the LVI field you have a number of players who have brought projects forward and Ypsomed is now working actively in this major new device class to compliment pens and autoinjectors.

So our device, YpsoDose (see Figure 3), is fully disposable, electromechanical, it has an auto-insertion needle mechanism, it has a glass container, prefilled with a sterile fluid path, and it is for 5 mL. We believe that there will be a need to develop a range of devices to cover the range of customers' volume requirements. We'll be presenting the first YpsoDose product at the PDA Universe of Prefilled Syringes & Injection Devices

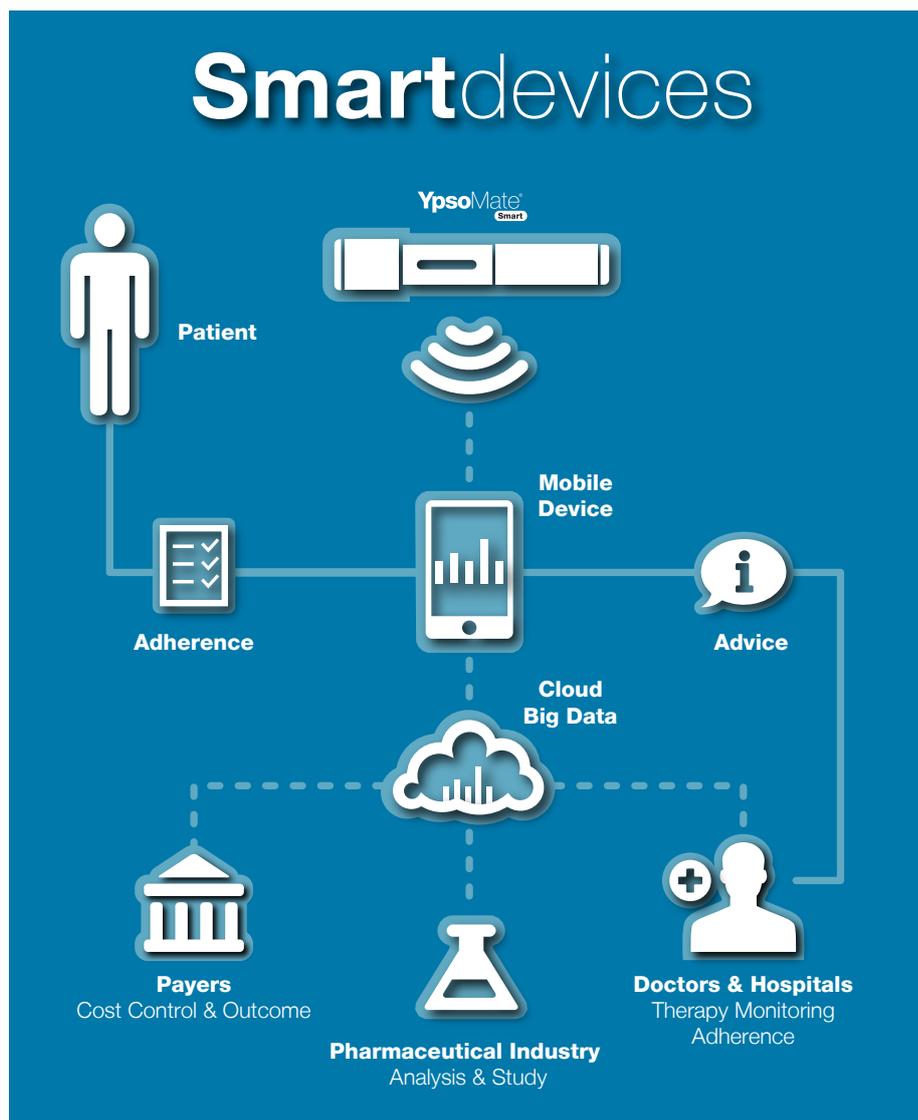


Figure 2: Typical architecture of how smart devices integrate into the complex healthcare environment.

conference in California later this year.

The communication, connectivity, is of course an important element for YpsoDose. In the pump world, it is much easier to integrate communication technology into the device. Take our insulin pump, for example. It is called YpsoPump, and it is being launched imminently in 18 markets in 18 months. It's half the size of the Medtronic pump, has a touch screen, no letters, symbols only. It's a prefilled solution so it avoids cumbersome manual filling of insulin. In this pump, weighing 83 grams, there is of course a Bluetooth module integrated because in a pump there is enough budget to build in a really smart, robust and stable module, and there is space.

So for YpsoDose, it is optional to have the connectivity module inside. Whether or not it is included for specific products will depend on whether it really adds value to have the information about whether the

patient has injected or not sent to the doctor or nurse. It depends on the therapy. If it is for a patient taking shots after chemotherapy then yes, the nurse wants to know. But for other diseases it is not useful that the doctor or nurse knows every day and every week whether or not the shots have been taken. It can be checked in a quarterly review. So it's really indication dependent but yes, of course YpsoDose has connected capability just as our YpsoPump does.

**Q** How do you see the future of self-injection systems moving forward?

**A** Earlier in the discussion I mentioned the different decades and different focuses and stages of development from the 1990s through to the 2020s. It is clear now in the industry that the next decade is about adherence. We have to achieve a situation where shots are taken. You know 70% of

Americans are not taking their insulin shots outside of home for various reasons – they might be ashamed, they might forget it, they might not care enough. This is traumatic.

The new products coming through are so user friendly they can be handled easily without a manual, without instructions – we have achieved that. So the next step is to motivate the patient. This can be achieved in several ways. One way is to automate, which, in the insulin world, is the discussion about closed-loop or semi-closed or smart loop systems. Also, looking at the longer term, on the sensor side, we are getting better and better with continuous sensing, which gives good enough data to, for example, at least to shut down the pump at night during a hypo, or to give more insulin during the hyper in the morning hours. There are some elements emerging here where automation is a way to achieve better adherence.

Then also of course, connectivity, the smart element, can be used to trigger the enhancement of the therapy. Parents will be able to see whether their child is taking their shots at school, and be able to send them a message or call them saying please take it. Eventually, and this is my hope, payers will be able to call up patients and remind them. In the US, for example, insurance companies might call a patient

and tell them that they have not taken their shots and that they need to take them in order to remain in the plan.

Information being used to enhance adherence is the future, and for this we need to have the connected delivery systems available.

A crucial advantage Ypsomed has here is our true understanding of patients and our ability to learn important lessons from our B2C side and apply them in our B2B side, to be able to transfer elements from our diabetes business, where we are in close contact with patients constantly, to our delivery systems business.

The subject we touched upon earlier, of which players are going to be the ones to provide the cloud is also a very important one, I believe, for the future of the injection devices industry. I would really like to motivate the pharma industry to think about their role, about who plays what role. We talk to more than 100 pharma companies. Very, very few of them, less than a handful, have decided whether they want to be the one to have their own cloud. My wish is that out there in the industry there will be independent players to build the cloud. No-one is stepping forward and without the cloud we cannot progress. It is not simple to implement safe, secure worldwide data provision. You have to

localise data. In some countries because of data protection laws you have to store data locally in national servers.

Somebody has to take up the job and to put the upfront investment into the cloud development. Without this we can talk about smart devices for a long time but it will not be safe to send the information via any normal protocol to some unknown server somewhere.

## ABOUT...

**Simon Michel**, Chief Executive Officer of Ypsomed Holding AG and the Ypsomed Group, has been with Ypsomed since October 2006, member of management since 2008, and responsible for Marketing & Sales.

From 2003 until 2006, Mr Michel worked for Orange Communications AG in Zurich and Lausanne, where he was responsible for, among other things, the introduction and marketing of UMTS.

Mr Michel studied economics at the University of St Gallen, Switzerland, and completed a Masters with a focus on media and communications management. Since 2006, he has been a member of the Board of Directors of Sphinx Werkzeuge AG and since 2008 a board member of the Burgdorf-Emmental Trade and Industry Association. Since 2015, he has been a member of the Board of Directors of the Solothurn Chamber of Commerce, Chairman of the Industry Commission and a member of the Board of Directors of FASMED, the Federation of Swiss Medical Devices Trade and Industry Associations, as well as a member of further boards of trustees and advisory boards.

**Mr Simon Michel**  
Chief Executive Officer  
E: [simon.michel@ypsomed.com](mailto:simon.michel@ypsomed.com)

**Ypsomed AG**  
Brunnmattstrasse 6  
3401 Burgdorf  
Switzerland

[www.ypsomed.com](http://www.ypsomed.com)



Figure 3: The YpsoDose large volume injector is fully disposable, has an auto-insertion mechanism, has a glass container, prefilled with a sterile drug path, and it is for 5 mL but can be expanded up to larger volumes.