

## **PERSPECTIVE ON JAPAN DIABETES SMART INSULIN PENS**

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### **Insulin Pens**

There exists a huge market opportunity here in Japan in the insulin pens space. A huge primarily disposable insulin pen target market of some 37 million pens sold annually, worth some ¥ 40 billion, delivering 11.2 tMU of insulin annually. Virtually all currently delivered via these legacy pens. This huge insulin pen market segment in Japan serves some 1.9 million T2DM patients utilizing these insulin pens.

The key driver here is market suction. It's really about somehow complementing, supplementing, piggy-backing, and otherwise smartening up these legacy pens. But how and with what? Does this mean that help may be or should be on the way?

The current disposable insulin pens are indeed simpler, more convenient, and lower cost than the more complicated and costlier insulin pumps and patch-pumps. With their lower and more affordable price points, the insulin pens are considered more cost-effective than the insulin pumps.

### **Legacy Insulin Pens**

One of the perhaps most venerable Japan institutions is the insulin injection pen monopoly that has been dominated by Novo Nordisk, Sanofi, and Lilly for more than two decades. The disposable pens were first introduced in the early 1990's and became first choice during the 2000's. However, pen injections continue to remain a painful, highly inconvenient, social stigma – thereby often and unfortunately not diligently adhered to, and clearly not the market path of least resistance. Does this again imply that help or improvements may be or should be on the way?

### **Smart Insulin Pens**

First, the smart insulin pump --- Next, the smart insulin pen.

"The smarts of an insulin pump in an insulin pen" -- i.e., Intelligent pen? Intellipen? InPen?

The current legacy durable reusable insulin pens basically run naked -- "dumb and unconnected". Coupled with higher cost and lesser convenience factors contributes to their current low market share here in Japan.

Novo Nordisk tried with a smart (not as smart as possible today) injection device in the early 2000's but failed.

There is a market segment that is ready for smarter devices, and that segment will grow, even though simplicity has been the preference up until now. Quality and reliability are key.

Recently, Sanofi has publicly announced that diabetes is outside their strategic focus.

In stark contrast, there's Companion Medical's uniquely FDA approved, value-add differentiator in its advanced "smart and connected" insulin InPen injector system. This smart insulin pen integrates with its InPen a diabetes data management system for bolus dosage calculation, tracking, and monitoring -- all conveniently connected via Bluetooth Apple IOS & Android mobile Apps.

Such an intelligent or smart pen would undoubtedly be expected to capture market share from the legacy disposable "dumb and unconnected" insulin pens.

Outside of Japan there are also other efforts in the works that have long recognized the smart insulin pen opportunity void, such as Novo Nordisk's recent pairing with Medtronic, Sanofi's recent pairing with Abbott, Eli Lilly's internally as well as recent pairing with Dexcom, Common Sensing's Gocap emanating out of MIT, for example.

### **Smartly Paralleling and Following the Recent Terumo Dexcom Smart Pairing for Insulin Pumps in Japan**

This parallels and follows Terumo's value-add pump strategy of smartening up their "Medisafe With" patch-pump device with their recent integrating with Dexcom's advanced smart connectivity to enable their "smart" insulin patch-pump here in Japan. Can such smart pairings as the Terumo-Dexcom patch-pump combine similarly be a significant product differentiator for the Japan durable reusable insulin pen syringe market? Can there be any other possible alternative avenue?

### **Positioning for the Future Smart Insulin Pens**

Is this a harbinger of the future to come? Does this present market and financial opportunities already in the making? This is especially relevant given the current "dumb and unconnected" product offerings of the current pure play disposable as well as the reusable durable insulin

pen device players here in Japan, and are furthermore without borders. The answer is obviously a clear and resounding yes!

### **Crossing the Digital Divide – “Smarten and Connect” Towards Closing the Loop**

Such combined and integrated insulin pen delivery devices are also now crossing the digital divide as they’re advancing to “smarten and connect” towards closing the loop by effectively “integrating” with the insulin pen user in the loop.

These systems are thus moving toward the ultimate holy grail of improved diabetes management and control via automatic closing the loop, such as advanced by Companion Medical for their smart insulin pens. The Companion Medical “smart and connected” pen may thus currently be the earliest to truly filling the major opportunity gap in the intelligent insulin pen space.

### **M&A Opportunities**

The above presents a quick overview summary of smart connected insulin pen M&A financial opportunities for both within and outside of Japan, but which are especially relevant for the significant Japan diabetic market and product spaces. Although the Japan medical device sector may not be as transparent nor as well understood as the USA or Europe, the above does present significant strategic and financial opportunities for Japan origination M&A that would confer substantial inherent medical-device-strategic advantages and benefits both domestically and internationally.

Such opportunities are therefore especially strategically and timely relevant, enabling significant value-add, such as to the marketing, sales, and service companies sector for example – providing, leveraging, and propelling their complementary assets to the advanced diabetes medical device makers. These marketing, sales, and service companies are highly complementary and synergistic in covering virtually all of the value-add chain for these advanced medical device makers, but lacking their own up-to-date and leading edge product lines and relevant and advanced technology knowledge base. Hence the age old MIT adage stressing and spelling out the classic strategic technologies and technology products that are sorely needed, and for which the marketing, sales, and service companies sector eagerly pay for. This constitutes timely technology-strategic prescience and foresight at the core.

In the insulin patch-pump space this M&A train is already under way. Sensile Medical was recently acquired by Gerresheimer – even with its “nice-to-have” but not “got-to-have” product. Just ask Sanofi who partnered with them. Integrity Applications with its unique non-invasive BGM GlucoTrack device clearly stands out as a leading M&A candidate with its proven and sorely needed non-invasive diabetes medical technology product. Early-stage VC-

backed EOFlow is yet another on the M&A radars. The smart and connected insulin pen category is clearly next.

So again, please do stay tuned. The Japan diabetes medical device landscape has already begun to change. Let's not be lulled asleep in thinking that nothing changes here in Japan.