

Medical Devices Today

April 01, 2010

At Last: Insulin Delivery Devices for the Bulk of the Diabetes Population

Full article reprinted from *Start Up* - February/March 2010

In some ways, companies developing advanced methods of delivering insulin are like the diabetics they hope to treat: they're out there but they've been keeping their intentions quiet, just as people struggling with diabetes often do. But diabetics keep their condition secret to avoid any perceived stigma or embarrassment that might go along with insulin injections necessary to manage the disease. Glucose delivery companies, however, have been maintaining a low profile because they're aware of what an amazingly competitive space this is becoming.

But their secrets are increasingly out. **Calibra Medical Inc.**, for example, has been operating for several years under the name Seattle Medical Technologies, keeping a tight lid on the details of the development of its designs for an insulin delivery device. Recently, however, Calibra has been basking in a bit of a welcome spotlight. In January, the company announced that it received 510(k) approval for its *Finesse* insulin patch pen, a new alternative to syringes and insulin pumps for insulin-using patients with diabetes. The next month, Calibra was in the news again, having raised \$9.3 million in the first closing of its Series C round with Canaan Partners, Three Arch Partners, Frazier Healthcare Partners and Intersouth Partners.

In raising funds, Calibra was far from a solo act. In fact, Calibra was the third device company focused on insulin delivery to raise money in as many months. That's a clear sign that a shift is occurring in the world of diabetes care as investors rally behind the space, which has always presented a huge market but even larger hurdles to the development of an effective product. Among those investments, **Cegur SA**, the developer of a low-cost insulin infuser, raised \$29.6 million at the end of December 2009. And **Tandem Diabetes Care Inc.** has raised \$52.3 million in its third funding round, which began in May 2009, with Domain Associates and TPG among its investors, according to regulatory documents filed in January.

The push into insulin delivery speaks to a broader trend in device investing. Investors and entrepreneurs are focusing more and more on bridging the gap between existing devices that treat only a small subset of patients and basic, low-cost, almost commoditized products aimed at larger patient populations. In many sectors, companies are beginning to look at providing relatively low-cost, but advantaged products for the large bulge of patients that fall into the middle of the continuum, in response to increasing pressure from payors, who don't want to pay for expensive high-end products that only benefit small groups of patients, and to be prepared for a wave of consumerism in medicine, because patients who are responsible for paying an ever increasing share of their health care bills are looking for better, but affordable solutions.

In diabetes both of these drivers are in full force. In fact, perhaps to an even greater extent than other diseases, diabetes lends itself to a consumer mentality because patients with diabetes have to take several steps every single day to manage their own care. Today, the bulk of patients that require insulin now resorts to the lowest-cost methods of insulin delivery, which are inconvenient, discourage compliance, and compromise outcomes. Very few patients opt for the very expensive, complex insulin pumps that are on the market.

Eleven million Americans and Europeans require regular injections of insulin, relying upon syringes or pens. At times, patients miss daily injections because it's just too difficult to comply with the regimen required. Pain is an issue, even with the relatively small needle pricks used, but inconvenience presents an even greater hurdle that impacts compliance, especially for mid-day injections. Patients miss those doses because of the hassle of carrying around supplies – syringes and vials of insulin, or insulin pens and needles. Finally, embarrassment

causes them to miss insulin doses; no one wants to advertise that they have the disease by injecting themselves in public. Everyone knows this, but an article by **Loyola University** professor of sociology Mark Peyrot, PhD, and colleagues, which was published in the February 2010 issue of *Diabetes Care*, backs up these suppositions with a survey of 502 patients (a mix of insulin-using type 1 and type 2 patients) who mentioned pain, inconvenience, and discretion as the top three reasons for lack of compliance.

Consider the venture capitalist with insulin-dependent type 2 diabetes who goes out to an important business lunch. He has to carry with him a glucose meter, syringes and bottles of insulin. He orders the pasta, and has to find someplace where it's possible to use a syringe to draw insulin out of a bottle, discreetly lift his shirt, and inject himself. Faced with public scrutiny or inconvenience, many patients just skip the injection. But Calibra Medical has introduced a tiny disposable device that holds three days worth of insulin. It sticks on the body with adhesive, and patients can shower with it on. The device can be activated through clothing – in fact, literature from the company shows that the low-profile device is barely visible through a clingy sweater. To administer insulin, the patient simply pushes a button. Going back to the business lunch, the VC reaches down to his belly, presses on his shirt to activate the Finesse, and no one's the wiser.