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Patch-Pump Hopefuls Aim for a Piece of the Pie

Growing demand for insulin patch pumps in the US—a market currently dominated by Insulet and the *Omnipod 5*—has ignited a firestorm of activity among would-be competitors, including Medtronic, Tandem Diabetes Care, Roche, and embecta, along with innovative smaller companies such as PharmaSens, Modular Medical, and ViCentra—all aiming to shake up the status quo.

► **Mary Thompson**

Competition in the insulin pump market is heating up as more companies aim for a spot in the fast-growing patch-pump segment, dominated in the US by **Insulet** and its *Omnipod 5* (O5) automated insulin delivery (AID) system. (See “Diabetes Devices: All Eyes on Patch Pumps,” *MedTech Strategist*, January 19, 2023.) Thanks to the O5, Insulet is now capturing nearly 60% of new pump patients in the US (both type 1s and type 2s) and holds a more than 50% revenue market share, according to analysts, with year/year US *Omnipod* revenue growth near 35% in Q3 2023.

As wearable pumps gain prominence, there is a growing list of would-be US competitors, some developing their own patch pumps and others attempting to acquire

their way into the space, a strategy that’s not devoid of risk, as **Medtronic** can attest. In May 2023, Medtronic signed an agreement to acquire South Korean patch-pump maker **EOFlow** for \$738 million, but in December, Medtronic pulled out of the deal, citing “multiple breaches” of the agreement by EOFlow (no termination fee is anticipated). Although Medtronic did not offer a detailed explanation for the decision, presumably EOFlow’s legal woes were top of mind. In August, Insulet filed suit against EOFlow alleging the company stole Insulet trade secrets and used them to develop its *EOPatch* pump, which is similar in design to *Omnipod*.

Medtronic says it remains “committed” to bringing an AID patch pump to market. But with its acquisition plans dashed, the company is now focusing on a “differentiated” patch pump it has under development in-house. There are no updates yet on the status of that program, but Medtronic will need to move that along to keep up with rival **Tandem Diabetes Care**, which last year acquired AMF Medical, maker of the *Sigi* semi-reusable patch pump, and hopes to launch a *Sigi* AID system in late ‘26 or early ‘27. Tandem is also pursuing a tubeless, wearable version of its new, compact *Mobi* durable pump. (See “As Insulin Pump Options Grow, Usability Is Key,” *MedTech Strategist*, August 1, 2023.)

Meanwhile, there are several others with patch pumps in development, including four that recently submitted first-generation devices to FDA. **Roche Diabetes Care** received FDA 510(k) clearance in August for the *Accu-Chek Solo* patch pump, and BD spinout **embecta** filed a 510(k) early in 2024 for a patch pump designed specifically for people with type 2 diabetes. (See “As Competitive Landscape Shifts, Diabetes Companies Jockey for Position,” *MedTech Strategist*, November 27, 2023 and “BD Spinout embecta Targets Diabetes Market With Three-Pronged Growth Strategy,” *MedTech Strategist*, December 12, 2022.)

"We are competing with pumps that look and feel like traditional medical devices. Our users tell us how much they value a premium consumer look and feel."

—Frans Cromme, ViCentra

Also in the mix: Swiss-based **PharmaSens**, which filed a 510(k) in December for the *niiia essential*, a round basal-bolus patch pump with an integrated steel cannula and a 3-mL insulin reservoir that is semi-reusable and designed to be the "easiest pump to learn and use," and San Diego-based **Modular Medical**, which filed in January 2024 for *MODD1*, a basal-bolus patch pump with a short infusion set that features a 90-day reusable pump and a three-day, 3-mL insulin cartridge. Both are designed with simplicity and low cost in mind to appeal to people (both type 1s and type 2s) on multiple daily insulin injections who could benefit from a pump but haven't yet adopted one. These "almost pumpers" represent a \$3 billion US market opportunity, according to Modular Medical.

At present, none of these four pumps is paired with a continuous glucose monitor (CGM) or automated dosing algorithm, although there are plans to add those features to future iterations. And there could be even more innovation on the horizon: PharmaSens, for example, is developing a patch pump and CGM combined into a single AID device, while Modular Medical has a working prototype of a closed-loop patch-pump system with a prefilled multi-chamber pump.

As the patch-pump field becomes more crowded, user-oriented design features

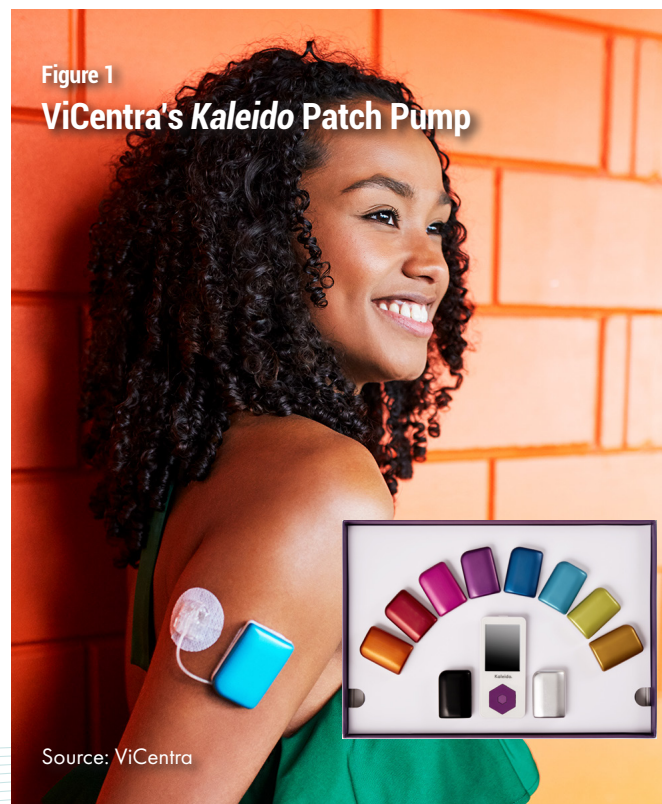
could emerge as important market differentiators, and one small OUS company with a unique pump form factor believes it has an edge in that regard. **ViCentra**, founded in 2013 and based in the Netherlands, has a tiny wearable insulin pump called *Kaleido* that is reusable, comes in 10 vibrant colors, and offers more flexibility than other patch pumps on the market.

The *Kaleido* patch-pump system comes with two durable pumps, a handheld controller, a disposable insulin cartridge that lasts three days, and a choice of two external infusion sets: a short set that can be placed on the body right next to the pump, or a longer infusion set that enables the pump to be carried in a pocket. Although the system is not tubeless, the pump is sleek, small, and lightweight (50 mm × 35 mm × 12.5 mm and about 19 grams) and comes in appealing colors that could strike a chord with pumpers (see *Figure 1*).

Kaleido was CE marked in 2016, with a soft launch OUS

in 2018, but ViCentra soon ran into manufacturing scalability challenges. In early 2020, the company voluntarily withdrew from the market while it worked to resolve these issues. After raising a \$74 million Series C round in late 2021, ViCentra was able to modernize its production facility, improve the manufacturing design, and transfer its infusion set manufacturing from a US contract manufacturer to its own facilities in the Netherlands.

In March 2023, ViCentra commenced a successful test relaunch of *Kaleido* in the Netherlands and France. This was followed in November by full commercial launch in Germany, the Netherlands, and France of both the stand-alone *Kaleido* system as well as a new hybrid closed-loop version using **Diabeloop's** DBLG1 self-learning AID algorithm and **Dexcom's** G6 CGM. The company expects to launch this year in additional European markets, including the UK.



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According to CEO Frans Cromme, ViCentra's philosophy around *Kaleido* centers on personalization, flexibility, and ease of use—attributes he says are important to pump users. *Kaleido* comes with two rechargeable pumps so that one is always charged and ready to go (a charge lasts three days), which gives people a sense of safety, Cromme points out. Moreover, users can pause the pump, take it off for a while, and then put it back on without having to change their infusion set.

The pump's small, sleek profile is also a key feature that appeals to users, says Cromme, allowing them to easily wear it under their clothes. "And you'd be surprised how many people like [being able to choose] the different colors. We are competing with pumps that look and feel like traditional medical devices. Our users tell us how much they value a premium consumer look and feel."

Overall, the system's flexibility is central to its appeal, Cromme states. "People can choose where and when to wear it—they can use the short tube or the long tube, so they can wear it on their skin or put it in their pocket, and they can pause the pump and take it off whenever they want to, which makes it more adaptable to a user's lifestyle."

The current *Kaleido* pump is considerably smaller than *Omnipod*, says Cromme, but the next-generation *Kaleido* is planned to be even smaller. That level of miniaturization is possible because the system uses a unique non-syringe pumping mechanism invented and patented by ViCentra.

Most insulin pumps are essentially automated syringes, but *Kaleido* is different. It has a small pumping mechanism in the head of the insulin cartridge that pulls up 0.5 μL with

every stroke; dosing is accomplished by the number of strokes per minute. Using this technology, the company has been able to design an extremely small pump that is very accurate, even at low doses, Cromme asserts.

ViCentra is also developing a smartphone app designed to be simple and intuitive to use, and it has a tubeless patch-pump prototype in early-stage development as well. The latter will still use a durable, rechargeable pump, and users will be able to disconnect from the pump at will, which is a "key feature people like," notes Cromme.

As for ViCentra's US plans, the company will wait until it has European Medical Device Regulation (EUMDR) certification, which it hopes to obtain early this year, before turning its attention to the US market. It plans to make a few modifications to the system, including adding smartphone control, prior to submitting a 510(k), and is unlikely to obtain US market clearance before 2026.

Meanwhile, ViCentra will continue to expand its presence in Europe, a pump market Cromme says is growing faster than the US market. Only about 20% of Europeans with type 1 diabetes currently use a pump; 80% are still using pens/syringes. So there is a lot of room for growth, he points out, particularly in Germany, which has reimbursement in place and is a "booming" market for AID systems and CGMs.

ViCentra is currently raising a Series D round to fund commercial expansion, complete its FDA submission, and further automate production processes. It is also seeking to broaden its investor pool (existing VCs include Partners in Equity BV, EQT, Invest-NL, INKEF Capital, and Health Innovations) and hopes the new round will bring US investors on board. 

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