NEWS RELEASE

Insulet Presents Promising Study Results for Fully Closed-Loop Automated Insulin Delivery System for Adults with Type 2 Diabetes

2026-03-11

- Outcomes from EVOLUTION 2 study include 68% time in range with no boluses
- Diverse multicenter feasibility study highlights the promise of future Omnipod innovation to address unmet needs, improve outcomes, and redefine user and clinician experience

ACTON, Mass.--(BUSINESS WIRE)-- Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), the global leader in **tubeless insulin pump technology** with its Omnipod® brand of products, has shared new clinical evidence related to the development of its first fully closed-loop (FCL)[A] automated insulin delivery (AID) system for type 2 diabetes.

“Developing and bringing to market a fully closed-loop AID system for people with type 2 diabetes—one that delivers therapy effortlessly and adapts automatically with no mealtime interactions or adjustments—is more than evolutionary; it’s revolutionary,” said Dr. Trang Ly, MBBS, FRACP, PhD, Senior Vice President and Chief Medical Officer. “Our latest EVOLUTION study brings us another important step closer to addressing significant unmet needs[B] while redefining both the provider and user experience.”

Presented at the 19th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD) in Barcelona, Spain, EVOLUTION 2[C] is the second in a series of feasibility studies supporting the development of an Omnipod fully closed-loop system.

This multicenter feasibility study was designed to drive rapid innovation, allowing investigators to evaluate multiple versions of the algorithm to support continued FCL system development. It included 24 adults in a highly diverse

cohort from New Zealand, aged 16-70 years with type 2 diabetes using insulin (basal-bolus or basal-only, pumps or injections with HbA1c under 12.0%). The participants had lived with type 2 diabetes for an average of 16 years.

When using the final algorithm version of FCL with no boluses, the participants' time in range (TIR) increased to an average of 68%, a 24% improvement over standard injection therapy. Time Below Range (TBR) remained very low, with a median of 0.14% below 70 mg/dL—well under the American Diabetes Association's recommended threshold of less than 4%. No severe hypoglycemia or diabetic ketoacidosis (DKA) events were observed. Users experienced improved glycemic outcomes without compromising on low glucose events. The benefits were observed across a diverse set of participant characteristics including sex, ethnicity, baseline HbA1c, and body mass index. More than 90% of participants chose to continue into the ongoing extension phase, showing strong interest and positive experiences with the FCL system.

"The EVOLUTION 2 study results show a high time in range can be reached using an easy to use, intuitive system that is fully automated with no mealtime interactions. This adds to the growing evidence in support of automated insulin delivery and how innovations grounded in science can improve outcomes, reduce stress, and make diabetes a smaller part of everyday life," said Dr. Martin de Bock, Professor and Pediatric Endocrinologist at the University of Otago, Christchurch in New Zealand. Dr. de Bock served as Chief Investigator for the EVOLUTION 2 study.

Evolving toward a breakthrough

EVOLUTION 2 builds on the 2024 EVOLUTION 1[D] feasibility study, which was the first evaluation of the Omnipod FCL algorithm in adults with type 2 diabetes. Participants in the EVOLUTION 1 study experienced significant improvements in TIR, from 52% to 65%, without boluses, representing more than three additional hours per day in target range with minimal hypoglycemia.

Insulet used these results to fine-tune the algorithm design, focusing on further simplifying the user experience and laying the groundwork for additional improvements studied with EVOLUTION 2.

The Company plans to start its pivotal study (EVOLVE) in 2026 to support a 510(k) filing in 2027 and a commercial launch in 2028.

[A] The FCL AID System is an investigational device. Limited by Federal (or United States) law to investigational use. This product has not been reviewed by the FDA or other regulatory agency.
[B] Only a quarter of individuals with type 2 diabetes on insulin are achieving an HbA1c of 7.0% or less, and half of this population has an HbA1c greater than 8.0%, Venkatraman S, et al. Trends and Disparities in Glycemic Control and Severe Hyperglycemia Among U.S. Adults with Diabetes Using Insulin, 1988-2020. JAMA Netw Open. 2022 Dec 1;5(12).
[C] **https://clinicaltrials.gov/study/NCT07039981**
[D] **https://journals.sagepub.com/doi/full/10.1089/dia.2024.0463**

About Insulet Corporation:

Insulet Corporation (NASDAQ: PODD), headquartered in Massachusetts, is an innovative medical device company dedicated to simplifying life for people with diabetes and other conditions through its Omnipod product platform. The Omnipod Insulin Management System provides a unique alternative to traditional insulin delivery methods. With its simple, wearable design, the tubeless disposable Pod provides up to three days of non-stop insulin delivery, without the need to see or handle a needle. Insulet's flagship innovation, the Omnipod 5 Automated Insulin Delivery System, integrates with a continuous glucose monitor to manage blood sugar with no multiple daily injections, zero fingersticks, and can be controlled by a compatible personal smartphone in the U.S. or by the Omnipod 5 Controller. Insulet also leverages the unique design of its Pod by tailoring its Omnipod technology platform for the delivery of non-insulin subcutaneous drugs across other therapeutic areas. For more information visit: **insulet.com** and **omnipod.com**.

Forward-Looking Statement:

This press release may contain forward-looking statements concerning Insulet's expectations, anticipations, intentions, beliefs, or strategies regarding the future. These forward-looking statements are based on its current expectations and beliefs concerning future developments and their potential effects on Insulet. There can be no assurance that future developments affecting Insulet will be those that it has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond its control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements, and other risks and uncertainties described in its Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on February 21, 2025 in the section entitled "Risk Factors," and in its other filings from time to time with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of its assumptions prove incorrect, actual results may vary materially from those projected in these forward-looking statements. Insulet undertakes no obligation to publicly update or revise any forward-looking statements.

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Source: Insulet Corporation