

A photograph of a woman with curly blonde hair wearing a straw hat and a light-colored sweater, smiling and looking out at the ocean. A man with a beard and glasses is partially visible next to her, also looking out. The background is a bright, hazy sky over the water.

Beta Bionics

Investor Presentation

April 2026

Disclaimer

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements in this presentation that are not statements of historical fact are forward-looking statements. Such forward-looking statements include, without limitation, statements regarding: expectations of Beta Bionics, Inc. (the “Company”) regarding the potential benefits, effectiveness, and safety of the iLet and other product candidates; our expectations with regard to the design, results and timing of our research and development efforts, clinical trials and real world use or experience, including the timing and availability of data from such trials and real world use; our regulatory development plans for the iLet and other product candidates; the markets and market opportunities for the iLet and other product candidates, if approved; the timing, likelihood or success of our business strategy, including commercialization and our multi-channel reimbursement strategy, as well as plans and objectives of management for future operations including market and indication expansion; and our anticipated growth and other measures of future operating results and financial performance including 2026 full year guidance regarding revenue, new patient starts through pharmacy, and gross margin. In some cases, you can identify forward-looking statements by terms such as “expect,” “should,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimates,” “potential” or “continue” or the negative of these terms or other similar expressions. These forward-looking statements are based on the beliefs of the management of the Company as well as assumptions made by and information currently available to the Company. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, timing of results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements.

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This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified the data generated by independent parties and cannot guarantee their accuracy or completeness. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

This presentation includes certain financial measures not presented in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”), which are presented for supplemental informational purposes only and are not intended to be substitutes for any GAAP financial measures, and may not be comparable to companies in other industries or within the same industry with similarly titled measures of performance. These non-GAAP measures have limitations as analytical tools and should not be construed as an inference that the Company’s future results will be unaffected by unusual or non-recurring items. Therefore, non-GAAP financial measures should be considered in addition to, not as a substitute for, or in isolation from, measures prepared in accordance with GAAP. As applicable, a reconciliation to the most directly comparable GAAP measures is provided in the Appendix.

A person is shown from the chest up, holding a smartphone in their right hand. The phone screen displays a glucose level of 107 mg/dL. On their left forearm, a circular Dexcom sensor is attached. The background is a soft-focus image of the person's face and hair, overlaid with a semi-transparent blue filter.

Our mission is to **simplify and alleviate**
the burden of managing diabetes with
life-changing solutions.

Market-Leading Innovators

iLet is the first and only fully adaptive insulin pump, and the most advanced system available¹

Key Operating Highlights

\$27.6M

Q1'26
Net Sales

59.5%

Q1'26
Gross Margin

~70%

New Patient Starts
from MDI in Q1'26

High 30s%

New Patient Starts
reimbursed through
pharmacy in Q1'26

By YE'27

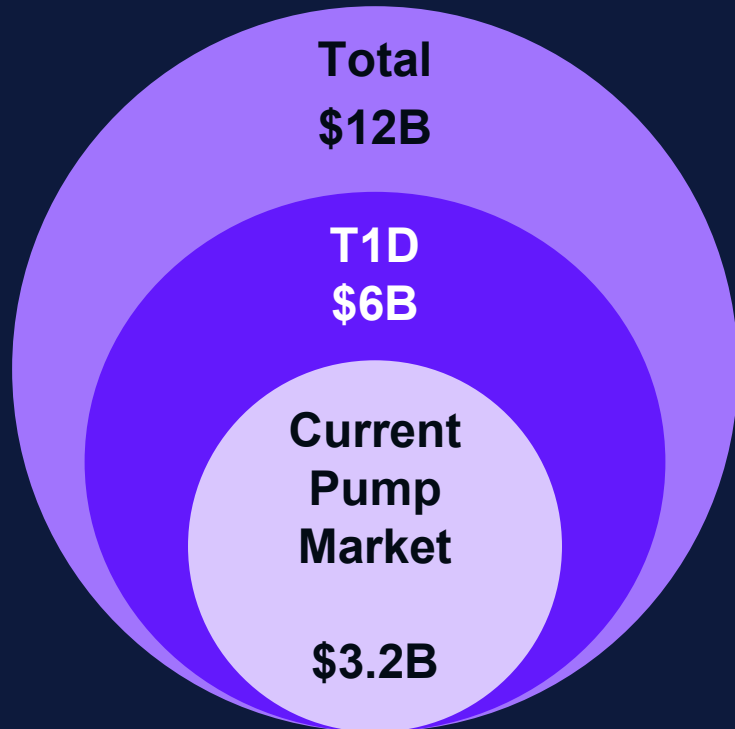
Targeted Mint patch pump
unconstrained launch²

- Note: Data as of Q1 2026. Multiple Daily Injections (MDI). Year End (YE).
1. Cook, K., et.al (2025). Defining the Automated Insulin Delivery Continuum: User Engagement and System Adaptation. ADCES 2025. Poster Presentation, 2025 Aug 9
 2. Commercialization of the Mint patch pump in development is subject to regulatory clearance, and the device is not available for sale.



Large & Underpenetrated Insulin Pump Market

Total Addressable Market for Insulin Delivery in the U.S.



Type 1 Diabetes



1.9M

People in the U.S.



~1.2M

On multiple daily injections (MDI)



~0.7M

On pump therapy



~39%

Pump penetration

Type 2 Diabetes (Insulin-Intensive)



1.9M

People in the U.S.



>1.7M

On multiple daily injections (MDI)



<0.2M

On pump therapy

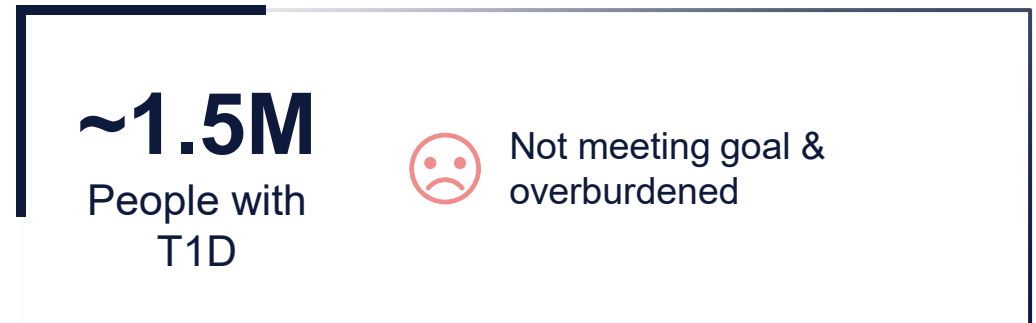
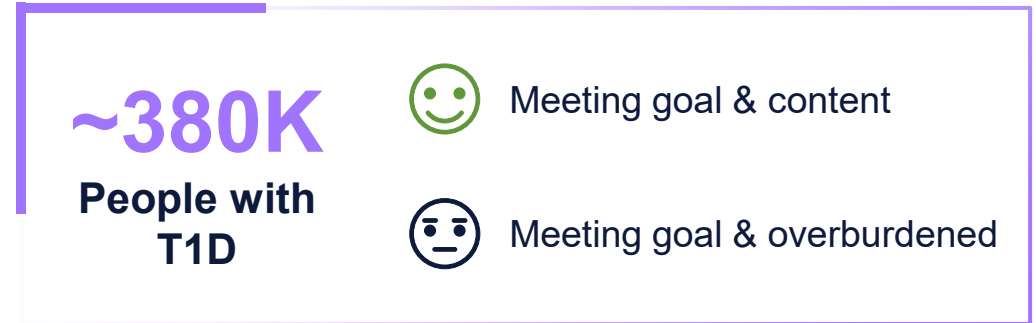
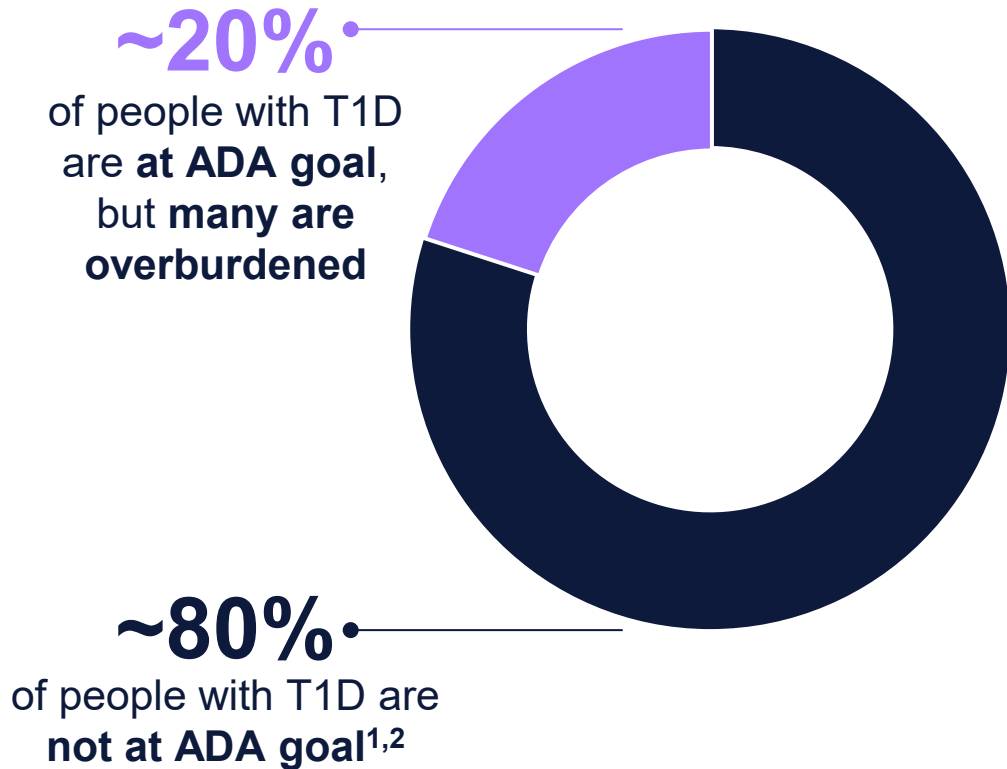


<10%

Pump penetration

Poor Clinical Outcomes for People with T1D in the U.S.

~80% not at treatment goal, defined by the ADA as HbA1c <7%



Source: Internal estimates informed by data from the CDC, Seagrove Partners, and publicly-reported 2025 product sales data.

Note: Type 1 Diabetes (T1D). American Diabetes Association (ADA).

1. Foster et al. Diabetes Technol Ther. 2019;21:66-72.
2. Pettus et al., Diabetes Care. 2019;42:2220-2227.

Significant Unmet Market Needs Remain

Pump complexity is a major obstacle to adoption

Complexity of Pumps



User

Adjusts everyday as needed

Carb Counting for Meal Doses

Manual Correction Doses

Temporary Basal Rate



Physician

Adjusts every 3 months

Insulin-to-Carb Ratio

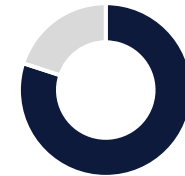
Correction Factor

Basal Rate

Obstacles to Pump Use

- Burdensome for users to manage everyday
- Difficult for physicians to setup and manage, particularly primary care providers
- Costly for users to purchase pump and monthly supplies

T1D Unmet Needs



~80%

Not at ADA treatment goal^{1,2}



~39%

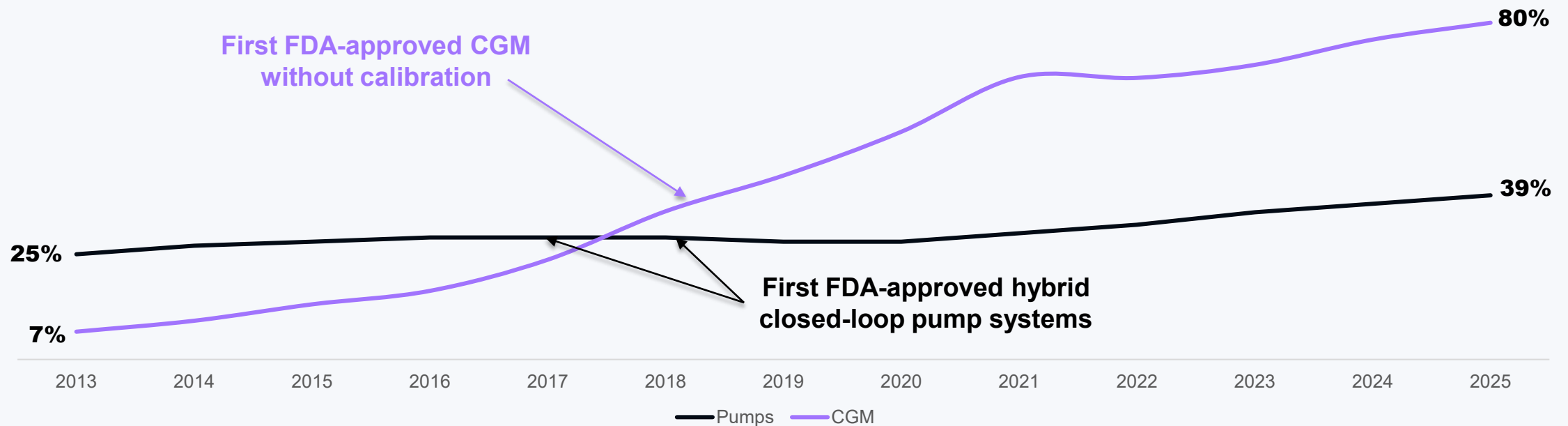
Insulin pump therapy penetration

Penetration remains low and treatment outcomes are poor

The Market Responds to Major Ease-of-Use Innovations

No fingerstick calibration was the key innovation for CGMs; iLet may be that innovation for pumps

CGM and Pump Penetration in T1D 2013-2025 in the U.S.



Beta Bionics

**We believe we can
do more for people
with diabetes.**



iLet Bionic Pancreas

Advanced adaptive algorithms learn each person's unique insulin requirements

- Determines and **delivers 100% of all insulin doses**¹
- **Automated, easy-to-use** system
- Generates the **same or better clinical outcomes**, with **substantially less work** for the user and provider^{2,3}

Compatible with leading CGMs

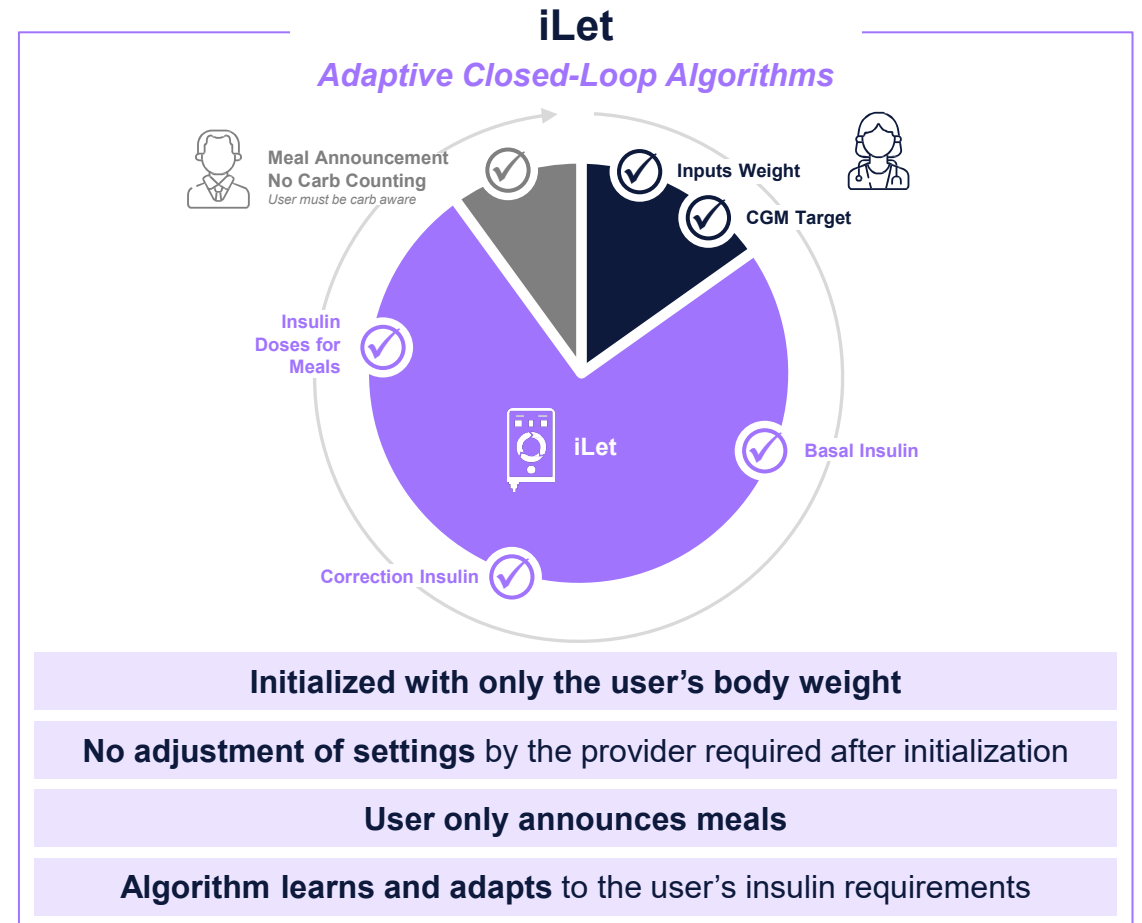
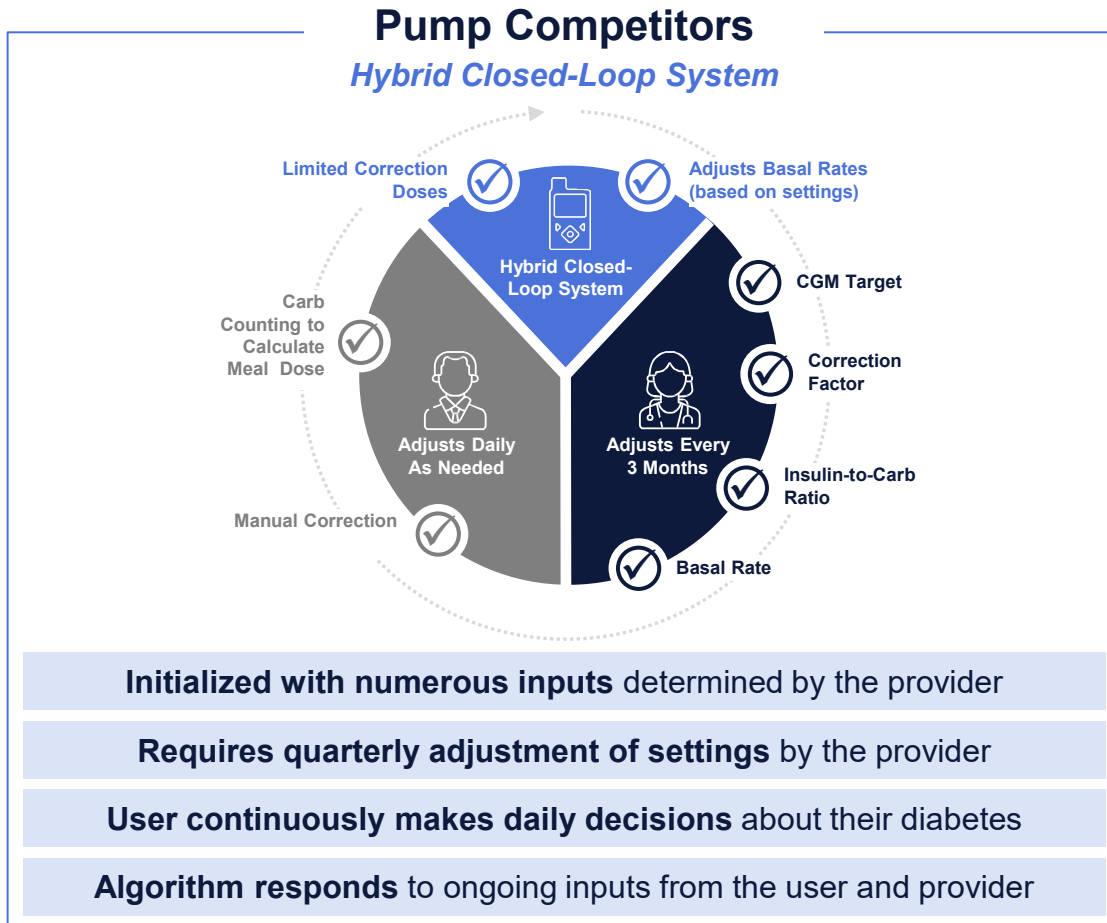
- Dexcom's G6 and G7
- Abbott's FreeStyle Libre 3 Plus

Option to use pre-filled Fiasp PumpCart



iLet Redefines the Pump Experience

Alleviates the burden of insulin pump setup and management for users and providers



Elevated Digital Experience

For our users, their caregivers, and their healthcare providers

iLet and iLet App

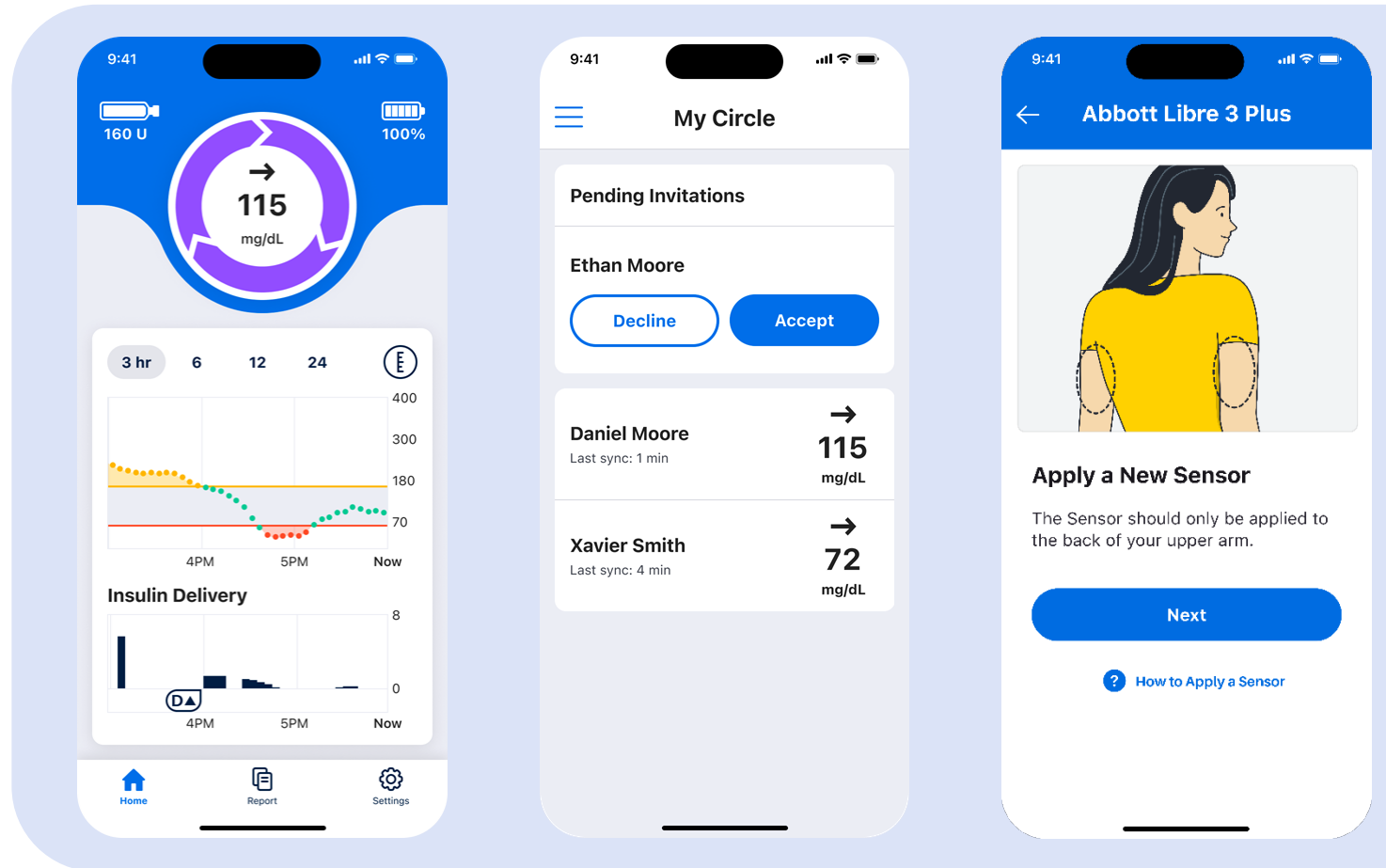
- Easy-to-use interface
- Firmware over-the-air upgrades
- Automatic data uploads to the cloud
- Compatibility with iOS and Android platforms

Bionic Circle App

- Remote monitoring experience for family members, friends, and caregivers
- Compatibility with iOS and Android platforms

Bionic Portal & Report

- Web-based portal for healthcare providers
- Easy-to-understand reports, actionable insights



Superior Pivotal Trial Outcomes vs. Standard of Care

HbA1c % Improvement with iLet¹

HbA1c % Improvement with SoC¹

- 0.6	All Users	- 0.0
- 0.7	Adults	- 0.1
- 0.6	Children	- 0.0
- 0.9	At least 7% Baseline HbA1c	- 0.1
- 1.0	Multiple Daily Injections (MDI)	- 0.0
- 0.5	Pumps	- 0.0
- 0.3	Hybrid Closed-Loop ²	- 0.1

iLet delivered greater reduction in HbA1c vs. competitive hybrid-closed loop systems³

Source: Russell, S.J., et al. (2022) A Multicenter Randomized Trial of a Bionic Pancreas in Type 1 Diabetes. The New England Journal of Medicine. 387:1161–1172., Data on File.

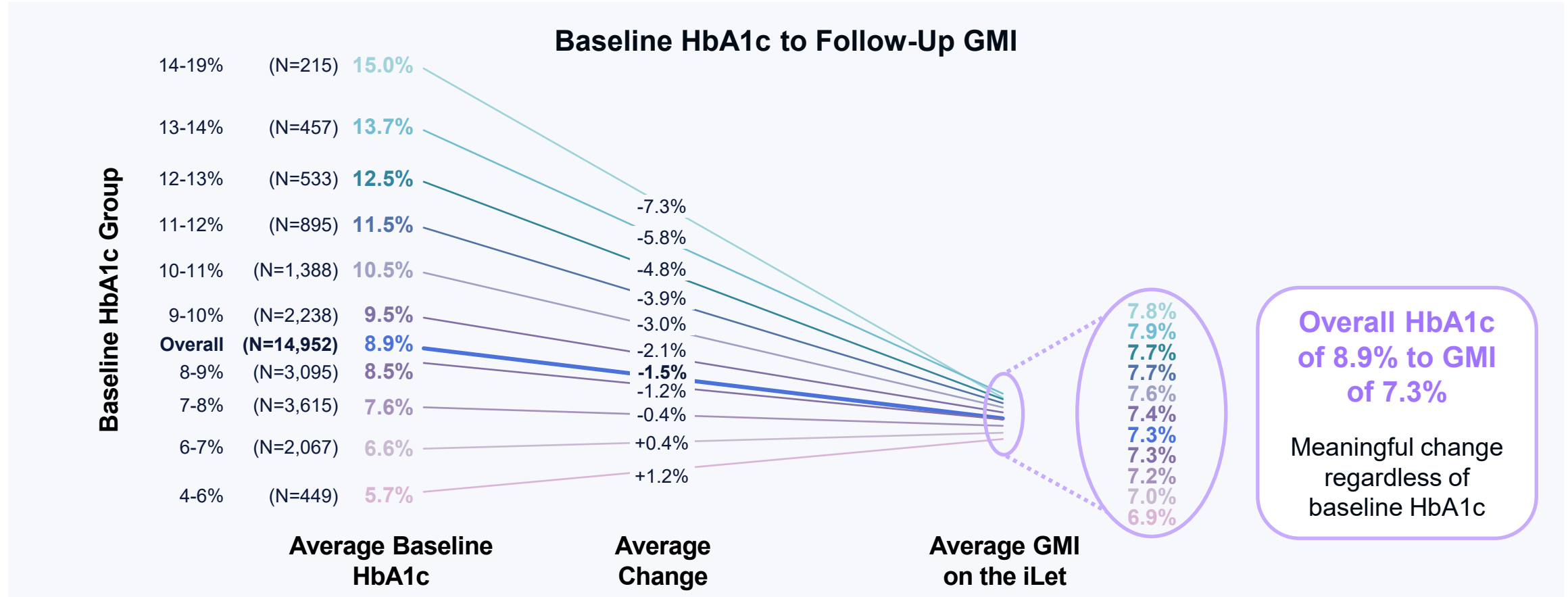
Note: Standard of Care (SoC).

1. Data reflects percentage point improvements in HbA1c measurements at 13 weeks as compared to baseline.

2. Hybrid-closed loop systems included t:slim X2 with Control-IQ, and MiniMed 670G or 770G

3. Analyses of subgroups represent post hoc analyses of the pivotal trial data. The pivotal trial was not designed to evaluate the effect of the iLet Bionic Pancreas in the listed subgroups.

Real World Results Are Consistent with the Pivotal Trial



>84% of users meeting ADA hypoglycemia goals of <4% time below 70 mg/dL and <1% time below 54 mg/dL¹

Source: The postmarket surveillance data presented is observational data. These data do not come from a prospective study designed to evaluate the effect of the iLet Bionic Pancreas in subgroups by baseline HbA1c. Real-world data comes from the first two years (5/19/2023–5/18/2025) of iLet usage among iLet users with baseline HbA1c data and who uploaded data to Beta Bionics, Inc., including users who do not meet all criteria in the Indications for use. Individual user results may vary from the average values shown here.

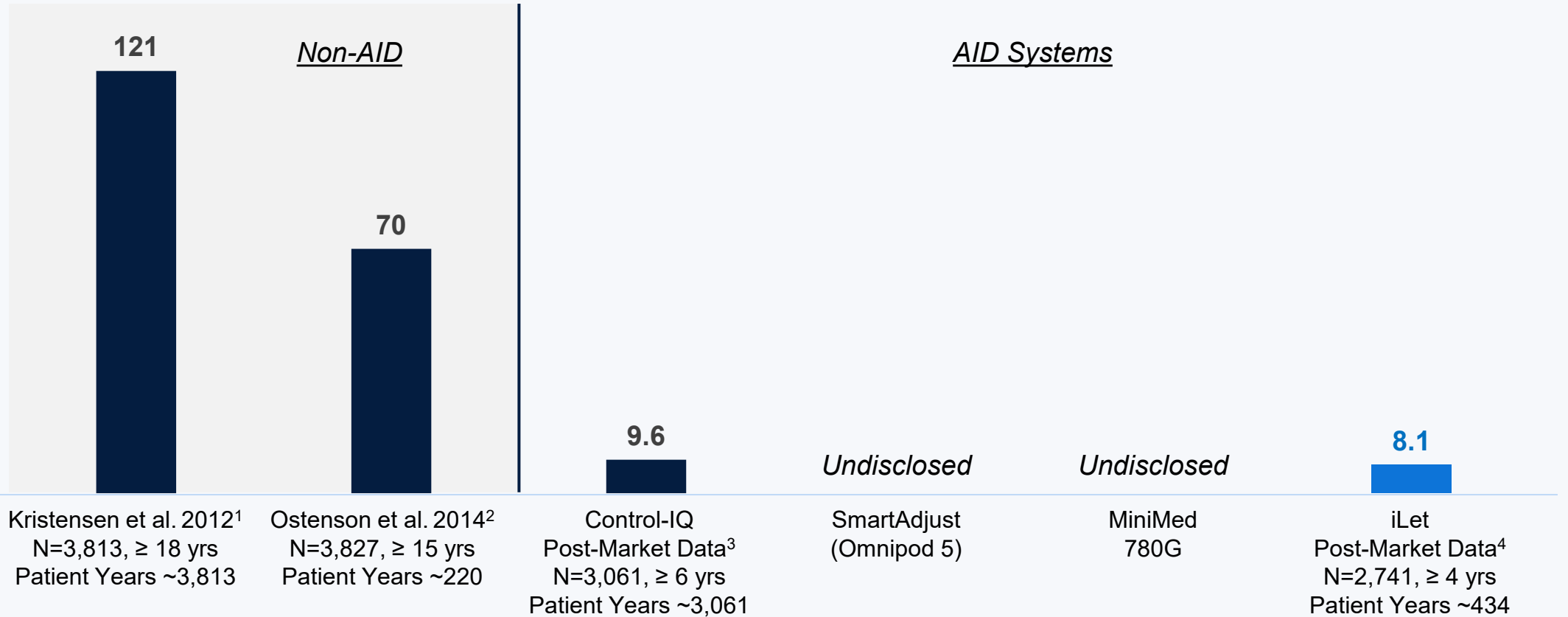
Note: Glucose Management Indicator (GMI). American Diabetes Association (ADA).

1. American Diabetes Association Professional Practice Committee. 6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes-2024. Diabetes Care. 2024;47:S111-S125

Real-World Severe Hypoglycemia in Non-AID vs. AID Systems

SH¹ Event(s) per 100 Patient Years

of Users with ≥ 1 SH¹ Event(s) per 100 Patient Years

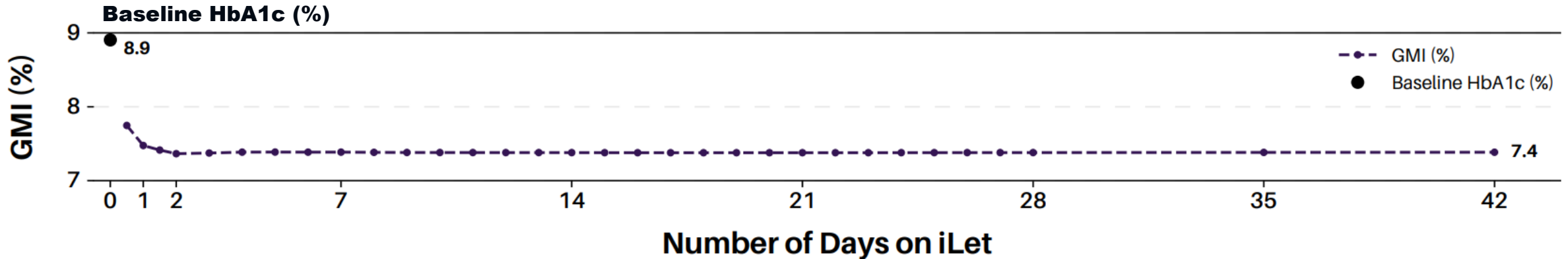


Note: Severe Hypoglycemia (SH) defined as hypoglycemia with cognitive impairment requiring the assistance of a third party for treatment. Automated Insulin Delivery (AID). Data presented are not based on head-to-head studies. As a result, cross-study comparisons cannot be made, and caution is advised when attempting to extrapolate these data to new patients.

- Kristensen et al. (2012) Insulin analogues and severe hypoglycaemia in type 1 diabetes. *Diabetes Res Clin Pract*; 96:17-23.
- Ostenson et al. (2014) Self-reported non-severe hypoglycaemic events in Europe. *Diabetic Medicine*; 31:92-101.
- Graham et al. (2024) Real-World Use of Control-IQ Technology Is Associated with a Lower Rate of Severe Hypoglycemia and Diabetic Ketoacidosis Than Historical Data: Results of the Control-IQ Observational (CLIO) Prospective Study. *Diabetes Technol Therapy*; 26: 24-32.
- Data on file. The iLet Bionic Pancreas is indicated for people with type 1 diabetes ages 6 years and older.

iLet's Adaptive Algorithm "Warms-Up" in ~2 Days

Time to Steady-State GMI
(N=30,077 sessions¹)



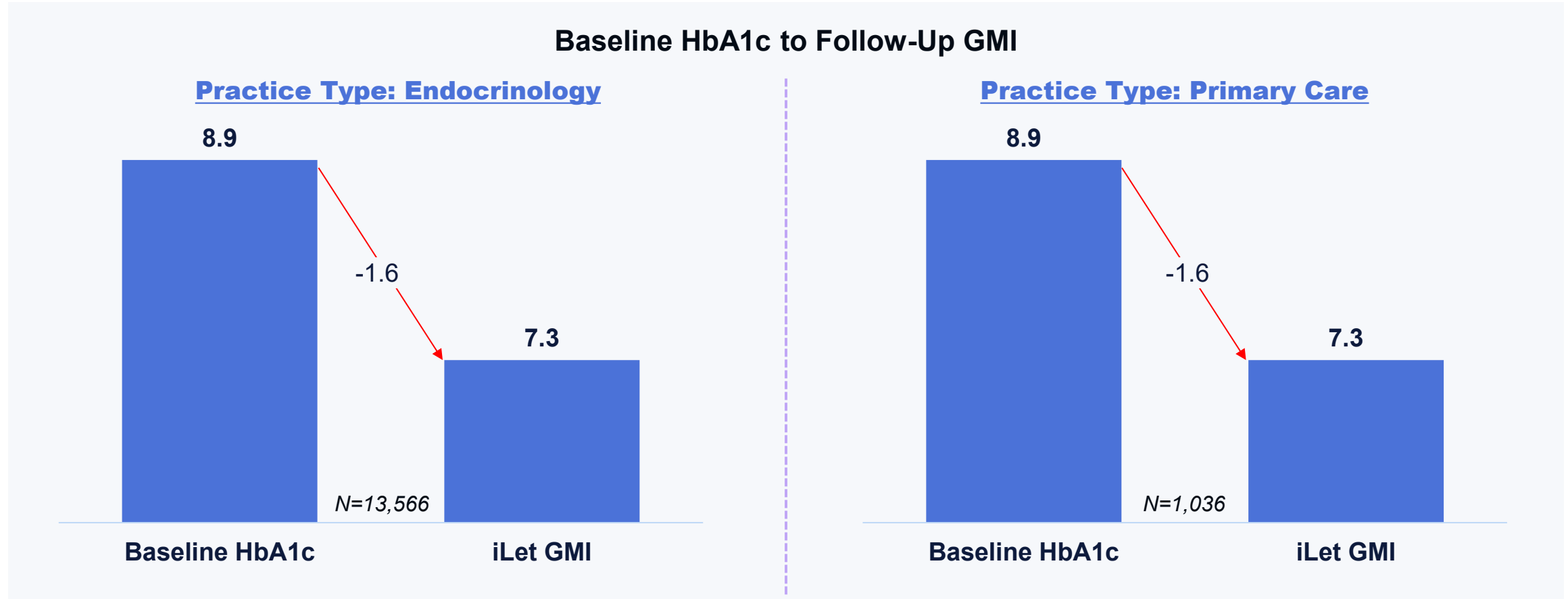
**Average baseline HbA1c of 8.9% to follow-up GMI on iLet of 7.4%
just 2 days after initiation**

Source: The real-world data presented are observational data. These data do not come from a prospective study designed to assess safety and efficacy of the iLet by duration of iLet use. Data comes from the first 2 years (5/18/2023-5/19/2025) of real-world iLet usage among those people who uploaded CGM data to Beta Bionics, Inc., including users who do not meet all criteria in the Indications for use. Ninety percent of users had a baseline HbA1c available. Individual user results may vary from the average values shown above.

Note: Glucose Management Indicator (GMI). Continuous Glucose Monitor (CGM).

1. Most iLets had only one session. A session reflects each initial use of an iLet or after a factory reset.

Similar Improvement in GMI Regardless of Provider Type

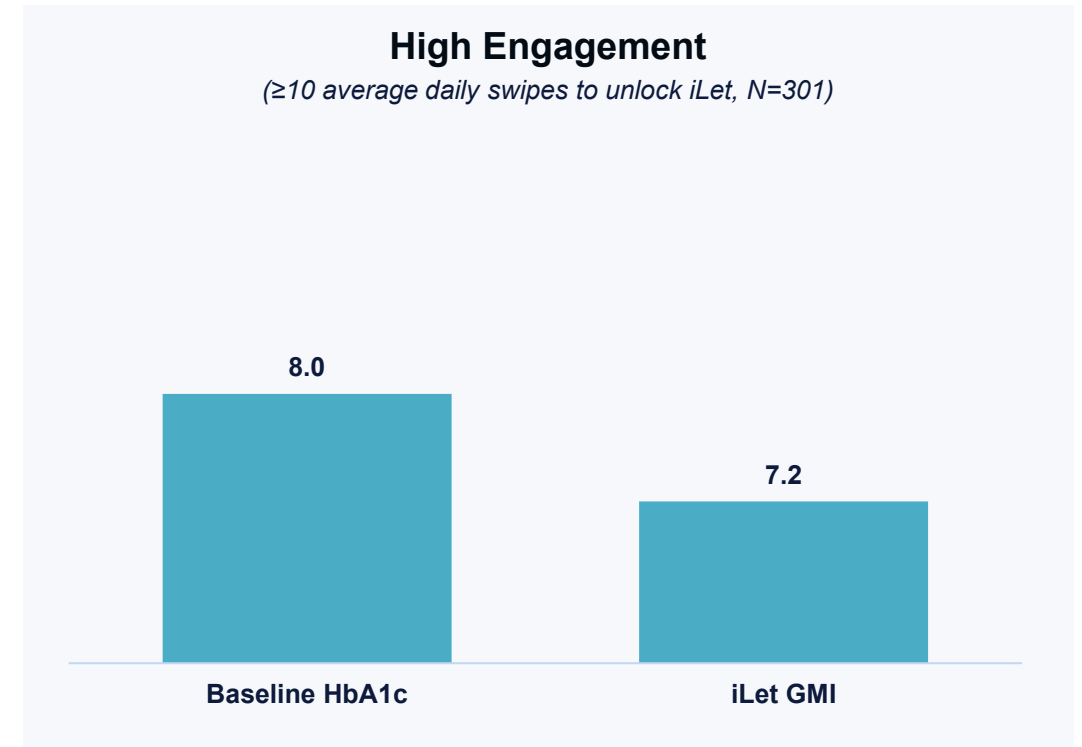
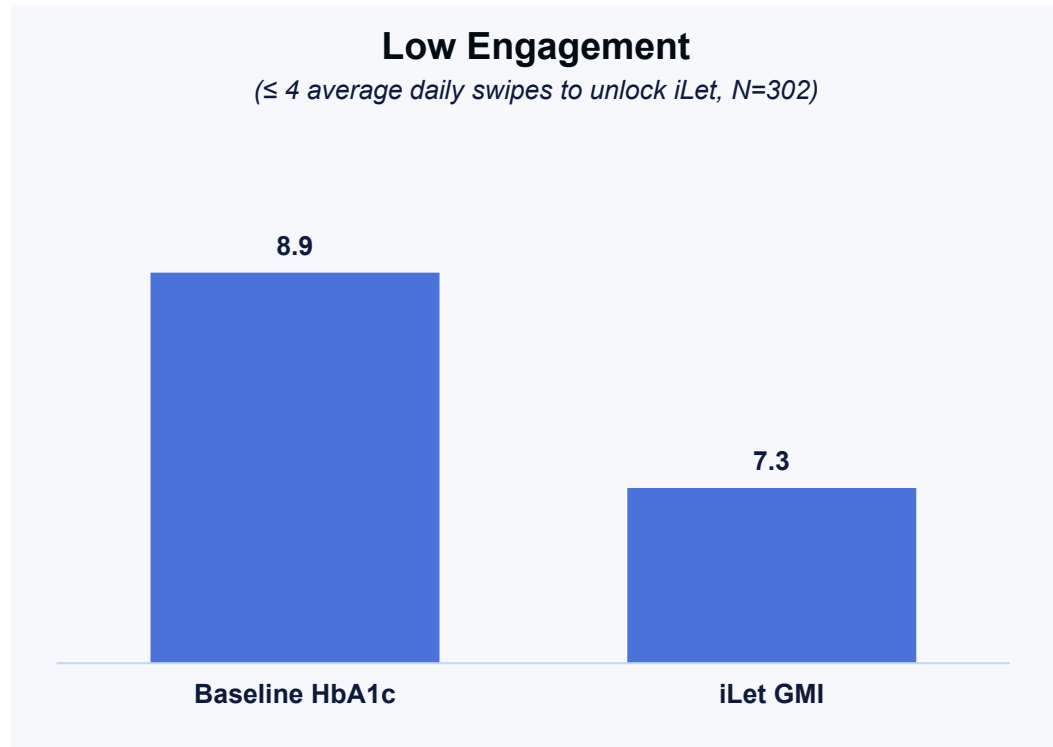


Similar improvement in GMI with >84% of users meeting ADA hypoglycemia goals, regardless of provider practice type

Clinical Results Are Independent of User Engagement

Historically, low engagement with pumps meant poor outcomes – not with iLet

iLet Real-world Data: Change from Baseline HbA1c to Mean GMI by Level of Engagement in Adults (≥ 18 years old)

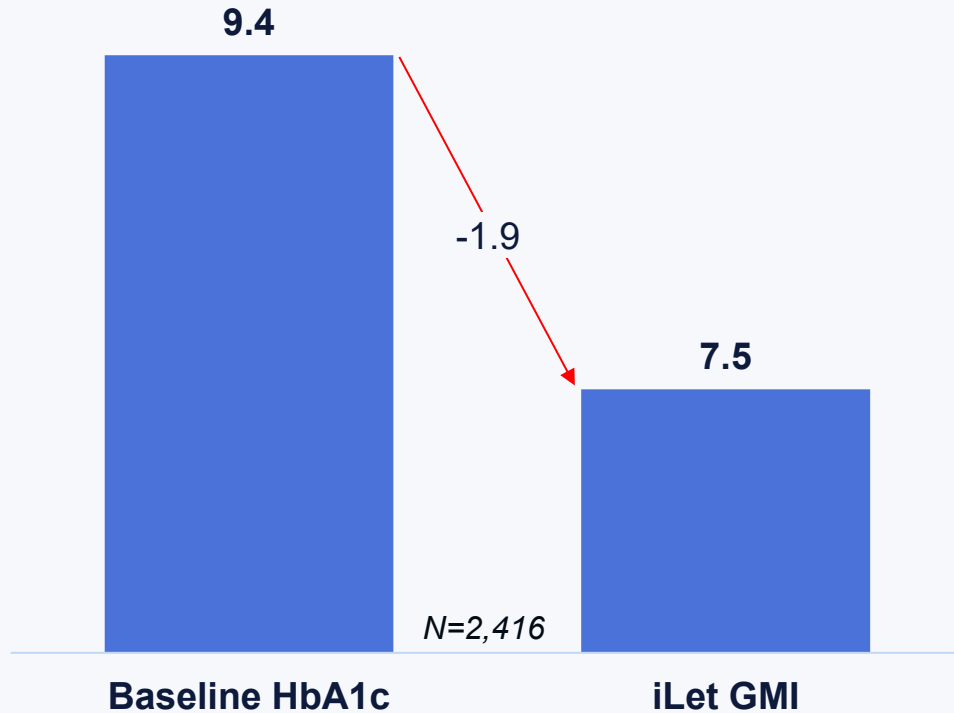


Source: The real-world data presented is observational data. These data do not come from a prospective study designed to evaluate the effect of the iLet Bionic Pancreas in subgroups by baseline HbA1c or user engagement. Real-world data comes from the first year (5/19/2023–5/18/2024) of iLet usage among those people with baseline HbA1c data and who uploaded data to Beta Bionics, Inc., including users who do not meet all criteria in the Indications for Use. Individual user results may vary from the average values shown here.

Note: Glucose Management Indicator (GMI).

Use of iLet in a “Fully-Closed Loop” Manner

Baseline HbA1c to Follow-Up GMI



- ~16% of iLet users (with available data) use the pump in a “fully-closed loop” manner¹
- On average, “fully-closed loop” iLet users announced ~1 meal every 3 days
- “Fully-closed loop” users achieved ~62% time in range, on average
- ~83% of “fully-closed loop” iLet users meeting ADA hypoglycemia goals
- **530 iLet users have not announced a single meal over the past 21 days**
 - ❑ Improvement from baseline A1c of 9.4% to a follow-up GMI of 7.4%
 - ❑ ~86% meeting ADA hypoglycemia goals

Source: The real-world data presented is observational data. These data do not come from a prospective study designed to evaluate the effect of the iLet Bionic Pancreas in subgroups by frequency of meal announcements. Real-world data comes from the 21-day period ending 5/18/2025 of iLet usage among those people with baseline HbA1c data and who uploaded data to Beta Bionics, Inc., including users who do not meet all criteria in the Indications for use. Individual user results may vary from the average values shown here.

Note: Glucose Management Indicator (GMI). American Diabetes Association (ADA).

1. Fully-closed loop iLet users defined as users who announced <1 meal per day on average over the 21-day period ending May 18, 2025

Beta Bionics

Positioning for success



Providing Flexible Reimbursement

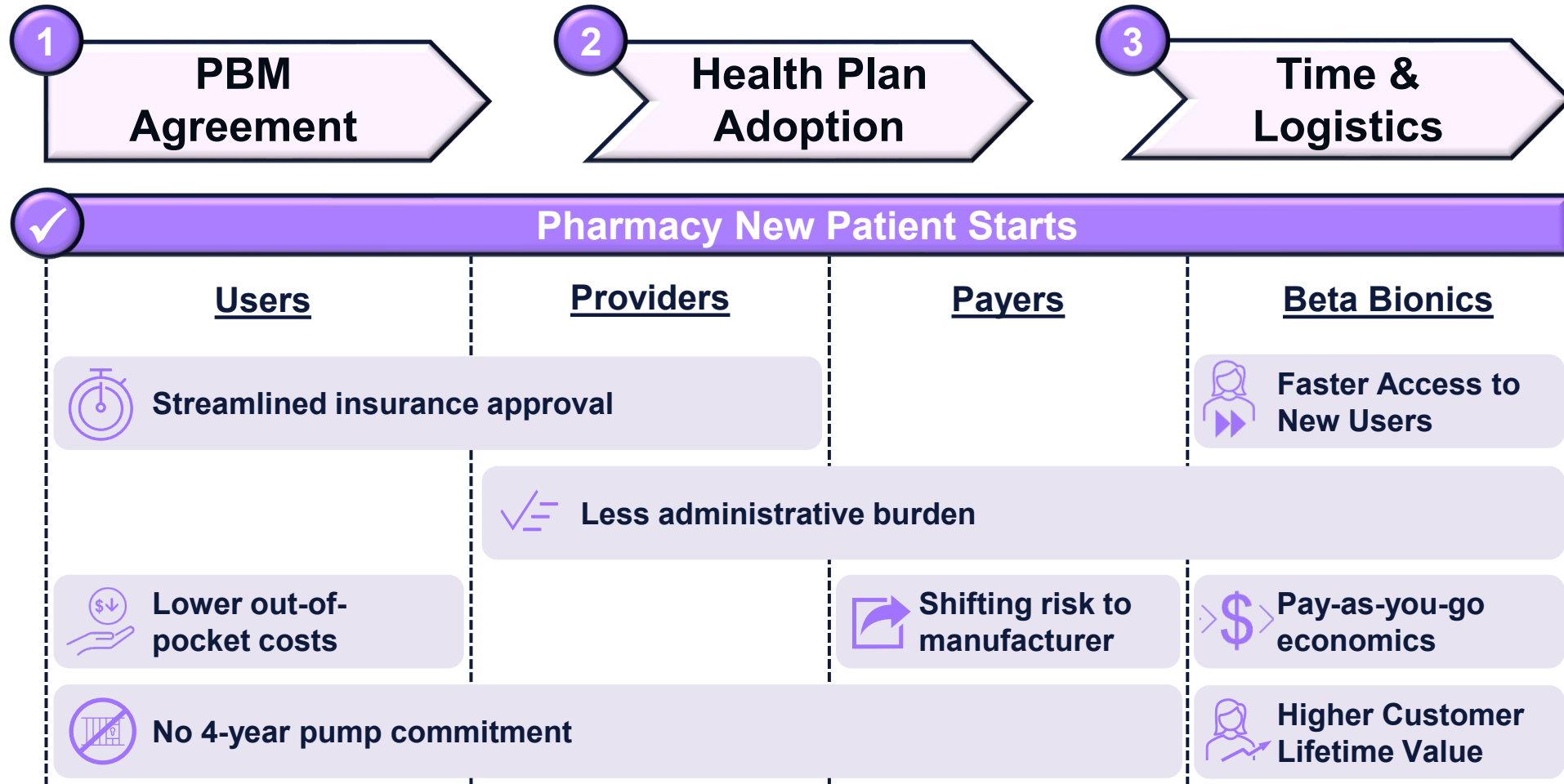
iLet is the first durable pump to access the pharmacy channel¹

	DME (Medical)	Pharmacy
	<i>Traditional reimbursement channel for durable insulin pumps</i>	<i>Pay-as-you-go model with advantages for users, providers, payors, and Beta Bionics</i>
Illustrative Economics for User and Payor		
User (out of pocket)		
Upfront cost	~\$500 to ~\$2,000	~\$0 to ~\$100
Monthly cost	~\$35	~\$25 or less
Commitment	Typically 4 years	None
Payor		
Pump	~\$3,500 up front	~\$450 / month
Supplies	~\$70 / month	



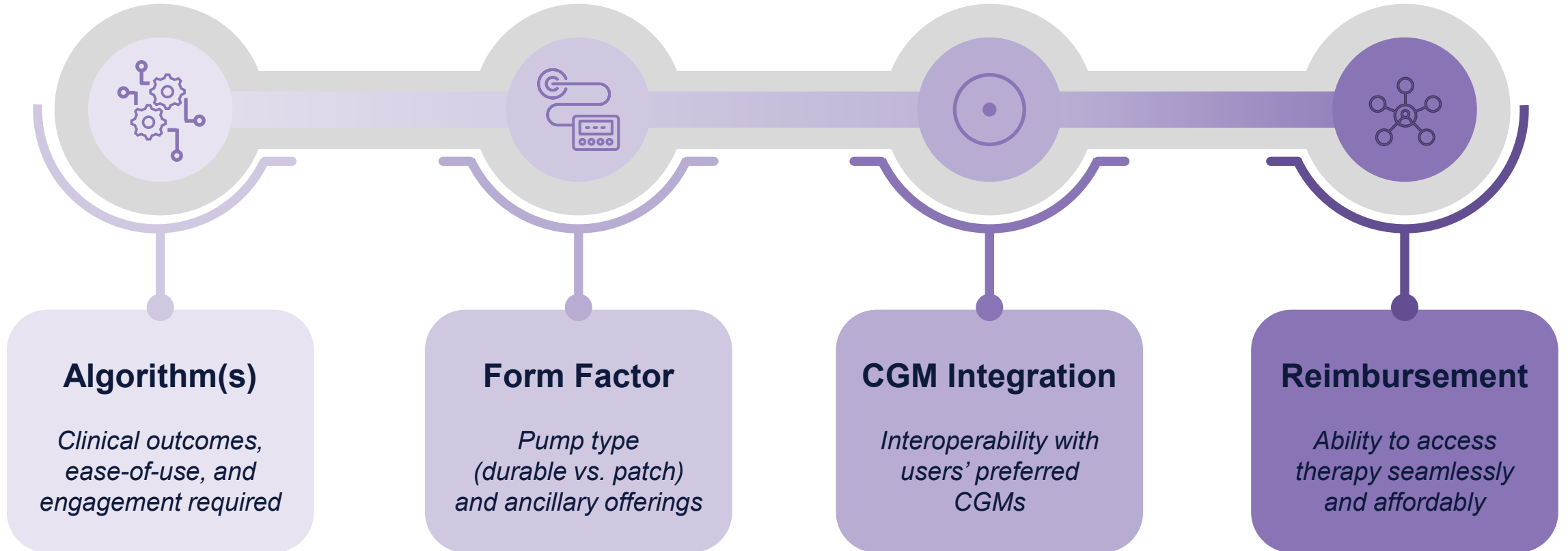
Pharmacy Channel Strategy

Three-step process delivers benefits to users, healthcare providers, payers, and Beta Bionics





Aligning to Users' Decision-Making Framework

What people with diabetes care about when selecting an insulin pump



Positioning iLet for Sustainable Success

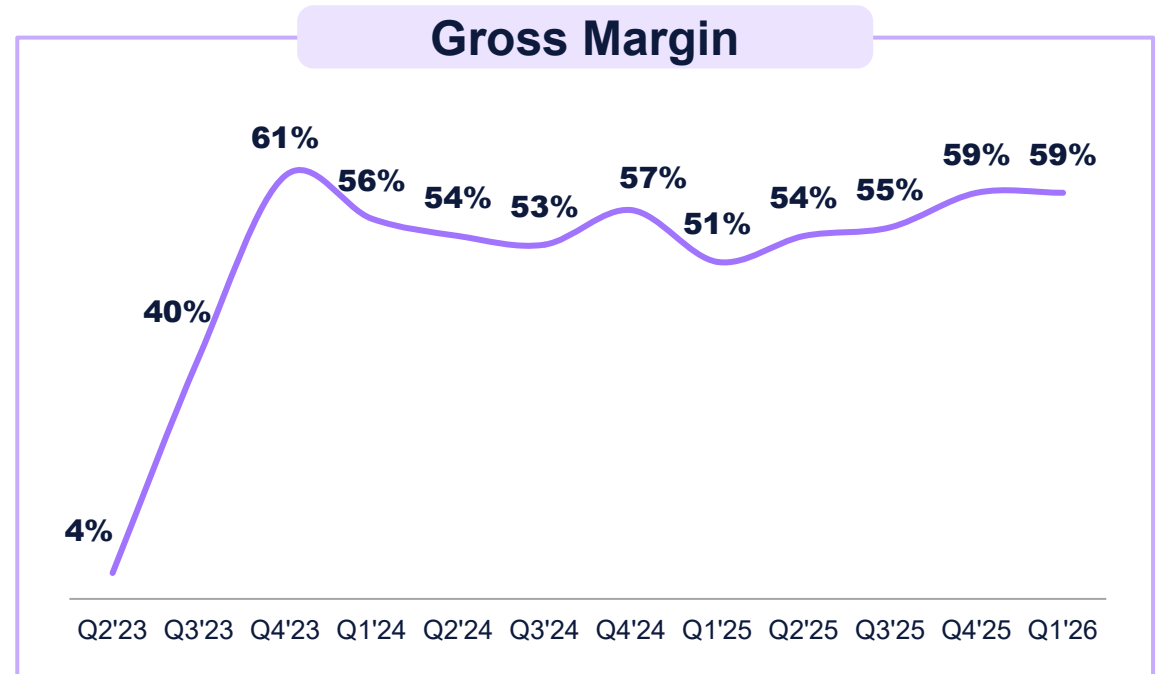
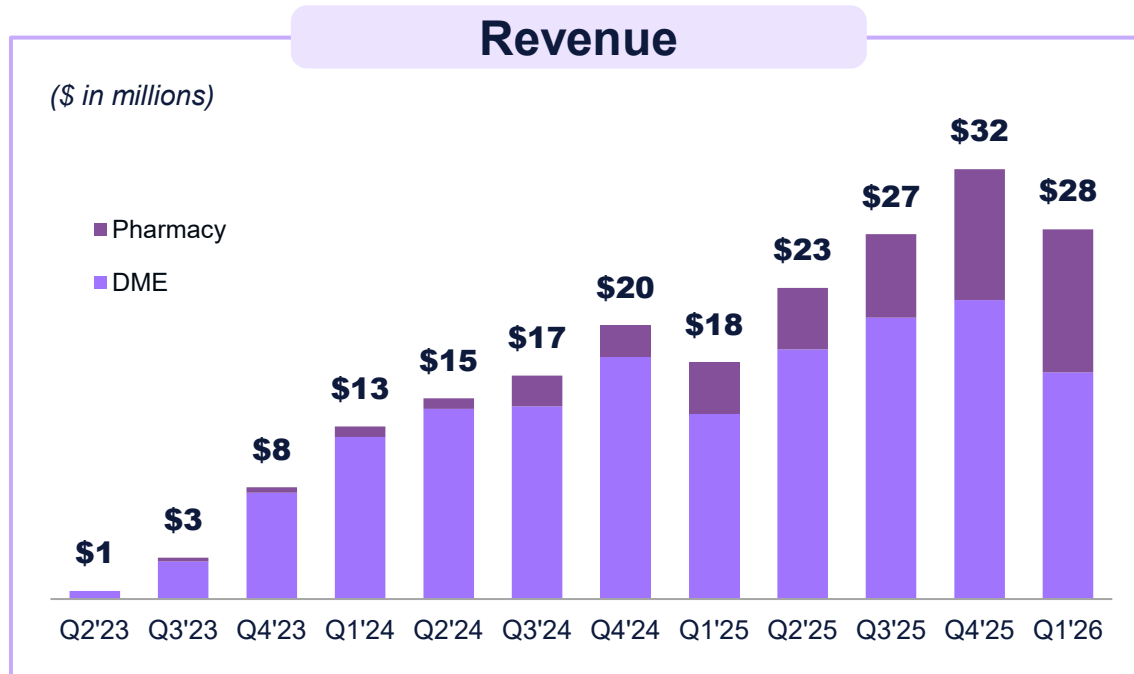
Differentiation where it matters

		 iLet Bionic Pancreas¹	Tubeless Hybrid Closed-loop System	Tubed Hybrid Closed-loop System	Smart Insulin Pens
User Decision-Making Framework		Beta Bionics	Insulet ²	Medtronic and Tandem ^{3,4}	Multiple
 Algorithm(s)	Algorithm(s) Initialized with only body weight	✓	×	×	×
	Algorithm(s) determines 100% of insulin doses	✓	×	×	×
	No carb counting ⁵	✓	×	×	×
 Form Factor	Tubed / Durable pump	✓	×	✓	×
	Prefilled cartridges	✓	×	×	×
	Patch pump	<i>(expected commercialization by end of 2027)⁶</i>	✓	×	×
 CGM Integration	Dexcom G6 & G7	✓	✓	✓ <i>(Tandem only)</i>	×
	Abbott Freestyle Libre 3 Plus	✓	×	✓	×
 Reimbursement	DME (medical) channel	✓	×	✓	×
	Pay-as-you-go pharmacy channel	✓	✓	✓	✓

Note: Continuous Glucose Monitor (CGM), Durable medical equipment (DME).
 1. Beta Bionics. iLet Bionic Pancreas User Guide. 2022.
 2. Insulet. Omnipod 5 User Guide. 2022.
 3. Medtronic. MiniMed 780g System User Guide. 2020.
 4. Tandem Diabetes Care. t:slimx2 Insulin Pump with Control IQ Technology User Guide. 2023.
 5. User must be carb aware.
 6. Subject to regulatory clearance

Delivering a Highly Successful Commercial Launch

Launched in May 2023, iLet is expanding the pump market and taking market share



High 30s %

New patient starts reimbursed through pharmacy in Q1'26

~70%

New patient starts coming from multiple daily injections in Q1'26

Beta Bionics



**Where we are
going next**

Patch Pump in Development

mintTM
by **Beta Bionics**



Intuitive Two-Part Design

Reusable Controller

- Electronics last 2 years
- Adaptive-closed loop algorithm
- iOS and Android smartphone controlled
- Never requires charging
- Waterproof for showering and swimming



Disposable Cartridge

- 3-day wear time
- 200U insulin reservoir
- Disposable batteries
- 4.5mm steel cannula
- 12-hour grace period
- Waterproof for showering and swimming

Expected User Experience Advantages



Adaptive-Closed Loop Algorithm

Same or better outcomes with substantially less work for the user and provider^{1,2}



Seamless Patch Change Process

No phone or charging required; 4.5mm steel cannula minimizes insertion discomfort



Pharmacy Channel Access

Streamlined insurance approval; minimal out-of-pocket costs



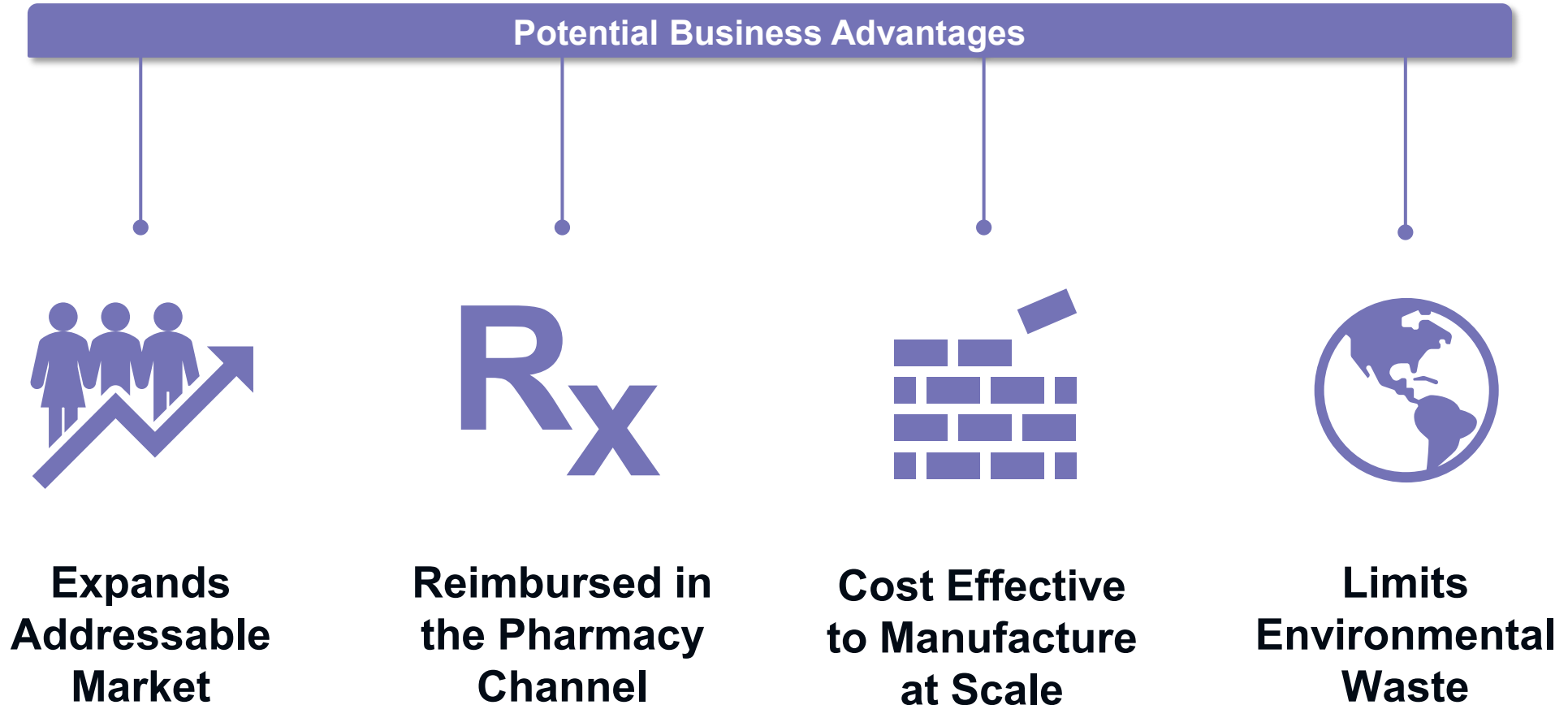
Robust Digital Ecosystem

Compatible with Dexcom G7 and Abbott Libre 3 Plus; iLet App and Bionic Circle for iOS and Android

Note: Commercialization of the Mint patch pump in development is subject to regulatory approval, and the device is not available for sale. The images shown are for illustrative purposes only. Actual product specifications may vary.

1. Russell, S.J., et al. (2022) A Multicenter Randomized Trial of a Bionic Pancreas in Type 1 Diabetes. The New England Journal of Medicine. 387:1161–1172.
2. Damiano et al. (2024) Glycemic and CGM Outcomes are nearly independent of the frequency of user engagement with the iLet in the Bionic Pancreas Pivotal Trial and real-world setting. <https://www.betabionics.com/wp-content/uploads/iLet-Glycemic-and-CGM-outcomes-vs-user-engagement.pdf>

Targeting Commercialization by the End of 2027



Bihormonal Pump in Development

Potential to revolutionize diabetes care

First-of-its-kind bihormonal configuration of the iLet

- Intended to utilize adaptive closed-loop algorithms that autonomously determine and deliver 100% of all insulin and glucagon doses
- Exclusive collaboration and license agreement with Xeris Pharmaceuticals for a pump-compatible, shelf-stable, glucagon formulation

Clear path to market

- **Phase 2a (current stage):** Feasibility trials to stress test the system's capabilities and iterate accordingly.
 - Completed first-in-human Phase 2a feasibility trial in Q4'25; additional Phase 2a feasibility trial initiated in Q1'26
- **Phase 2b:** Robust pivotal-enabling feasibility trial
- **Phase 3:** Concurrent pivotal trials to support regulatory filings for the glucagon asset (NDA), algorithm (510(k)), and pump (510(k))

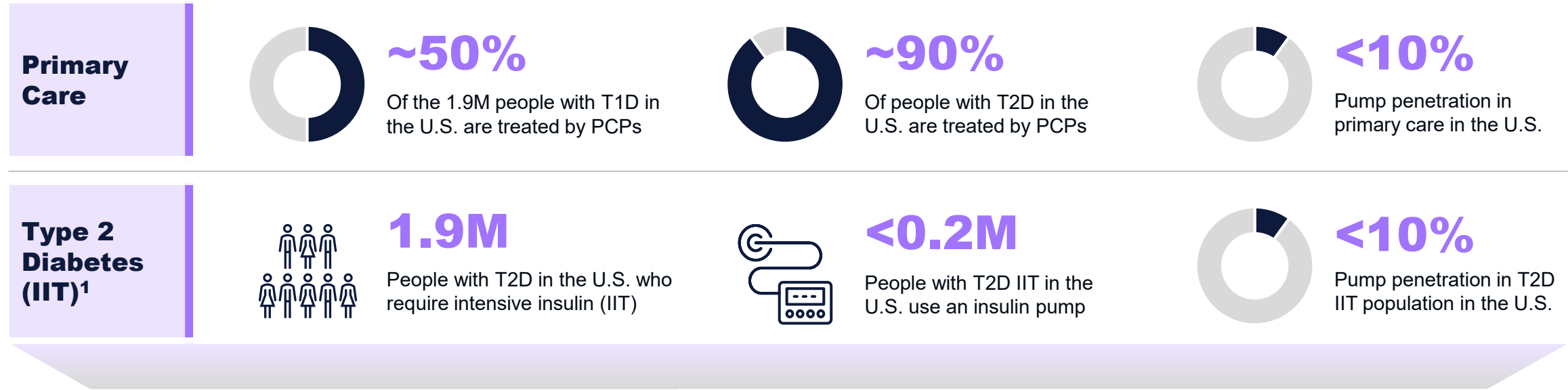
Potentially transformative treatment outcomes and burden reduction

- In 6 pre-pivotal outpatient clinical trials, participants utilizing our bihormonal configuration achieved **reduced hypoglycemia and increased time in range relative to both standard-of-care treatment and our insulin-only bionic pancreas configuration**^{1,2,3,4,5}
- Potential to substantially reduce fear of hypoglycemia and regimen burden which could lead to **reduction in the challenges associated with diabetes management**^{6,7}

1. Russell et al. (2014) New England Journal of Medicine, 371:313-325
2. Russell et al. (2016) The Lancet Diabetes and Endocrinology, 4:233-243
3. El-Khatib et al. (2017) The Lancet, 389:369-380
4. Balliro et al. (2017) 77th Scientific Sessions of the American Diabetes Association, 1062-P
5. Sherwood et al. (2018) 78th Scientific Sessions of the American Diabetes Association, 299-OR
6. Weissberg-Benchell et al. (2017) Diabetes Technology & Therapeutics, 12: 723-729
7. Weissberg-Benchell et al. (2016) Journal of Diabetes Science & Technology 4: 840-4

Expansion in Primary Care & Type 2 Diabetes

Largely untapped segments of the diabetes market that iLet may be uniquely positioned to address



Our Ability to Win

- **iLet's combination of simplicity and efficacy** may be particularly appealing to people with T2D as well as PCPs
- **Training and initiation of iLet by PCPs results in similar glycemic outcomes** relative to usual care¹

Our Approach

- **Pharmacy reimbursement** reduces administrative burden for PCPs and streamlines the approval process for people with T2D
- **Execute a clinical trial** to assess iLet's performance in the T2D population and pursue FDA approval
- **Change institution-level protocols that drive PCP prescribing patterns** at the clinic level

Full Year 2026 Guidance

Previous

New

\$130-135M



\$131-136M

Total Revenue

36-38%



37-39%

New Patient Starts through Pharmacy

55.5-57.5%



57.5-59.5%

Gross Margin

Assumptions & Drivers

- **iLet continues to generate robust demand**, driving pump market expansion and taking market share
- **Stable utilization and retention rates** in DME and pharmacy channel
- Contribution from **at least 20 new sales territories** expected to be onboarded throughout 2026
- **Execution of additional formulary agreements and deeper adoption of iLet at the individual health plan level** to drive increases in pharmacy new patient starts
- **Continued cost discipline and improved leverage of manufacturing overhead** at greater scale

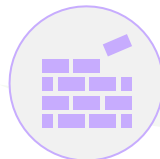
Strategic Outlook

Innovating for today and the future

Lay the Foundation

2023 to 2024 Achievements

- iLet launch (Black & White)
- CGM integrations (Dexcom G6 & G7, Abbott Freestyle Libre 3 Plus)
- Formulary agreements (e.g., Express Scripts & CVS Caremark)
- Collaboration and licensing agreement with Xeris Pharmaceuticals
- Color iLet launch
- Expansion to 43 sales territories



Execute Relentlessly

2025 to 2026 Objectives

- Capitalize on recent launches (Color iLet, Libre 3 Plus, Bionic Circle, Bionic Portal)
- Continued expansion of sales territories
- Additional formulary agreements
- Growth of pharmacy coverage at the individual health plan level
- Advance patch pump and bi-hormonal pump R&D projects



Revolutionize Care

Future Objectives

- Mint commercialization¹
- Bi-hormonal system commercialization¹
- Expansion of sales territories
- Growth of pharmacy channel mix
- Market and indication expansion
 - Primary care
 - Type 2 insulin-intensive Diabetes¹
 - International markets¹
 - Other insulin-requiring diseases¹



Beta Bionics

Appendix



Quarterly Financials & Reconciliation to GAAP Financials

(\$ in millions)

	Q2 2024	Q3 2024	Q4 2024	Q1 2025	Q2 2025	Q3 2025	Q4 2025	Q1 2026
Net Sales	\$15.0	\$16.7	\$20.4	\$17.6	\$23.2	\$27.3	\$32.1	\$27.6
Gross Profit	\$8.1	\$8.9	\$11.7	\$9.0	\$12.5	\$15.1	\$18.9	\$16.4
<i>% Margin</i>	<i>54%</i>	<i>53%</i>	<i>57%</i>	<i>51%</i>	<i>54%</i>	<i>55%</i>	<i>59%</i>	<i>59%</i>
Total Operating Expenses	\$19.9	\$19.9	\$24.7	\$27.6	\$32.4	\$32.2	\$35.1	\$40.7
Adjusted EBITDA¹	(\$10.0)	(\$8.7)	(\$11.3)	(\$15.5)	(\$14.5)	(\$12.2)	(\$10.5)	(\$17.7)
Stock-Based Compensation Expense	(1.5)	(2.0)	(1.6)	(2.8)	(4.8)	(4.5)	(4.3)	(5.4)
Change in Fair Value of Warrant Liabilit	(3.7)	0.4	(6.0)	(12.5)	0.0	0.0	0.0	0.0
Depreciation Expense	(0.3)	(0.3)	(0.2)	(0.3)	(0.3)	(0.4)	(0.5)	(0.6)
Interest Income	1.0	0.8	1.0	2.4	3.0	2.8	2.7	2.4
Income Tax Expense (Benefit)	(0.0)	0.0	0.0	0.0	(0.0)	0.0	0.0	0.0
Litigation Settlement & Other Related E	0.0	0.0	0.0	0.0	(0.2)	0.0	(0.2)	0.0
Quality System Remediation ²	0.0	0.0	0.0	0.0	0.0	0.0	(0.6)	(0.6)
Net Loss	(\$14.5)	(\$9.7)	(\$18.1)	(\$28.7)	(\$16.9)	(\$14.2)	(\$13.5)	(\$21.9)

- Adjusted EBITDA addbacks include stock-based compensation expense, depreciation and amortization expense, interest income, provision for state taxes, litigation settlement expense, quality system remediation, and change in fair value of warrant liabilities.
- Amounts presented under "Quality system remediation" for the three months ended December 31, 2025 and March 31, 2026 reflect the same category of expenses previously labeled "Other non-recurring" in our Form 10-K for the year ended December 31, 2025. These expenses relate to our one-time remediation efforts in response to the Form 483 and the Warning Letter, including contractor support and the various updates to our quality system to meet FDA expectations.