UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2026

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-42491

BETA BIONICS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**47-5386878**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11 Hughes Irvine, California	**92618**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (949) 427-7785

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	BBNX	Nasdaq Global Market

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The number of shares of the Registrant's Common Stock outstanding as of October 26, 2026 was 54,367,067.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this Quarterly Report) contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations, financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will" or "would," or the negative of these words or other similar terms or expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, factors and assumptions described under Part II. Item 1A. "Risk Factors" and elsewhere in this Quarterly Report, regarding, among other things:

- our expected future growth;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- our ability to accurately forecast demand for our products;
- the rate and degree of market acceptance of our products;
- the expected future growth of our sales and marketing organization;
- expectations about and our ability to implement our multi-channel coverage and reimbursement strategy;
- the performance of, and our reliance on, third parties in connection with the commercialization of our products, including single source suppliers;
- forecasts regarding commercial demand for our products and our manufacturing expectations and capabilities;
- regulatory developments in the United States;
- our ability to maintain regulatory approval for our products or obtain regulatory approval for new products in the United States;
- our research and development, regulatory approval and commercialization of existing products and any future products and related timing;
- the development, regulatory approval and commercialization of competing products;
- our ability to retain and hire senior management and key personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act (JOBS Act);
- our expectations regarding the impact of geopolitical and macroeconomic factors;
- our financial performance and capital requirements;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others;
- our expected use of our existing cash, cash equivalents and short-term and long-term investments, including expected use of net proceeds from our initial public offering and other financing transactions; and
- other risks and uncertainties, including those described under Part II. Item 1A. "Risk Factors" in this Quarterly Report.

These risks are not exhaustive. Other sections of this Quarterly Report may include additional factors that could harm our business and financial performance. We operate in a very competitive and rapidly changing environment where new risk factors may emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. These forward-looking statements speak only as of the date of this Quarterly Report. We undertake no obligation to update any forward-looking statements made in this Quarterly Report to reflect events or circumstances after the date of this Quarterly Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments. We intend the forward-looking statements contained in this Quarterly Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act).

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Quarterly Report. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report and have filed as exhibits with the understanding that our actual future results, levels of activity, performance and achievements may be different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

PART I. Financial Information

Item 1. Financial Statements.

BETA BIONICS, INC.

CONDENSED BALANCE SHEETS

(In thousands, except number of shares)

	September 30, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 81,551	$ 31,576
Restricted cash, current	100	100
Short-term investments	158,653	187,549
Accounts receivable, net	20,667	17,118
Inventories	22,971	21,722
Prepaid expenses and other current assets	9,004	9,840
Total current assets	292,946	267,905
Property and equipment, net	11,764	8,600
Operating lease right-of-use asset	5,401	6,627
Long-term investments	133,436	45,431
Other long-term assets	212	180
Total assets	$ 443,759	$ 328,743
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,682	$ 4,998
Accrued expenses and other current liabilities	24,656	22,431
Operating lease liabilities	1,452	1,938
Deferred revenue	2,046	1,557
Total current liabilities	32,836	30,924
Operating lease liabilities, net of current portion	4,649	5,365
Deferred revenue, net of current portion	3,480	3,297
Other long-term liabilities	1,411	1,547
Total liabilities	42,376	41,133
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Common stock, $0.0001 par value, 700,000,000 shares authorized; 54,362,972 and 44,360,873 issued and outstanding at September 30, 2026 and December 31, 2025, respectively	5	4
Additional paid-in capital	841,843	657,140
Accumulated other comprehensive income (loss)	(877)	403
Accumulated deficit	(439,588)	(369,937)
Total stockholders' equity	401,383	287,610
Total liabilities and stockholders' equity	$ 443,759	$ 328,743

The accompanying notes are an integral part of these unaudited condensed financial statements.

BETA BIONICS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except number of shares and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net sales	$ 35,505	$ 27,253	$ 95,144	$ 68,130
Cost of sales	15,174	12,134	39,474	31,537
Gross profit	20,331	15,119	55,670	36,593
Operating expenses:				
Research and development	11,975	8,195	32,571	24,658
Sales and marketing	25,124	16,045	70,499	45,070
General and administrative	9,841	7,922	29,058	22,422
Total operating expenses	46,940	32,162	132,128	92,150
Loss from operations	(26,609)	(17,043)	(76,458)	(55,557)
Other income (expense):				
Interest income	2,258	2,833	6,811	8,274
Other income (expense), net	(2)	1	(4)	(1)
Change in fair value of warrant liabilities	—	—	—	(12,450)
Total other income (expense), net	2,256	2,834	6,807	(4,177)
Net loss	$ (24,353)	$ (14,209)	$ (69,651)	$ (59,734)
Other comprehensive income (loss):				
Unrealized gain (loss) on short-term and long-term investments	(487)	205	(1,280)	289
Comprehensive loss	$ (24,840)	$ (14,004)	$ (70,931)	$ (59,445)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.52)	$ (0.33)	$ (1.54)	$ (1.52)
Weighted-average common shares outstanding, basic and diluted	46,541,997	43,634,006	45,224,038	39,293,798

The accompanying notes are an integral part of these unaudited condensed financial statements.

BETA BIONICS, INC.

CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

(Unaudited)

(In thousands, except number of shares)

Nine months ended September 30, 2026

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2025	—	$ —	44,360,873	$ 4	$ 657,140	$ 403	$ (369,937)	$ 287,610
Vesting of restricted stock units	—	—	513,953	—	—	—	—	—
Stock option exercises	—	—	439,418	1	2,995	—	—	2,996
Issuance of common stock for Employee Stock Purchase Plan	—	—	92,205	—	1,228	—	—	1,228
Stock-based compensation expense	—	—	—	—	19,137	—	—	19,137
Unrealized gain (loss) on short-term investments	—	—	—	—	—	(1,280)	—	(1,280)
Issuance of common stock and pre-funded warrant in follow-on public offering, net of underwriting discounts and commissions and offering costs of $11.2 million	—	—	8,956,523	—	161,343	—	—	161,343
Net loss	—	—	—	—	—	—	(69,651)	(69,651)
Balance at September 30, 2026	—	$ —	54,362,972	$ 5	$ 841,843	$ (877)	$ (439,588)	$ 401,383

Three months ended September 30, 2026

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at June 30, 2026	—	$ —	44,981,606	$ 5	$ 671,986	$ (390)	$ (415,235)	$ 256,366
Vesting of restricted stock units	—	—	210,325	—	—	—	—	—
Stock option exercises	—	—	214,518	—	1,799	—	—	1,799
Issuance of common stock for Employee Stock Purchase Plan	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	6,715	—	—	6,715
Unrealized gain (loss) on short-term investments	—	—	—	—	—	(487)	—	(487)
Issuance of common stock and pre-funded warrant in follow-on public offering, net of underwriting discounts and commissions and offering costs of $11.2 million	—	—	8,956,523	—	161,343	—	—	161,343
Net loss	—	—	—	—	—	—	(24,353)	(24,353)
Balance at September 30, 2026	—	$ —	54,362,972	$ 5	$ 841,843	$ (877)	$ (439,588)	$ 401,383

Nine months ended September 30, 2025

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2024	17,228,954	$ 321,373	6,667,793	$ 1	$ 51,311	$ 65	$ (296,737)	$ (245,360)
Conversion of convertible preferred stock into common stock on initial public offering	(17,228,954)	(321,373)	19,827,003	2	321,371	—	—	321,373
Issuance of common stock in initial public offering, net of underwriting discounts and commissions and offering costs of $21.7 million	—	—	12,475,000	1	190,378	—	—	190,379
Issuance of common stock under private placement offering, net of offering costs of $1.4 million			1,000,000	—	15,591	—	—	15,591
Reclassification of convertible preferred stock and common stock warrants into common stock on initial public offering	—	—	3,369,473	—	57,348	—	—	57,348
Vesting of restricted stock units	—	—	190,222	—	—	—	—	—
Stock option exercises	—	—	462,107	—	2,793	—	—	2,793
Stock-based compensation expense	—	—	—	—	12,081	—	—	12,081
Unrealized gain (loss) on short-term investments	—	—	—	—	—	289	—	289
Net loss	—	—	—	—	—	—	(59,734)	(59,734)
Balance at September 30, 2025	—	$ —	43,991,598	$ 4	$ 650,873	$ 354	$ (356,471)	$ 294,760

Three months ended September 30, 2025

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at June 30, 2025	—	$ —	43,465,136	$ 4	$ 643,742	$ 149	$ (342,262)	$ 301,633
Conversion of convertible preferred stock into common stock on initial public offering	—	—	—	—	—	—	—	—
Issuance of common stock in initial public offering, net of underwriting discounts and commissions and offering costs of $21.7 million	—	—	—	—	—	—	—	—
Issuance of common stock under private placement offering, net of offering costs of $1.4 million			—	—	—	—	—	—
Reclassification of convertible preferred stock and common stock warrants into common stock on initial public offering	—	—	—	—	—	—	—	—
Vesting of restricted stock units	—	—	85,732	—	—	—	—	—
Stock option exercises	—	—	440,730	—	2,653	—	—	2,653
Stock-based compensation expense	—	—	—	—	4,478	—	—	4,478
Unrealized gain (loss) on short-term investments	—	—	—	—	—	205	—	205
Net loss	—	—	—	—	—	—	(14,209)	(14,209)
Balance at September 30, 2025	—	$ —	43,991,598	$ 4	$ 650,873	$ 354	$ (356,471)	$ 294,760

The accompanying notes are an integral part of these unaudited condensed financial statements.

BETA BIONICS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (69,651)	$ (59,734)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	2,186	1,035
Provision for expected credit losses	52	24
Stock-based compensation expense	19,137	12,081
Net provision (recovery) for excess and obsolete inventory	(567)	624
Change in fair value of warrant liabilities	—	12,450
Amortization of premium (discount) on short-term and long-term investments	228	(2,029)
Amortization of operating lease right-of-use asset	1,226	905
Loss on disposal of property and equipment	86	—
Changes in operating assets and liabilities:		
Accounts receivable	(3,601)	433
Inventories	(682)	(7,677)
Prepaid expenses and other current assets	836	(5,395)
Other long-term assets	(32)	(33)
Accounts payable	(823)	1,571
Accrued expenses and other current liabilities	1,530	1,565
Other long-term liabilities	(136)	1,205
Operating lease liability	(1,202)	(852)
Deferred revenue	672	1,529
Net cash used in operating activities	(50,741)	(42,298)
Cash flows from investing activities:		
Purchases of short-term investments	(43,944)	(236,772)
Purchases of long-term investments	(158,673)	(45,297)
Proceeds from maturities and redemptions of short-term investments	142,000	122,000
Purchases of property and equipment	(4,691)	(3,394)
Net cash used in investing activities	(65,308)	(163,463)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of underwriting discounts, commissions and issuance costs	—	195,430
Proceeds from the issuance of common stock from private placement, net of issuance costs	—	15,591
Proceeds from the issuance of common stock and pre-funded warrants, net of underwriting discounts, commissions and issuance costs	161,801	—
Proceeds from stock option exercises and employee stock purchase plan issuances	4,223	2,793
Net cash provided by financing activities	166,024	213,814
Net increase in cash, cash equivalents and restricted cash	49,975	8,053
Cash, cash equivalents and restricted cash at beginning of period	31,676	30,532
Cash, cash equivalents and restricted cash at end of period	$ 81,651	$ 38,585
Supplemental disclosure of non-cash investing and financing information:		
Reclassification of long-term investments to short-term investments	$ 70,174	$ 125,842
Conversion of convertible preferred stock upon initial public offering	$ —	$ 321,373
Conversion of warrants net exercise upon initial public offering	$ —	$ 57,348
Reclassification of deferred offering costs to equity upon initial public offering	$ —	$ 5,051
Operating lease right-of-use asset obtained in exchange for operating lease obligations	$ —	$ 1,284
Accrued offering costs	$ 456	$ —
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 81,551	$ 38,485
Restricted cash	100	100
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 81,651	$ 38,585

The accompanying notes are an integral part of these unaudited condensed financial statements.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

1. Organization and Basis of Presentation

The Company

Beta Bionics, Inc. (the "Company") is a commercial-stage medical device company focused on the design, development and commercialization of solutions to improve the health and quality of life of insulin-requiring people with diabetes (PWD) through the use of adaptive closed-loop algorithms. The Company was incorporated as a Massachusetts benefit corporation in October 2015 and converted to a Delaware corporation in August 2024. The Company's commercially available product, the iLet, was cleared by the U.S. Food and Drug Administration (the "FDA") in May 2023 for the treatment of type 1 diabetes in adults and children six years of age and older, and the Company commenced U.S. commercialization in May 2023. In September 2026, the Company received FDA clearance for Mint, its patch pump. The Company has not yet commenced commercial sales of Mint.

The Company has devoted its resources to research and development, manufacturing scale-up and commercialization of its products. The Company has funded its operations primarily through equity financings and revenue from product sales.

Basis of Presentation

The Company's unaudited condensed financial statements have been prepared pursuant to the rules and regulations of the U.S. Securities and Exchange Commission applicable to interim financial information. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles in the United States ("GAAP") have been condensed or omitted pursuant to such rules and regulations. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC").

Interim financial results are not necessarily indicative of results anticipated for the full year or any other period(s). These unaudited condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025 ("2025 Annual Report").

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the JOBS Act, enacted in 2012. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

2. Significant Accounting Policies

Use of Estimates

The preparation of the financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, certain judgments regarding revenue recognition, including variable consideration, inventory valuation, warranty reserve and valuation of stock-based compensation awards. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

Short-Term Investments

The Company classifies its short-term investments as available-for-sale securities. Available-for-sale securities are carried at fair value with net unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in

stockholders' equity and as a component of other comprehensive income (loss) within the statements of operations and comprehensive loss. The Company determines realized gains or losses on the sale of available-for-sale securities using the specific identification method and includes net realized gains and losses as a component of other income or expense within the statements of operations and comprehensive loss. The Company periodically evaluates its short-term investments for credit losses, considering the significance of the decline in value and the market and economy in general. The Company has not recognized any impairment losses related to its short-term investments during the nine months ended September 30, 2026 and 2025. All short-term investments are classified as current based on the nature of the investments and their availability for use in current operations.

Long-Term Investments

Long-term investments include U.S. Treasury securities with maturities of 12 months or more. The Company classifies its long-term investments as available-for-sale securities. Available-for-sale securities are carried at fair value, with net unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity and as a component of other comprehensive income (loss) within the statements of operations and comprehensive loss. The Company determines realized gains or losses on the sale of available-for-sale securities using the specific identification method and includes net realized gains and losses as a component of other income (expense), net within the statements of operations and comprehensive loss. The Company periodically evaluates its available-for-sale securities in unrealized loss positions to determine whether a credit loss exists. If a U.S. Treasury security has an unrealized loss and the Company either intends to sell the security or it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis, the Company will recognize an impairment charge in other income (expense), net for the entire amount of the unrealized loss and adjust the amortized cost basis of the security. The Company has not recognized any impairment losses related to its long-term investments during the nine months ended September 30, 2026 and 2025. All long-term investments are classified as noncurrent based on the nature of the investments.

Concentrations of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash and cash equivalents and short-term and long-term investments. The Company maintains its cash and cash equivalents in accounts at multiple accredited financial institutions and short-term and long-term investments in custodian accounts, in excess of federally insured limits. Additionally, the Company has established guidelines regarding investment instruments and their maturities, which are designed to maintain preservation of principal and liquidity. The Company does not believe that it is subject to unusual risk beyond the normal credit risk associated with commercial banking relationships.

The Company is exposed to concentration risk as it relates to its customers. The following table summarizes the percentages of total sales and accounts receivable, net for customers who accounted for 10% or more of the respective amounts for the periods presented:

	Net Sales		Net Sales		Accounts Receivable, net	
	Three Months Ended September 30,		Nine Months Ended September 30,			
	2026	2025	2026	2025	September 30, 2026	December 31, 2025
Distributor A	12.0%	13.8%	12.4%	14.0%	15.1%	14.7%
Distributor B	10.2%	12.7%	10.6%	13.1%	*	*
Distributor C	*	*	*	12.6%	*	*
Distributor D	10.5%	14.1%	10.2%	12.1%	*	*
Distributor E	*	*	*	*	*	14.0%
Distributor F	*	*	*	*	12.2%	19.4%
Distributor G	18.9%	11.7%	17.1%	12.1%	20.1%	10.9%
Distributor H	20.1%	*	19.7%	*	17.5%	16.0%

* Amount related to the respective customer represented less than 10% for the period presented.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the price received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at their fair values, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the assets or liabilities, such as inherent risk, transfer restrictions and risk of nonperformance. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair

value are classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

The Company's cash equivalents, restricted cash, short-term investments and long-term investments are carried at fair value, determined according to the fair value hierarchy described above (see Note 4). The fair values of the Company's accounts receivable, accounts payable and accrued expenses approximate their carrying values due to the short-term nature of these assets and liabilities.

Leases

Leases include all agreements in which the Company obtains control of an identified asset. A lease liability is recognized at the commencement date based on the present value of the lease payments over the lease term. When available, the Company uses the rate implicit in the lease to discount lease payments to present value; otherwise, the Company estimates the incremental borrowing rate to discount the lease payments based on information available at lease commencement (see Note 14).

The Company's leases have initial lease terms of approximately one to six years, with some including options to extend for up to five additional years. If a lease includes options to extend the lease term, the Company only includes the periods it is reasonably certain to exercise as of the lease commencement date. The decision to exercise lease renewal options is at the Company's sole discretion. Variable lease costs, including maintenance and utilities, real estate taxes, and insurance are expensed as incurred and excluded from the measurement of the lease liability. Lease agreements that include lease and non-lease components are accounted for as a single lease component. Leases with an initial term of 12 months or less are expensed and not recorded on the balance sheet. The Company's leases provide for fixed rental payments with annual rent escalations. The Company does not have any leases that are classified as financing leases.

Segment Information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's Chief Executive Officer is the Company's CODM. The CODM reviews financial information presented on a total company basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. As such, the Company has determined that it operates as one operating segment. The measure of segment assets is presented as total assets in the balance sheets. The Company has concluded that gross profit and net income (loss) are the primary measures of segment profit or loss used by the CODM. The CODM assesses performance for the Company, monitors budget versus actual results, and determines how to allocate resources based on net income (loss) as reported in the statements of operations and comprehensive loss. There are no other expense categories regularly provided to the CODM that are not already included in the primary financial statements herein. During the nine months ended September 30, 2026 and 2025, the Company did not generate any international revenues and as of September 30, 2026 and December 31, 2025, the Company did not have a material amount of assets located outside of the United States.

Revenue Recognition

Net Sales

Revenue is generated primarily from sales of the iLet and its associated single-use products, such as cartridges for insulin storage and delivery, and infusion sets that connect the iLet to a user's body. These products are distributed through a network of distributors and pharmacies, which then resell the products to insulin-requiring PWD. The Company recognizes revenue when it transfers control of the promised goods or services to its distributor and pharmacy customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services, net of estimated returns and estimated variable consideration adjustments, including rebates, patient assistance and chargebacks.

Revenue Recognition for Arrangements with Multiple Performance Obligations

The Company considers the individual deliverables in its contracts with customers as separate performance obligations. The iLet and single-use products that are used together with the iLet are deemed performance obligations that are satisfied at a point in time when the customer obtains control of the promised good, which typically is upon shipment. The Company has determined that the user's ability to access the mobile application and receive unspecified software updates through the mobile application are considered distinct performance obligations that are satisfied over time, as access and support are provided throughout the typical four-year warranty period of the iLet. Accordingly, revenue related to access to the mobile application and unspecified software updates is deferred and recognized ratably over a four-year period. Given that access to the mobile application and unspecified software updates follow the same pattern of transfer to the customer and are provided over the same four-year period, the Company recognizes revenue for these performance obligations as if they were a single performance obligation.

The transaction price is determined based on the consideration expected to be received, based on the stated value in contractual arrangements. The Company allocates the consideration to the individual performance obligations based on the estimated relative standalone selling price of the performance obligations and recognizes the consideration based on when the performance obligation is satisfied, considering whether or not this occurs at a point in time or over time. Where there is no observable standalone selling price, the Company estimates standalone selling price by applying the expected cost plus a margin approach.

Variable Consideration

The amount of variable consideration that is included in the transaction price is included in revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. The Company estimates reductions to revenues for rebates paid to pharmacy benefit managers. Rebates are based on contractual arrangements, which may vary by customer. The estimates are based on products sold, historical experience, trends, specific known market events and, as available, channel inventory data. Provisions for rebates and patient assistance are accounted for as a reduction of sales when revenue is recognized and are included within accrued expenses and other current liabilities within the balance sheets. Provisions for chargebacks are accounted for as a reduction of sales when revenue is recognized and are included as a reduction of accounts receivable, net within the balance sheets, as the right of offset exists. If the actual amounts of consideration that the Company receives differ from estimates, the Company adjusts these estimates, which affects reported revenue, in the period that such variances become known or at the end of each reporting period.

Sales Returns

The Company offers a 90-day right of return from the date of shipment of its iLet from one of its authorized distributors, provided a physician's confirmation of the good faith medical reason for the return is received. Estimated allowances for sales returns are based on historical returned quantities as compared to iLet shipments in those same periods of return, adjusted for known or expected changes in the marketplace when appropriate. Actual product returns have not differed materially from estimated amounts recorded in the accompanying financial statements.

Contract Costs

The Company recognizes an asset for incremental costs of obtaining a contract with a customer if it expects to recover those costs. The Company has elected the practical expedient to expense the costs as they are incurred, within sales and marketing expenses, since the amortization period is less than one year.

Product Warranty

The Company provides a four-year warranty on the iLet to end-users to replace any iLets that do not function as intended in accordance with the product specifications. Estimated warranty costs are recorded at the time of shipment. Warranty costs are estimated primarily based on the current expected product replacement cost and expected replacement rates which utilize management's understanding of the hardware and factor in a patient attrition rate to reserve for only the active patient population using the pump. Although the Company's history of product sales is limited, management also utilizes historical warranty cost data to reevaluate the estimated warranty obligation on a regular basis. Product returns and warranty replacements to date have been consistent with amounts accrued. Warranty expense is recorded as a component of cost of sales in the statements of operations and comprehensive loss.

Reconciliations of the changes in the Company's product warranty liability for the three and nine months ended September 30, 2026 and 2025 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Product warranty liability at beginning of period	$ 3,288	$ 2,062	$ 3,154	$ 657
Warranty expense	517	1,046	1,651	3,406
Warranty fulfillment	(638)	(553)	(1,638)	(1,508)
Product warranty liability at end of period	$ 3,167	$ 2,555	$ 3,167	$ 2,555

As of September 30, 2026 and December 31, 2025, total product warranty reserves were included in the following balance sheet accounts:

	September 30, 2026	December 31, 2025
	(in thousands)	
Accrued expenses and other current liabilities	$ 1,756	$ 1,607
Other long-term liabilities	1,411	1,547
Total warranty liability	$ 3,167	$ 3,154

Net Loss Per Share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Shares issuable for nominal or no cash consideration are considered outstanding common shares for the purposes of the computation of basic net loss per share. Accordingly, the 1,043,484 shares of common stock underlying the pre-funded warrant issued on September 17, 2026 are included in the weighted-average number of shares of common stock outstanding beginning on September 17, 2026, as the remaining exercise price of $0.0001 per share is nominal. Diluted net loss per share is computed by giving effect to all potentially dilutive securities outstanding during the period, unless their effect is anti-dilutive. Potentially dilutive securities include stock options and restricted stock units. Because the shares underlying the pre-funded warrant are included in basic net loss per share, the pre-funded warrant does not result in incremental dilutive shares and is therefore not included in the table below. The amounts presented below represent potentially dilutive securities outstanding as of the end of each period, including both vested and unvested awards, that were excluded from the calculation of diluted net loss per share as their effect would have been anti-dilutive.

	Nine Months Ended September 30,	
	2026	2025
Stock options to purchase common stock	6,730,716	6,765,251
RSUs	2,287,525	824,771
Total	9,018,241	7,590,022

For the three and nine months ended September 30, 2026 and 2025, there was no difference in the weighted average number of shares used to calculate basic and diluted net loss per share due to the Company's net loss position in each period.

Recently Adopted Accounting Pronouncements

In July 2025, FASB issued ASU 2025-05, *Credit Losses (Topic 326) – Measurement of Credit Losses for Accounts Receivable and Contract Assets*, which provides a practical expedient to assume that the current conditions as of the balance sheet date will remain unchanged for the remaining life of the asset when developing a reasonable and supportable forecast as part of estimating expected credit losses on current accounts receivable and current contract assets arising from revenue transactions. The Company adopted ASU 2025-05 on January 1, 2026. The adoption of this guidance did not have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses (ASU 2024-03)*, and in January 2025,

the FASB issued ASU 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date* ("ASU 2025-01"). ASU 2024-03 requires additional disclosure of the nature of expenses included in the income statement as well as disclosures about specific types of expenses included in the expense captions presented in the income statement. ASU 2024-03, as clarified by ASU 2025-01, is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact that this guidance may have on its financial statements.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*, which clarifies the applicability of Topic 270, the form and content of interim financial statements, and interim disclosure requirements. The guidance also establishes a principle requiring disclosure of events since the end of the most recent annual reporting period that have a material impact on an entity. The amendments are effective for the Company for interim reporting periods within annual reporting periods beginning after December 15, 2028 under the extended transition period available to emerging growth companies, provided the Company continues to qualify for and utilize such extended transition period. Early adoption is permitted. The Company is currently evaluating the guidance and does not expect adoption to have a material impact on its financial statements.

3. Revenue

The Company disaggregates net sales by product category and reimbursement channel, which the Company believes provides a meaningful depiction of how the nature, timing and uncertainty of net sales are affected by economic factors.

During the three and nine months ended September 30, 2026 and 2025, the Company's revenues were predominantly generated from sales of the iLet and its associated single-use products. The iLet requires the use of separately purchased single-use products which include cartridges for storing and delivering insulin, and infusion sets that connect the iLet to the user's body. These single-use products generate recurring revenue for the Company, as these are typically replaced by the end-user every 2-3 days or as directed by a healthcare provider.

The Company's customers are distributors and pharmacies who sell these products to insulin-requiring PWD, through the durable medical equipment ("DME") and the pharmacy benefit plan ("PBP") reimbursement channels, which entail differing payment outlays. For the three and nine months ended September 30, 2026 and 2025, the majority of the Company's sales were through the DME channel.

The following table summarizes the Company's disaggregated revenues:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
DME channel				
iLet[(1)]	$ 11,563	$ 14,175	$ 34,303	$ 37,217
Single-use products	10,334	6,840	24,930	16,269
Total DME channel	21,897	21,015	59,233	53,486
PBP channel				
iLet[(1)]	(37)	148	649	859
Single-use products	13,645	6,090	35,262	13,785
Total PBP channel	13,608	6,238	35,911	14,644
Total net sales	$ 35,505	$ 27,253	$ 95,144	$ 68,130

(1) iLet includes the over-time recognition related to software updates and mobile app access.

The Company recognizes revenue at a point in time once control has transferred to the customer, as well as over time for the performance obligation to provide ongoing services such as unspecified software updates. Revenue recognized during the nine months ended September 30, 2026 that was included in the deferred revenue balance as of December 31, 2025 was approximately $1.2 million.

At September 30, 2026 and December 31, 2025, $5.5 million and $4.9 million, respectively, were recorded as deferred revenue on the accompanying balance sheets for the portion of the transaction price allocated to performance obligations that were not yet satisfied. At September 30, 2026 and December 31, 2025, of the performance obligations not yet satisfied, $2.0 million and $1.6

million for each period, respectively, is expected to be recognized as revenue in the next 12 months, with the remainder expected to be recognized over the next 36 months. At September 30, 2026 and December 31, 2025, the $5.5 million and $4.9 million, respectively, relate to amounts deferred associated with the unspecified software updates promised to users and the users' access to the mobile application.

4. Financial Instruments and Fair Value Measurements

The following tables present the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis:

	Fair Value Measurements at September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets	(in thousands)			
Cash equivalents:				
Money market fund	$ 74,219	$ —	$ —	$ 74,219
Restricted cash:				
Money market fund	100	—	—	100
Short-term investments				
U.S. Treasury securities	158,653	—	—	158,653
Long-term investments				
U.S. Treasury securities	133,436	—	—	133,436
Total assets	$ 366,408	$ —	$ —	$ 366,408

	Fair Value Measurements at December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets	(in thousands)			
Cash equivalents:				
Money market fund	$ 26,249	$ —	$ —	$ 26,249
Restricted cash:				
Money market fund	100	—	—	100
Short-term investments				
U.S. Treasury securities	187,549	—	—	187,549
Long-term investments				
U.S. Treasury securities	45,431	—	—	45,431
Total assets	$ 259,329	$ —	$ —	$ 259,329

Money market funds and U.S. Treasury securities were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. There were no changes to the valuation methods during the nine months ended September 30, 2026 and 2025. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between Level 1 or Level 2 during the nine months ended September 30, 2026 and 2025.

Warrant Liabilities

In connection with the Company's initial public offering ("IPO") in January 2025, all outstanding warrant liabilities were remeasured and subsequently net exercised and reclassified to stockholders' equity. No warrant liabilities were outstanding as of September 30, 2026 or December 31, 2025.

Pre-Funded Warrant

In September 2026, the Company completed a follow-on public offering in which it issued 8,956,523 shares of common stock and, in lieu of shares of common stock to certain investors, a pre-funded warrant to purchase 1,043,484 shares of the Company's common stock. The pre-funded warrant is immediately exercisable at an exercise price of $0.0001 per share, subject to a beneficial ownership limitation, and does not expire until exercised in full.

The Company determined that the pre-funded warrant does not meet the definition of a derivative under ASC 815. The Company further determined that the pre-funded warrant is indexed to the Company's own stock and meets the requirements for

classification within stockholders' equity. Accordingly, amounts attributable to the pre-funded warrant were recorded in additional paid-in capital and the warrant is not subsequently remeasured. As of September 30, 2026, 1,043,484 shares of common stock remained issuable upon exercise of the pre-funded warrant. Refer to Note 2 for the treatment of the pre-funded warrant in the Company's calculation of net loss per share.

5. Short-Term and Long-Term Investments

The following represents a summary of the estimated fair value of short-term and long-term investments at September 30, 2026 and December 31, 2025:

	Fair Value Measurements at September 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(in thousands)			
Short-term investments				
U.S. Treasury securities	$ 159,069	—	$ (416)	$ 158,653
Long-term investments				
U.S. Treasury securities	133,897	—	(461)	133,436
Total	$ 292,966	$ —	$ (877)	$ 292,089

	Fair Value Measurements at December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(in thousands)			
Short-term investments				
U.S. Treasury securities	$ 187,167	$ 382	$ —	$ 187,549
Long-term investments				
U.S. Treasury securities	45,411	20	—	45,431
Total	$ 232,578	$ 402	$ —	$ 232,980

As of September 30, 2026, all available-for-sale debt securities in an unrealized loss position had been in a continuous unrealized loss position for less than 12 months. There were no available-for-sale debt securities in an unrealized loss position as of December 31, 2025. The Company did not record an allowance for credit losses on its available-for-sale debt securities because the unrealized losses were primarily attributable to changes in market interest rates and not credit deterioration. The Company does not intend to sell these securities and expects to hold them until recovery of their amortized cost bases upon maturity.

The following represents the contractual maturities of available-for-sale debt securities as of September 30, 2026:

	Fair Value Measurements at September 30, 2026			
	Years to Maturity			
	Within One Year	One to Two Years	More Than Two Years	Estimated Fair Value
	(in thousands)			
U.S. Treasury securities	$ 158,653	$ 133,436	$ —	$ 292,089
Total	$ 158,653	$ 133,436	$ —	$ 292,089

6. Accounts Receivable, Net

Accounts receivable, net consisted of the following:

	September 30, 2026	December 31, 2025
	(in thousands)	
Accounts receivable	$ 20,875	$ 17,274
Less: allowance for credit losses	(208)	(156)
Accounts receivable, net	$ 20,667	$ 17,118

Accounts receivable are stated at the amount expected to be collected. The allowance for credit losses reflects expected losses on accounts receivable based primarily on historical experience and customer credit quality. The allowance for credit losses and related write-offs were not material for the periods presented.

7. Inventories

Inventories consisted of the following:

	September 30, 2026	December 31, 2025
	(in thousands)	
Raw materials	$ 9,812	$ 8,556
Work in process	2,811	2,750
Finished goods	10,348	10,416
Total inventories	$ 22,971	$ 21,722

8. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	September 30, 2026	December 31, 2025
	(in thousands)	
Prepaid expenses	$ 5,924	$ 7,064
Interest receivable	2,787	2,511
Income tax receivable and other current assets	293	265
Prepaid expenses and other current assets	$ 9,004	$ 9,840

9. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2026	December 31, 2025
	(in thousands)	
Manufacturing equipment	$ 13,865	$ 9,247
Leasehold improvements	2,859	830
Furniture	1,020	939
Construction in progress	1,958	3,339
Total cost	19,702	14,355
Less: Accumulated depreciation and amortization	(7,938)	(5,755)
Property and equipment, net	$ 11,764	$ 8,600

Depreciation expense was $2.2 million and $1.0 million for the nine months ended September 30, 2026 and 2025, respectively.

10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2026	December 31, 2025
	(in thousands)	
Employee compensation and benefits	$ 13,654	$ 12,656
Sales returns, rebates and patient assistance	3,050	3,161
Professional fees	2,660	1,713
Warranty	1,756	1,607
Inventory in transit	1,310	1,961
Royalties	876	1,005
Clinical trials	81	—
Other	1,269	328
Accrued expenses and other current liabilities	$ 24,656	$ 22,431

11. Stock-Based Compensation

2016 Stock Incentive Plan

The Company's 2016 Stock Incentive Plan, as amended (the "2016 Plan"), previously provided for the grant of stock options and restricted stock awards to employees, officers, directors and consultants. Following the adoption of the 2025 Equity Incentive Plan in connection with the Company's IPO in January 2025, no further awards are granted under the 2016 Plan. Outstanding awards previously granted under the 2016 Plan continue to be governed by their original terms.

2025 Equity Incentive Plan

The Company maintains the 2025 Equity Incentive Plan (the "2025 Plan"), which became effective in January 2025. The 2025 Plan provides for the grant of incentive stock options, restricted stock units and other equity-based awards to employees, directors and consultants. The 2025 Plan replaced the 2016 Plan, and no further awards are granted under the 2016 Plan. A total of 12,016,744 shares of common stock were initially reserved for issuance under the 2025 Plan. As of September 30, 2026, 14,234,787 shares of common stock were reserved for issuance under the 2025 Plan.

Stock Options

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option pricing model to determine the grant-date fair value of stock options granted:

	Nine Months Ended September 30,	
	2026	2025
Weighted average grant date fair value per share	$ 8.22	$ 14.38
Risk-free interest rate	3.69%	4.25%
Expected term (in years)	5.86	5.97
Expected volatility	70.58%	100.01%
Expected dividend yield	0%	0%

The following table summarizes stock option activity for the nine months ended September 30, 2026:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	6,453,036	$ 9.87	7.4	$ 141,925
Granted	872,846	$ 12.67		
Exercised	(439,418)	$ 6.81		
Forfeited or cancelled	(153,263)	$ 13.64		
Expired	(2,485)	$ 10.93		
Outstanding at September 30, 2026	6,730,716	$ 10.34	7.1	$ 58,497
Vested and expected to vest at September 30, 2026	6,730,716	$ 10.34	7.1	$ 58,497
Options exercisable at September 30, 2026	4,383,804	$ 8.93	6.4	$ 44,233

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The total intrinsic value of options exercised during the nine months ended September 30, 2026 and 2025 was $4.2 million and $6.3 million, respectively.

The weighted-average grant-date fair value of stock options granted during the nine months ended September 30, 2026 and 2025 was $8.22 per share and $14.38 per share, respectively. The total fair value of stock options vested during the nine months ended September 30, 2026 and 2025 was $7.2 million and $6.5 million, respectively.

The following table summarizes the non-vested stock options that were outstanding as of September 30, 2026 and December 31, 2025:

	Number of Options	Weighted-Average Exercise Price
Non-vested options, September 30, 2026	2,346,912	$ 12.98
Non-vested options, December 31, 2025	2,840,777	$ 12.21

Restricted Stock Units

The following table summarizes RSU activity under the Company's incentive plans for the nine months ended September 30, 2026:

	Number of Shares	Weighted-Average Grant Date Fair Value
RSUs outstanding, December 31, 2025	753,885	$ 15.12
Granted	2,219,735	$ 13.00
Vested	(513,953)	$ 13.71
Cancelled	(172,142)	$ 13.72
RSUs outstanding, September 30, 2026	2,287,525	$ 13.48

Stock-Based Compensation Expense

Stock-based compensation expense by type and financial statement line is included in the Company's statements of operations and comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Options	$ 3,176	$ 3,116	$ 9,695	$ 8,721
RSUs	3,330	1,362	8,500	3,360
Employee stock purchase plan	209	—	942	—
Total stock-based compensation expense	$ 6,715	$ 4,478	$ 19,137	$ 12,081

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Cost of sales	$ 187	$ 140	$ 557	$ 399
Research and development	1,559	893	4,333	2,319
Sales and marketing	2,136	1,273	5,990	3,388
General and administrative	2,833	2,172	8,257	5,975
Total stock-based compensation expense	$ 6,715	$ 4,478	$ 19,137	$ 12,081

As of September 30, 2026, total unrecognized stock-based compensation expense related to the unvested options was $21.8 million, which is expected to be recognized over a weighted-average period of 2.1 years. As of September 30, 2026, total unrecognized stock-based compensation expense related to the unvested RSUs was $28.7 million, which is expected to be recognized over a weighted-average period of 2.2 years.

Employee Stock Purchase Plan

The Company's Employee Stock Purchase Plan ("ESPP") was approved by the Board in January 2025. The ESPP enables eligible employees to purchase shares of the Company's common stock using their after-tax payroll deductions, subject to certain conditions. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. Eligible employees may contribute, through payroll deductions, up to 15% of their earnings for the purchase of common stock under the ESPP. The purchase price of common stock under the ESPP is the lesser of: (a) 85% of the fair market value of a share of the Company's common stock on the first date of an offering or (b) 85% of the fair market value of a share of the Company's common stock on the date of purchase, limited to the maximum number of shares they may purchase on any single purchase date. Each offering under the ESPP has a six-month duration, beginning on January 1 and July 1 of each year, with purchases occurring on June 30 and December 31, respectively. The initial offering period under the ESPP commenced on January 1, 2026, and the first purchase under the ESPP occurred on June 30, 2026. A total of 410,000 shares of common stock were initially reserved for issuance under the ESPP. As of September 30, 2026, 853,608 shares of common stock were reserved for issuance under the ESPP, including shares added pursuant to the annual evergreen provision.

12. Employee Benefit Plan

The Company maintains a 401(k) retirement plan (the "401(k) Plan") for the benefit of eligible employees. Each participant may elect to contribute up to 100% of his or her compensation to the 401(k) Plan each year, subject to certain Internal Revenue Service (the "IRS") limitations. Under the terms of the Plan, the Company matches 100% of the first 6% of employee contributions. During the nine months ended September 30, 2026 and 2025, the Company contributed $2.9 million and $2.2 million, respectively, to the 401(k) Plan.

13. Income Taxes

During the nine months ended September 30, 2026 and 2025, the Company did not record income tax benefits for the net operating losses ("NOLs") incurred or for the research and development tax credits generated in each year, due to its uncertainty of realizing a benefit from those items. The Company does not have any foreign operations and therefore has no foreign income taxes.

The Company files income tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company is open to future tax examination under statute by the IRS from 2022 to present and by most state tax authorities from 2021 to present. However, to the extent allowed by law, the taxing authorities may have the right to examine periods where NOLs and research and development credits were generated and carried forward, and make adjustments to the amount of the NOL and research credits carryforwards.

14. Leases

The Company leases office and manufacturing facilities under operating lease arrangements. The components of lease expense were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Operating lease cost–fixed	$ 516	$ 409	$ 1,561	$ 1,242
Operating lease cost–variable	47	62	145	146
Short-term lease expense	13	20	40	28
Total lease expense	$ 576	$ 491	$ 1,746	$ 1,416

Cash paid for amounts included in the measurement of operating lease liabilities was $1.5 million and $1.2 million, respectively, for the nine months ended September 30, 2026 and 2025.

The weighted-average remaining lease term and discount rate were as follows:

	September 30, 2026
Weighted-average remaining lease term	4.99
Weighted-average discount rate	6.89%

Future lease payments under non-cancellable leases as of September 30, 2026 were as follows:

(in thousands) Year Ending December 31,	
2026	466
2027	1,418
2028	1,384
2029	1,092
2030	1,136
Thereafter	1,782
Total future lease payments	$ 7,278
Less: imputed interest	(1,177)
Total lease liabilities	$ 6,101

15. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may become involved in various legal proceedings, including those that may arise in the ordinary course of business. In September 2026, a purported stockholder of the Company filed a securities class action against the Company and certain of its executive officers in the United States District Court for the Central District of California, captioned *Holtzman vs. Beta Bionics, Inc. et al.*, Case No. 8:26-cv-2612-JWH (KESx). The complaint alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and SEC Rule 10b-5 promulgated thereunder, by making material misstatements or omissions concerning the safety, efficacy, and commercial success of iLet. The complaint seeks, on behalf of the putative class, unspecified damages, pre- and post-judgment interest, attorneys' fees, expert fees and costs, as well as class certification and such other relief as the court may deem just and proper. The Company intends to vigorously defend against the claims in this action. Any potential loss arising from this claim is not currently probable nor estimable.

Xeris Agreements

In May 2024, the Company and Xeris Pharmaceuticals, Inc. ("Xeris") entered into a collaboration and license agreement ("Collaboration and License Agreement") to develop and commercialize glucagon products for use in the Company's pump-based systems. Under the Collaboration and License Agreement, the Company received a worldwide, exclusive, sublicensable license to certain Xeris technology for use in the field of chronic glycemic control, as well as a manufacturing license subject to a future technology transfer and commercial supply arrangement.

In consideration for the rights granted under the agreement, the Company paid Xeris an upfront fee of $0.5 million and a development milestone payment of $3.0 million, both of which were recognized as research and development expenses when incurred. The Company is also required to pay Xeris tiered royalties in the low double-digit percentage range on future net sales of licensed products, subject to customary reductions.

In connection with clinical development activities, the Company entered into the Clinical Supply Agreement with Xeris and incurred $0.9 million of costs for Phase 2 clinical materials during 2024, with the remaining balance paid in 2025. In May 2026, the Company entered into a letter agreement under the Clinical Supply Agreement with Xeris for additional Phase 2 clinical material, including a one-time non-refundable payment of $0.5 million and reimbursement of certain internal and travel costs. In connection with entering into Phase 3 of the collaboration, the Company expects to incur development and manufacturing costs, including ordering clinical materials and technical transfer, development, and testing of the product, totaling up to $5.1 million. As of September 30, 2026, the Company has completed payments totaling $4.0 million. Amounts are initially recorded as prepaid expenses and recognized as research and development expense as the related services are performed. The Company may incur additional research and development expenses and, upon commercialization, royalty obligations under these agreements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed financial statements and the related notes included elsewhere in this Quarterly Report, our financial statements and the related notes thereto for the fiscal year ended December 31, 2025 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our planned investments in our research and development, sales and marketing and general and administrative functions, and our current plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section titled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" in both our Annual Report on Form 10-K for the year ended December 31, 2025 and in this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Unless the context requires otherwise, references in this Quarterly Report to the "Company," "we," "us" and "our" refer to Beta Bionics, Inc.

Overview

We are a commercial-stage medical device company engaged in the design, development, and commercialization of innovative solutions to improve the health and quality of life of insulin-requiring people with diabetes (PWD) by utilizing advanced adaptive closed-loop algorithms to simplify and improve the treatment of their disease. Diabetes is a chronic condition that requires ongoing insulin management, and despite advances in care, many PWD continue to struggle to achieve optimal outcomes. Despite decades of innovation, a significant unmet need remains. Our product, the iLet, is the first insulin delivery device cleared by the U.S. Food and Drug Administration (FDA) to utilize adaptive closed-loop algorithms to autonomously determine every insulin dose without requiring a user to count carbohydrate intake. We believe this represents a significant advancement over currently available insulin delivery options by offering a differentiated combination of improved glycemic control and a simplified experience for users and caregivers. Our mission is to simplify and alleviate the burden of managing diabetes with life-changing solutions. Our vision is to make diabetes easier, for everyone, every day. Our goal is to establish the iLet as the standard of care for insulin delivery.

The iLet was specifically designed to provide improvements in glycemic control relative to currently available treatment options, such as insulin pumps, including partially automated insulin delivery (AID) systems (also known as hybrid closed-loop systems), and multiple daily injections (MDI), also reducing the complexity and burden of achieving these improved results for PWD. It is enabled by adaptive closed-loop algorithms that continuously learn each person's unique and ever-changing insulin requirements and then autonomously delivers the correct insulin doses every five minutes throughout the day and night. Only the user's body weight is required for device initialization and the autonomous determination of all insulin doses, unlike insulin pumps and hybrid closed-loop systems, which require a complex host of parameters to configure.

Our initial commercialization efforts for the iLet are in type 1 diabetes (T1D), an indication for which we received FDA clearance in patients six and older in May 2023, in the United States. According to the Centers for Disease Control and Prevention (CDC), there are approximately 1.9 million people with T1D currently in the United States, all of whom require daily insulin replacement to manage their disease. We believe that one of the principal causes of suboptimal outcomes as it relates to disease management is the complexity of the user experience with most currently available insulin pumps and hybrid closed-loop systems, which has kept the majority of PWD from adopting them despite the improved disease management they can offer. We believe that approximately one-third of people with T1D in the United States utilize insulin pumps or hybrid closed-loop systems to receive their daily insulin, while the majority receive their daily insulin via MDI, which is less complex, but often less effective, and has been shown to be associated with higher HbA1c levels. Our initial commercial results suggest that the iLet's value proposition is resonating strongly within the MDI population as approximately 69% and 70% of the iLet's adoption during the nine months ended September 30, 2026 and 2025, respectively, came from PWD who were previously utilizing MDI.

We have also partnered with Dexcom and Abbott—global leaders in popular and easy to use iCGM technology—to integrate the iLet with the Dexcom G6 and G7 iCGMs and with Abbott's FreeStyle Libre 3 Plus Continuous Glucose Monitor (CGM) sensor. Use of the iLet requires the independent purchase of a compatible third-party iCGM to provide real-time data to the iLet user.

In September 2026, we announced a partnership with Senseonics Holdings, Inc. to integrate its Eversense 365 continuous glucose monitoring system with the iLet and Mint. We expect to commercially launch the integrated iLet and Eversense 365 system in the fourth quarter of 2026, subject to completion of integration, testing and validation activities and applicable regulatory requirements. We have also committed to integrate Mint with Eversense 365 in the future.

The iLet requires the use of single-use products, which we sell separately to our customers. These single-use products include cartridges for storing and delivering insulin, as well as infusion sets. These single-use products are generally recommended to be disposed of entirely every 2-3 days, or as directed by a healthcare provider. We also offer a mobile application that receives information from the iLet and displays that information discreetly to the user. This intuitive mobile application delivers real-time glucose readings, trends and graphs, with data securely stored in the cloud.

To maximize the commercial value of the iLet opportunity, we have assembled a team across our organization with broad experience in the successful commercialization of innovative technologies in the field of diabetes disease management. We are promoting sales of the iLet through an internal sales organization focused on high-volume endocrinology practices in the United States and may expand to primary care physicians (PCP) over time. We believe that the iLet's core value proposition of marrying effective glycemic control with the simplicity of use that is brought about by adaptive closed-loop algorithm insulin-dose determination may resonate particularly well among PCP who do not have the subspecialty-level of expertise, the resources, or the clinical bandwidth that is needed to initiate insulin-pump or hybrid closed-loop therapy or for the continual demand (such as adjustments at quarterly visits) those systems place on clinical practices in follow-on care.

Our primary customers are distributors and pharmacies who sell the iLet and single-use products that are used together with the iLet. PWD acquire our products through the DME channel and the PBP channel. Currently, the majority of our new patient starts are reimbursed through the DME channel.

We are pursuing a multi-channel coverage and reimbursement strategy to maximize access to the iLet within the T1D population, provide flexibility for PWD in choosing their device and provide PWD with advantageous coverage and reimbursement terms. We are working with payors to establish coverage and reimbursement under both the DME and PBP channels as we believe this strategy increases access and optimizes the potential for better medical outcomes for PWD through the adoption of the iLet.

The durable medical equipment (DME) and pharmacy benefit plans (PBP) reimbursement channels for the iLet and its single-use products entail different payment outlays and therefore differentially impact PWD and our financial results. DME reimbursement requires the user and insurance carrier to make a large, upfront payment and reimbursement, respectively, for the iLet, which is typically in the thousands of dollars.

By contrast, PBP reimbursement requires the user and insurance carrier to make a small upfront payment and reimbursement, respectively, for the iLet, allowing for a potentially higher rate of adoption by PWD. The insurance carrier then makes larger reimbursement payments for the purchase of single-use products, with the user's payments for the single-use products being generally consistent with what the user would likely pay for single-use products in DME reimbursement. As a result, we recognize a small amount of revenue at or around the date the iLet is sold in the PBP channel and we absorb initial negative gross margin. iLet sales in the PBP channel are generally expected to then start generating cumulative positive gross margin for us following the third month the user utilizes the iLet and continues to purchase single-use products. For the nine months ended September 30, 2026 and 2025, PBP channel sales represented 38% and 21% of net sales, respectively.

When considering the overall economics over the lifetime of each iLet, sales through the DME channel generally result in higher upfront cash flows from the large upfront payment and reimbursement for the iLet, but lead to lower cash flows over time as the user purchases the necessary single-use products. By contrast, sales through the PBP channel generally result in lower upfront cash flows from the small payment and reimbursement for the iLet, but lead to higher cash flows over time as the user purchases the necessary single-use products. This reflects differences in both the upfront device economics and the pricing of recurring single-use products across channels. When comparing sales through the DME and PBP channels, we expect sales through the PBP channel will have a more favorable economic impact on our financial results over the expected life of the iLet, which we generally expect to be four years. As such, our current strategic priority is to direct demand to the PBP reimbursement channel.

On September 14, 2026, we announced FDA clearance of Mint, our patch pump featuring a transformative reusable and disposable architecture that does not require recharging, integrates with industry-leading CGMs and enables smartphone control for iOS and Android users. We expect to initiate the full commercial launch of Mint in the United States in the first quarter of 2027 and anticipate manufacturing capacity to produce at least 1.5 million total disposable units in the full year 2027. Mint is expected to launch exclusively through the pharmacy channel, with approximately 40% of insured U.S. lives expected to be able to purchase it using their pharmacy benefit. We anticipate coverage for Mint to increase to at least 50% of insured U.S. lives within the first year of full commercialization as we leverage our market access footprint.

In addition to our commercialized product and to maintain our competitive position in the marketplace, we intend to continue investing in disruptive technologies through our experienced research and development team.

We are in the early stages of developing a first-of-its-kind bihormonal system of the iLet, which combines automated delivery of insulin and glucagon, the BG-raising hormone that protects against low blood sugar, or hypoglycemia, with adaptive closed-loop algorithms where all doses of both hormones are autonomously determined. As part of our development plans, in September 2025, we completed a clinical trial in Canada assessing the pharmacokinetics (PK) and pharmacodynamics (PD) of our glucagon product candidate (also referred to as the glucagon asset, and referred to herein as the PK-PD Trial). The completion of the PK-PD Trial enables us to bridge our previous bihormonal clinical data to our glucagon product candidate. We believe that the results from the PK-PD Trial are supportive of the continued development of our glucagon product candidate for use in our bihormonal system of the iLet. In the fourth quarter of 2025, we completed our first-in-human Phase 2a feasibility trial in New Zealand evaluating the integrated bihormonal system, including the glucagon formulation, pump, and dosing algorithms. In the first quarter of 2026, we initiated an additional Phase 2a feasibility trial to further evaluate the system, including the glucagon formulation, pump, and dosing algorithms. Based on the results from this feasibility work, we identified opportunities to improve the system, including the glucagon asset's excipient profile and dosing algorithms. During the third quarter of 2026, we continued our efforts to reformulate the glucagon asset and refine the dosing algorithms. We are also pursuing the development of the iLet for expanded patient populations and indications, including people with type 2 diabetes (T2D). In October 2026, we completed enrollment of adults with T2D in a pivotal trial in the United States, with the goal of expanding the iLet's indications for use to include adults with T2D around mid-year 2027, subject to regulatory clearance by the FDA. Also, in the fourth quarter of 2026, we intend to initiate a pivotal trial studying a next-generation fully-closed loop (FCL) algorithm in adults with type 1 and type 2 diabetes.

License and Collaboration Agreements

Below is a summary of the key terms of certain of our license and collaboration agreements. For a more detailed description of these agreements, see "Business—License and Collaboration Agreements" in our Annual Report on Form 10-K for the year ended December 31, 2025.

Device License Agreement with Boston University

We have a Device License Agreement with Boston University (BU) that requires ongoing royalty payments and other financial obligations related to products incorporating BU-licensed technology. Under the agreement, we are required to pay (i) quarterly royalties in the mid-single-digit percentage range based on net sales of licensed products by us and our affiliates, (ii) quarterly royalties in the low double-digit percentage range based on net sales by sublicensees, which are creditable against a minimum annual royalty amount, and (iii) quarterly lump-sum payments in the low double-digit percentage range based on certain non-royalty sublicensing revenue. We are also responsible for reimbursing BU for patent-related costs and may be required to pay an assignment fee in the event of a sale of substantially all assets related to the licensed technology. During the nine months ended September 30, 2026, we continued to incur royalty and license-related costs under this agreement which were recorded as cost of sales or operating expenses, as applicable, and expect these costs to increase as sales volumes grow.

Control Algorithm License Agreement with Boston University

We have a Control Algorithm license agreement with BU covering automated control system technology incorporated into the iLet. Under the financial terms of the agreement, we are required to pay BU (i) quarterly royalties of a mid-single-digit percentage based on net sales by us and our affiliates, (ii) quarterly royalties of a low double-digit percentage based on net sales by sublicensees, in each case of (i) and (ii) creditable against a minimum annual royalty amount, and (iii) quarterly lump-sum payments of a low double-digit percentage of certain non-royalty sublicensing revenue received from sublicensees. We are also responsible for reimbursing patent-related costs and are required to make a one-time change-of-control payment of $65,000 if such an event occurs. During the nine months ended September 30, 2026, we continued to incur royalty and license-related costs under this agreement and expect these costs to increase as sales volumes grow.

Collaboration and License Agreement with Xeris Pharmaceuticals, Inc.

We have a Collaboration and License Agreement with Xeris Pharmaceuticals, Inc. to develop and commercialize a glucagon formulation for use in our bihormonal system. Under this agreement, we paid an upfront fee of $0.5 million and a milestone payment of $3.0 million, both of which were recognized as research and development expense when incurred. We are also obligated to pay tiered royalties in the low double-digit percentage range on future net sales of glucagon products, subject to customary reductions.

In connection with clinical development activities, we entered into the Clinical Supply Agreement with Xeris and incurred $0.9 million of costs for Phase 2 clinical materials during 2024, with the remaining balance paid in early 2025. In May 2026, we entered into a letter agreement under the Clinical Supply Agreement with Xeris for additional Phase 2 clinical material to support ongoing development activities for our bihormonal system. We expect to incur up to $5.1 million in additional development and manufacturing costs related to Phase 3 activities, of which $4.0 million had been paid as of September 30, 2026. Amounts are

recorded as prepaid expenses and expensed to research and development as services are performed. The Company may incur additional research and development expenses and, upon commercialization, royalty obligations under these agreements.

Development and Commercial Agreements

Below is a summary of the key terms of certain of our development and commercial agreements. For a more detailed description of these agreements, see "Business—Development and Commercial Agreements" in our Annual Report on Form 10-K for the year ended December 31, 2025.

We have a Commercialization Agreement and Development and Commercialization Agreement with DexCom, Inc. and Abbott Diabetes Care Inc., respectively, related to integrated automated insulin delivery systems. These agreements primarily involve shared development responsibilities and cross-licensing of technology and trademarks and do not require upfront payments, milestone payments, or ongoing royalty obligations. As a result, these arrangements have not had a material direct impact on our results of operations or cash flows to date, though they may affect future operating expenses associated with development, regulatory activities, and commercialization. As of September 30, 2026, there have been no material changes to the terms of these agreements or their impact on our results of operations or cash flows.

Key Factors Affecting Our Performance

Our ability to successfully address the factors below is subject to various risks and uncertainties, including those described in the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2025, and the risk factors described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q.

New Patient Adoption and iLet Sales

Our financial performance has largely been driven by, and in the future will continue to be impacted by, the rate of sales of our products to new patients. Management focuses on new patient starts as a key indicator of current business success. We expect our new patient starts to continue to grow as we increase penetration in our existing markets and expand into, or offer new features and solutions that appeal to, new markets.

We plan to grow our sales in the coming years through multiple strategies, including expanding our sales efforts to focus on the more diffuse population of people with T1D who are treated by PCP over time, expanding our marketing initiatives including via the Bionic Universe, leveraging our partnerships with global leaders in CGM technology like Dexcom and Abbott, growing our internal customer support team, continuing to enhance our product offerings and pursuing a multi-channel coverage and reimbursement strategy.

Third-Party Payor Reimbursement and Impact of Our Multi-Channel Reimbursement Strategy

As a medical device company, our revenue and results of operations may be impacted if we are unable to secure sufficient coverage or reimbursement from third-party payors for our current or future products, or if reimbursement structures change under our multi-channel strategy.

We are pursuing a multi-channel coverage and reimbursement strategy to maximize access to the iLet within the T1D population, provide flexibility for PWD in choosing their device and provide PWD with advantageous coverage and reimbursement terms. We are working with payors to establish coverage and reimbursement under both the DME and PBP channels as we believe this strategy increases access and optimizes the potential for better medical outcomes for PWD through the adoption of the iLet. The DME and PBP channels for the iLet and its single-use products entail different payment outlays and therefore differentially impact PWD and our financial results. When considering the overall economics over the lifetime of each iLet, sales through the DME channel generally result in higher upfront cash flows from the large, upfront payment and reimbursement for the iLet, but lead to lower cash flows over time as the user purchases the necessary single-use products. By contrast, sales through the PBP channel generally result in lower upfront cash flows from the small payment and reimbursement for the iLet, but lead to higher cash flows over time as the user purchases the necessary single-use products. This is because single-use products under the PBP channel are sold at a much higher per unit cost than under the DME. As a result of a small amount of revenue recognized at or around the date the iLet is sold in the PBP channel, we absorb initial negative gross margin. iLet sales in the PBP channel are generally expected to start generating cumulative positive gross margin for us following the third month the user utilizes the iLet and continues to purchase single-use products. For the nine months ended September 30, 2026 and 2025, PBP channel sales represented 38% and 21%, respectively, of net sales. When comparing sales through the DME and PBP channels, we expect sales through the PBP channel will have a more favorable economic impact on our financial results over the lifetime of the iLet. To the extent that our mix of channel reimbursement fluctuates, our financial results may vary from period to period.

Continued Investment In Growth and Innovation

Our revenue growth has been driven by rapid innovation and quick adoption of our products by our customer base. We intend to continue to make focused investments to increase revenue and grow our business, and therefore expect expenses in this area to increase.

We have invested, and will continue to invest, significantly in our manufacturing capabilities and commercial and customer support infrastructure. We expect that our 50,000 square foot facility in Irvine, California, which commenced operations in 2020, will have sufficient production capacity to support our anticipated clinical and commercial demand for the foreseeable future. We also plan to invest in sales and marketing activities, expect to incur additional general and administrative expenses and to have higher stock-based compensation expenses as we support our growth.

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products, treatment techniques or technologies. We expect our business to be impacted by the introduction of new diabetes devices and treatments by us or our competitors. In order to maintain our competitive position in the marketplace, we intend, through our experienced research and development team, to continue investing in disruptive technologies, such as a bihormonal system of the iLet, as well as pursuing the development of the iLet and Mint, our patch pump, for expanded patient populations and indications such as people with T2D.

As cost of revenue, operating expenses and capital expenditures fluctuate over time, we may experience short-term, negative impacts to our results of operations and cash flows, but we are undertaking such investments in the belief that they will contribute to long-term growth. Moreover, introduction of new products may negatively impact aspects of our financial performance such as our overall gross margins.

Regulatory Approvals and Actions

The medical devices we manufacture are subject to laws and regulation by numerous regulatory bodies, including the FDA. The laws and regulations govern, among other things, the research and development, design, testing, manufacture, packaging, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution and import and export of medical devices. Any adverse event involving any products that we distribute could result in future corrective actions, such as recalls or customer notifications, or regulatory agency actions, which could include warning letters, inspection, mandatory recalls or other enforcement actions. For example, in January 2026, we received a Warning Letter ("Warning Letter") from the FDA following inspection of our facility in Irvine, California that occurred from June 9, 2025 through June 26, 2025. In the Warning Letter, the FDA cited deficiencies in the response letters we sent to the FDA following the FDA's issuance of a Form 483, List of Inspectional Observations ("Form 483") in June 2025. The Warning Letter highlights non-conformities observed by the FDA in relation to our Quality Management System, Medical Device Reporting, and Correction and Removals, which were previously communicated by the FDA in the Form 483. We have responded to the FDA regarding the Warning Letter and continue to work to address the FDA's observations. In the future, we also intend to pursue additional products, such as a bihormonal system of the iLet, as well as pursue the development of the iLet and Mint, our patch pump, for expanded patient populations and indications such as people with T2D, which will increase our expenses and subject us to increased regulatory-related risks.

For additional information regarding regulatory approval and actions, including the Warning Letter and the Form 483, see the section titled "Business—Government Regulation and Product Approval" in Part I, Item 1. "Business" in our Annual Report on Form 10-K for the year ended December 31, 2025, the related risk factors described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2025, and the risk factors described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q.

Seasonality

We anticipate that the revenue generated from our product sales will vary from quarter to quarter as we continue to commercialize the iLet. Specifically, we expect to typically experience lower sales in the first quarter of each year compared to the preceding fourth quarter. This seasonal sales pattern in the United States is associated with the annual insurance deductible resets and coinsurance requirements of the medical insurance plans providing coverage to PWD using the iLet.

Macroeconomic Factors, Global Supply Chain Challenges and Inventory

Our costs are subject to fluctuation, and we continue to evaluate contributing factors, specifically those leading to inflationary cost increases in logistics, price of raw materials, cost of labor, transportation and operating supplies. While we are experiencing higher raw material, labor, transportation, and operating supply costs, we intend to continue to work to improve productivity to help offset these costs as we navigate these global macroeconomic challenges, including tariffs or other trade measures, future bank

failures, increased geopolitical tensions and conflicts, global pandemics, global economic conditions, including changes in monetary and fiscal policy, U.S. political developments and other sources of instability.

We currently rely on a number of suppliers who manufacture the components of the iLet and obtain them on a purchase order basis. We have a supply agreement with Unomedical for the production of infusion sets for our iLet, a contract manufacturing agreement with PMC SMART Solutions LLC (PMC) for the manufacture of our cartridge connectors and a supplier quality agreement with Maxon Precision Motors, Inc. (Maxon) for the supply of pump motors for our iLet. Unomedical, PMC and Maxon are our only suppliers of infusion sets, cartridge connections and pump motors, respectively. For additional information regarding the risks of our reliance on these suppliers, please see the risk factors described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2025, and the risk factors described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q.

To date, we have not experienced a material interruption in supply to our customers. However, there may be times at which we determine that our inventory does not meet our product requirements or we maintain an insufficient level of inventory. We may also over- or underestimate the quantities of required components, in which case we may expend extra resources or be constrained in the amount of end product that we can procure. These factors subject us to the risk of obsolescence and expiration, which may lead to impairment charges.

Components of Results of Operations

Net Sales

We generate product revenue from the sale of the iLet and single-use products that are used together with the iLet, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body. We recognize revenue when control of the promised goods or services is transferred to our distributor and pharmacy partners, in an amount that reflects the consideration we expect to receive, net of estimated returns and variable consideration adjustments, including rebates, chargebacks and patient assistance, which differ by product and sales mix. Revenue is recognized either over time or at a point in time, depending on when control of the associated performance obligation is transferred to the customer.

Cost of Sales

Cost of sales includes raw materials, labor costs, manufacturing overhead expenses, royalties, freight, import tariffs, scrap and reserves for expected warranty costs and excess and obsolete inventory. Manufacturing overhead expenses include expenses relating to manufacturing engineering, material procurement, inventory and quality control, facilities, depreciation, information technology and operations supervision and management.

Gross Profit and Gross Margin

Gross profit and gross margin, or gross profit as a percentage of revenue, has been and will continue to be affected by various factors, including the timing of new patient adoption, iLet and associated single-use products sales, reimbursement, length of product usage, our introduction of new products, including the costs associated with producing and bringing those new products to market, cost reduction and operational efficiency. As a result of the small revenue recognized at or around the date the iLet is sold in the PBP channel, we absorb initial negative gross margin. iLet sales in the PBP channel are generally expected to start generating cumulative positive gross margin for us beyond the third month the user uses the iLet and continues to purchase single-use products. Given the differences in the timing and amount of outlays which correlate directly to revenue between the DME and PBP channels, changes in our future sales mix may also impact our gross profit and gross margin.

Operating Expenses

Our operating expenses consist of (i) research and development expenses, (ii) sales and marketing expenses and (iii) general and administrative expenses.

Research and Development

Our research and development expenses include engineering and clinical trial activities for the iLet and Mint, our patch pump, regulatory efforts, personnel costs such as salaries, bonuses, stock-based compensation and benefits, payments under third-party license agreements, supplies, development prototypes, design and testing services, depreciation and allocated facilities and information technology expenses, all of which are expensed as incurred. We track research and development expenses by individual product candidate. We expect research and development expenses to increase significantly for the foreseeable future as we advance clinical development, pursue new products and indications including the bihormonal system and potential T2D use, enhance the iLet

and Mint, expand technical and operational staffing, make required payments under license arrangements, and establish commercial scale manufacturing capabilities.

Sales and Marketing

We are in the early commercialization stages of the iLet and are focused on driving awareness and adoption among new customers. Sales and marketing expenses primarily include personnel costs for our sales and clinical teams, the development of customer support infrastructure, marketing and branding activities, healthcare conference and market research costs, payer education and market access initiatives, data purchases, website and consulting fees, and facilities, travel, and other related operating expenses. We anticipate a significant increase in sales and marketing expenses for the foreseeable future to support the continued commercialization of the iLet and our future products.

General and Administrative

General and administrative expenses include personnel-related costs, including salaries, bonuses, stock-based compensation expense and benefits for our personnel in executive, legal, finance, accounting, human resources, information technology, quality assurance and other administrative functions, as well as expenses for patent filings, legal services, accounting and tax services, insurance, travel, facilities and depreciation. We expect these expenses to increase significantly as we continue operating as a public company, driven by higher professional services costs, director and officer insurance, investor and public relations activities and compliance with SEC and stock exchange listing requirements. We anticipate a significant increase in general and administrative expenses for the foreseeable future in order to continue to scale the business and support future demand.

Other Income (Expense)

Our other income (expense) consists of (i) interest income, and (ii) other income (expense).

Interest Income

Interest income consists of cash interest earned on our cash, cash equivalents and short-term and long-term investment balances.

Other Income (Expense)

Other income (expense) consists of miscellaneous income or expenses unrelated to our core operations.

Results of Operations

Comparison of the three and nine months ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated:

	Three Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Net sales	$ 35,505	$ 27,253	$ 8,252	30%
Cost of sales[(1)]	15,174	12,134	3,040	25%
Gross profit	20,331	15,119	5,212	34%
Operating expenses:				
Research and development[(1)]	11,975	8,195	3,780	46%
Sales and marketing[(1)]	25,124	16,045	9,079	57%
General and administrative[(1)]	9,841	7,922	1,919	24%
Total operating expenses	46,940	32,162	14,778	46%
Loss from operations	(26,609)	(17,043)	(9,566)	56%
Other income (expense):				
Interest income	2,258	2,833	(575)	-20%
Other income (expense), net	(2)	1	(3)	*
Total other income (expense), net	2,256	2,834	(578)	-20%
Net loss	$ (24,353)	$ (14,209)	$ (10,144)	71%

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
Net sales	$ 95,144	$ 68,130	$ 27,014	40%
Cost of sales[(1)]	39,474	31,537	7,937	25%
Gross profit	55,670	36,593	19,077	52%
Operating expenses:				
Research and development[(1)]	32,571	24,658	7,913	32%
Sales and marketing[(1)]	70,499	45,070	25,429	56%
General and administrative[(1)]	29,058	22,422	6,636	30%
Total operating expenses	132,128	92,150	39,978	43%
Loss from operations	(76,458)	(55,557)	(20,901)	38%
Other income (expense):				
Interest income	6,811	8,274	(1,463)	-18%
Other income (expense), net	(4)	(1)	(3)	*
Change in fair value of warrant liabilities	—	(12,450)	12,450	-100%
Total other income (expense), net	6,807	(4,177)	10,984	-263%
Net loss	$ (69,651)	$ (59,734)	$ (9,917)	17%

* Not meaningful

(1) Includes stock-based compensation expense. See Note 11, Stock-Based Compensation, for stock-based compensation expense by financial statement line item.

Net Sales

Net sales for the three months ended September 30, 2026 were $35.5 million, compared to $27.3 million for the three months ended September 30, 2025. The increase in net sales of $8.2 million was primarily driven by an increase in the number of single-use products sold, correlated to the growth in our installed base, and growth in new patient starts. For the three months ended September 30, 2026, single-use products accounted for 68% of net sales, up from 47% for the three months ended September 30, 2025.

For the three months ended September 30, 2026, 62% of net sales were generated through the DME channel and 38% through the PBP channel, compared to 77% and 23%, respectively, for the three months ended September 30, 2025. The shift toward the PBP channel was driven by expanded pharmacy benefit coverage enabled through contracts with PBMs and their affiliated health plans, resulting in a higher proportion of new patient starts being reimbursed through this channel.

Net sales for the nine months ended September 30, 2026 were $95.1 million, compared to $68.1 million for the nine months ended September 30, 2025. This increase in net sales of $27.0 million was primarily driven by an increase in the number of single-use products sold, correlated to the growth in our installed base, and growth in new patient starts. For the nine months ended September 30, 2026, single-use products accounted for 63% of net sales, up from 44% for the nine months ended September 30, 2025.

For the nine months ended September 30, 2026, 62% of net sales were generated through the DME channel and 38% through the PBP channel, compared to 79% and 21%, respectively, for the nine months ended September 30, 2025. The shift toward the PBP channel was driven by expanded pharmacy benefit coverage, resulting in a larger percentage of new patient starts reimbursed through this channel.

Cost of Sales

Cost of sales for the three months ended September 30, 2026 was $15.2 million, compared to $12.1 million for the three months ended September 30, 2025. This increase of $3.1 million was primarily attributable to increased volumes of single-use products and iLets sold through the PBM channel.

Cost of sales for the nine months ended September 30, 2026 was $39.5 million, compared to $31.5 million for the nine months ended September 30, 2025. This increase of $8.0 million was primarily attributable to increased volumes of single-use products and iLets sold through the PBM channel.

Gross Profit and Gross Margin

Gross profit for the three months ended September 30, 2026 was $20.3 million, compared to $15.1 million for the three months ended September 30, 2025. Gross margin was 57% for the three months ended September 30, 2026, compared to 55% in the three months ended September 30, 2025. Gross profit increased by $5.2 million, primarily driven by higher sales volume. Gross margin improved year over year due to increased production scale, lower warranty expense and improved cost absorption.

Gross profit for the nine months ended September 30, 2026 was $55.7 million, compared to $36.6 million for the nine months ended September 30, 2025. Gross margin was 59% for the nine months ended September 30, 2026, compared to 54% in the nine months ended September 30, 2025. Gross profit increased by $19.1 million, primarily driven by higher sales volume. Gross margin improved year over year due to increased production scale, lower warranty expense and improved cost absorption.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2026 were $12.0 million, compared to $8.2 million for the three months ended September 30, 2025. The increase of $3.8 million was primarily attributable to a net increase of $3.1 million in materials, engineering and clinical trial-related expenses incurred in the development of Mint, our patch pump, the bihormonal system of the iLet and incremental software and product updates. The remaining increase is attributable to payroll-related expenses, including stock-based compensation, driven by an increase in headcount focused on supporting our innovation activities.

Research and development expenses for the nine months ended September 30, 2026 were $32.6 million, compared to $24.7 million for the nine months ended September 30, 2025. The increase of $7.9 million was primarily attributable to a net increase of $4.2 million in materials, engineering and clinical trial-related expenses incurred in the development of Mint, our patch pump, the bihormonal system of the iLet and incremental software and product updates. The remaining increase is attributable to payroll-related expenses, including stock-based compensation, driven by an increase in headcount focused on supporting our innovation activities.

The table below summarizes the nature of research and development expense by major expense category:

	Three Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
External research and development[(1)]	$ 2,341	$ 1,129	$ 1,212	107%
Internal research and development[(2)]	8,075	6,173	1,902	31%
Stock-based compensation	1,559	893	666	75%
Total research and development expense	$ 11,975	$ 8,195	$ 3,780	46%

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
	(in thousands, except percentages)			
External research and development[(1)]	$ 4,742	$ 4,250	$ 492	12%
Internal research and development[(2)]	23,496	18,089	5,407	30%
Stock-based compensation	4,333	2,319	2,014	87%
Total research and development expense	$ 32,571	$ 24,658	$ 7,913	32%

(1) External research and development costs primarily include expenses incurred with third parties such as clinical research organizations conducting the clinical trials and engineering and product development consulting services associated with our development of the iLet and Mint, our patch pump.

(2) Internal research and development costs primarily include personnel-related expenses for research and development functions, excluding stock-based compensation and internal costs to manufacture product candidates before FDA marketing authorization, such as raw materials and internal facilities-related expenses.

Sales and Marketing Expenses

Sales and marketing expenses for the three months ended September 30, 2026 were $25.1 million, compared to $16.0 million for the three months ended September 30, 2025. The increase of $9.1 million was primarily attributable to an increase of $6.2 million in payroll-related costs, including salaries and wages, sales incentive bonuses, and stock-based compensation due to an increase in headcount of our sales force and customer care team in connection with the expansion of our sales territories within the United States. The remaining increase includes healthcare provider (HCP)-related marketing and travel-related costs to support our business growth.

Sales and marketing expenses for the nine months ended September 30, 2026 were $70.5 million, compared to $45.1 million for the nine months ended September 30, 2025. The increase of $25.4 million was primarily attributable to an increase of $17.5 million in payroll-related costs, including salaries and wages, sales incentive bonuses, and stock-based compensation due to an increase in headcount of our sales force and customer care team in connection with the expansion of our sales territories within the United States. The remaining increase includes HCP-related marketing and training and travel-related costs to support our business growth.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2026 were $9.8 million, compared to $7.9 million for the three months ended September 30, 2025. The increase of $1.9 million was primarily attributable to a $2.1 million increase in software-related expenses, professional service fees and payroll-related expenses, including stock-based compensation, due to an increase in headcount. These increases were partially offset by a decrease in legal fees.

General and administrative expenses for the nine months ended September 30, 2026 were $29.1 million, compared to $22.4 million for the nine months ended September 30, 2025. The increase of $6.7 million was primarily attributable to an increase of $3.7 million in payroll-related expenses, including stock-based compensation, due to an increase in headcount, as well as increases of $3.5 million in software-related expenses, quality remediation expenses, and professional service fees. These increases were partially offset by a decrease in accounting and legal fees.

Other Income (Expense)

Total other income (expense), net for the three months ended September 30, 2026 was $2.3 million of income, compared to $2.8 million of income for the three months ended September 30, 2025. This change of $0.6 million was primarily attributable to lower interest income on investments, reflecting a reduction in invested balances as IPO proceeds were used to fund operating activities.

Total other income (expense), net for the nine months ended September 30, 2026 was $6.8 million of income, compared to $4.2 million of expense for the nine months ended September 30, 2025. This change of $11.0 million was primarily attributable to the absence of a loss from the change in fair value of warrant liabilities in the current period, as the warrants were remeasured and net exercised in connection with our IPO in January 2025, partially offset by lower interest income on investments, reflecting a reduction in invested balances as IPO proceeds were used to fund operating activities.

Selected Quarterly Financial Information

The following tables set forth our selected unaudited quarterly statements of operations data for each of the eight quarters in the period ended September 30, 2026. The information for each of these quarters has been prepared in accordance with GAAP, on a basis consistent with our unaudited condensed financial statements included elsewhere in this Quarterly Report and our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2025 and include, in our opinion, all normal recurring adjustments necessary for the fair presentation of the results of operations for the periods presented, with the exception of adjusted earnings before interest, taxes, depreciation and amortization (EBITDA), which is a non-GAAP financial measure discussed below. Our historical quarterly results are not necessarily indicative of the results that may be expected in the future and these quarterly results are not necessarily indicative of our operating results for a full year. The following quarterly financial information should be read in conjunction with our financial statements and related notes thereto included elsewhere in this Quarterly Report.

The following tables set forth our selected unaudited quarterly statements of operations data for the periods presented:

	Three Months Ended			
	December 31, 2025	March 31, 2026	June 30, 2026	September 30, 2026
	(unaudited) (in thousands, except percentages)			
Net sales	$ 32,121	$ 27,626	$ 32,013	$ 35,505
Cost of sales[1]	13,177	11,189	13,111	15,174
Gross profit	18,944	16,437	18,902	20,331
Gross margin	59.0%	59.5%	59.0%	57.3%
Operating expenses:				
Research and development[1]	10,131	10,356	10,240	11,975
Sales and marketing[1]	16,334	20,735	24,640	25,124
General and administrative[1]	8,603	9,617	9,600	9,841
Total operating expenses	35,068	40,708	44,480	46,940
Loss from operations	(16,124)	(24,271)	(25,578)	(26,609)
Other income (expense):				
Interest income	2,658	2,376	2,177	2,258
Other income (expense), net	—	—	(2)	(2)
Total other income (expense), net	2,658	2,376	2,175	2,256
Net loss	$ (13,466)	$ (21,895)	$ (23,403)	$ (24,353)
Adjusted EBITDA	$ (10,512)	$ (17,718)	$ (17,656)	$ (18,906)

	Three Months Ended			
	December 31, 2024	March 31, 2025	June 30, 2025	September 30, 2025
	(unaudited) (in thousands, except percentages)			
Net sales	$ 20,440	$ 17,639	$ 23,238	$ 27,253
Cost of sales[1]	8,751	8,668	10,735	12,134
Gross profit	11,689	8,971	12,503	15,119
Gross margin	57.2%	50.9%	53.8%	55.5%
Operating expenses:				
Research and development[1]	9,214	7,590	8,873	8,195
Sales and marketing[1]	10,804	13,402	15,623	16,045
General and administrative[1]	4,708	6,621	7,879	7,922
Total operating expenses	24,726	27,613	32,375	32,162
Loss from operations	(13,037)	(18,642)	(19,872)	(17,043)
Other income (expense):				
Interest income	951	2,436	3,005	2,833
Other income (expense), net	—	—	(2)	1
Change in fair value of warrant liabilities	(6,022)	(12,450)	—	—
Total other income (expense), net	(5,071)	(10,014)	3,003	2,834
Net loss	$ (18,108)	$ (28,656)	$ (16,869)	$ (14,209)
Adjusted EBITDA	$ (11,254)	$ (15,535)	$ (14,526)	$ (12,179)

[1] Includes stock-based compensation expense as follows:

	Three Months Ended			
	December 31, 2025	March 31, 2026	June 30, 2026	September 30, 2026
	(unaudited) (in thousands)			
Cost of sales	$ 143	$ 164	$ 206	$ 187
Research and development	886	1,138	1,636	1,559
Sales and marketing	1,237	1,615	2,239	2,136
General and administrative	2,037	2,489	2,935	2,833
Total stock-based compensation expense	$ 4,303	$ 5,406	$ 7,016	$ 6,715

	Three Months Ended			
	December 31, 2024	March 31, 2025	June 30, 2025	September 30, 2025
	(unaudited)			
	(in thousands)			
Cost of sales	$ 74	$ 106	$ 153	$ 140
Research and development	300	502	924	893
Sales and marketing	511	801	1,314	1,273
General and administrative	666	1,395	2,408	2,172
Total stock-based compensation expense	$ 1,551	$ 2,804	$ 4,799	$ 4,478

The following tables set forth our selected unaudited quarterly key business metrics for the periods presented:

	Three Months Ended			
	December 31, 2025	March 31, 2026	June 30, 2026	September 30, 2026
	(unaudited)			
% of Total Net Sales:				
Durable Medical Equipment (DME) Channel	70%	61%	64%	62%
Pharmacy Benefit Plan (PBP) Channel	30%	39%	36%	38%
Total	100%	100%	100%	100%
% of New Patient Starts (NPS) Reimbursed Through Pharmacy	Low 30s %	High 30s %	High 30s %	High 30s %

	Three Months Ended			
	December 31, 2024	March 31, 2025	June 30, 2025	September 30, 2025
	(unaudited)			
% of Total Net Sales:				
Durable Medical Equipment (DME) Channel	88%	78%	80%	77%
Pharmacy Benefit Plan (PBP) Channel	12%	22%	20%	23%
Total	100%	100%	100%	100%
% of New Patient Starts (NPS) Reimbursed Through Pharmacy	Low-teens %	Low 20s %	High 20s %	Low 30s %

Adjusted EBITDA

In addition to our financial results determined in accordance with GAAP, we believe the following adjusted EBITDA non-GAAP measure is useful in evaluating our operating performance. We use adjusted EBITDA to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that this non-GAAP financial measure, when taken together with the corresponding GAAP financial measures, provide meaningful supplemental information regarding our performance by excluding certain items that may not be indicative of our business, results of operations, or outlook. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. In addition, other companies, including companies in our industry, may calculate similarly-titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison. A reconciliation is provided below for adjusted EBITDA to the most directly comparable financial measure stated in accordance with GAAP. Investors are encouraged to review the related GAAP financial measures and the reconciliation of this non-GAAP financial measure to its most directly comparable GAAP financial measure, and not to rely on any single financial measure to evaluate our business.

The following table presents a reconciliation of adjusted EBITDA from the most comparable GAAP measure, net loss, for the eight quarters in the period ended September 30, 2026:

	Three Months Ended			
	December 31, 2025	March 31, 2026	June 30, 2026	September 30, 2026
	(unaudited) (in thousands)			
Net loss	$ (13,466)	$ (21,895)	$ (23,403)	$ (24,353)
Add:				
Depreciation expense	537	585	709	892
Stock-based compensation expense	4,303	5,406	7,016	6,715
Interest income	(2,658)	(2,376)	(2,177)	(2,258)
Income tax expense (benefit)	—	—	2	2
Litigation settlement and other related expense	210	—	135	66
Quality system remediation[(1)]	562	562	62	30
Adjusted EBITDA	$ (10,512)	$ (17,718)	$ (17,656)	$ (18,906)

(1) Amounts presented under "Quality system remediation" for the three months ended December 31, 2025, March 31, 2026, June 30, 2026, and September 30, 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.

	Three Months Ended			
	December 31, 2024	March 31, 2025	June 30, 2025	September 30, 2025
	(unaudited) (in thousands)			
Net loss	$ (18,108)	$ (28,656)	$ (16,869)	$ (14,209)
Add:				
Depreciation expense	232	303	347	386
Stock-based compensation expense	1,551	2,804	4,799	4,478
Interest income	(951)	(2,436)	(3,005)	(2,833)
Income tax expense	—	—	2	(1)
Litigation settlement and other related expense	—	—	200	—
Change in fair value of warrant liabilities	6,022	12,450	—	—
Adjusted EBITDA	$ (11,254)	$ (15,535)	$ (14,526)	$ (12,179)

Adjusted EBITDA is a key performance measure that we use to assess our operating performance. Because adjusted EBITDA facilitates internal comparisons of our historical operating performance on a more consistent basis, we use this measure for business planning purposes.

We calculate adjusted EBITDA as net loss adjusted to exclude (i) depreciation expense, (ii) stock-based compensation expense, (iii) interest income, (iv) income tax expense (benefit), (v) litigation settlement and other related expenses, (vi) quality system remediation and (vii) change in fair value of warrant liabilities.

Some of the limitations of adjusted EBITDA include: (i) adjusted EBITDA does not properly reflect capital commitments to be paid in the future and (ii) although depreciation expense includes non-cash charges, the underlying assets may need to be replaced and adjusted EBITDA does not reflect these capital expenditures. Our adjusted EBITDA may not be comparable to similarly titled measures of other companies because they may not calculate adjusted EBITDA in the same manner as we calculate the measure, limiting its usefulness as a comparative measure. In evaluating adjusted EBITDA, you should be aware that in the future we will incur expenses similar to the adjustments in this presentation. Our presentation of adjusted EBITDA should not be construed as an inference that our future results will be unaffected by these expenses or any unusual or non-recurring items. When evaluating our performance, you should consider adjusted EBITDA alongside other financial performance measures, including our net loss and other GAAP results.

Selected Quarterly Trends

Net sales

Net sales generally increased across the periods presented, primarily due to higher sales volumes, driven by continued growth in new patient starts and the installed base, which resulted in higher sales of both iLets and supplies. The quarterly trend reflects continued commercial adoption of the iLet and growth in our installed base, with seasonal decreases in net sales in the first quarters of 2026 and 2025 compared to the immediately preceding fourth quarters.

Cost of sales

Cost of sales generally increased across the periods presented, primarily driven by higher sales volume, including increased pharmacy channel iLet sales, partially offset by improved manufacturing efficiencies. Cost of sales increased in the third quarter of 2026 compared to the second quarter of 2026, primarily due to higher sales volume and a less favorable product mix within the DME channel, reflecting a higher contribution from DME supplies and a lower contribution from DME iLets. Consistent with seasonal sales trends, cost of sales decreased in the first quarters of 2026 and 2025 compared to the immediately preceding fourth quarters.

Gross Margin

Gross margin generally improved across the periods presented through the second quarter of 2026, driven by lower material costs, increased production volumes, and improved manufacturing cost absorption. Gross margin decreased to 57.3% in the third quarter of 2026 from approximately 59% in the second quarter of 2026, primarily due to unfavorable product mix within the DME channel.

The proportion of new patient starts reimbursed through the PBP remained in the high-30% range in the third quarter of 2026, consistent with the first and second quarter of 2026.

Operating expenses

Research and development expenses generally increased over the periods presented, reflecting the timing of various clinical trial-related expenses, as well as increased engineering, materials, third-party consulting and payroll-related costs to support ongoing product development and enhancement efforts, including Mint, our patch pump, the bihormonal system, and incremental software and product updates.

Sales and marketing expenses increased across the periods presented, primarily driven by higher payroll-related costs associated with expansion of the sales force and customer care team, as well as increased marketing efforts.

General and administrative expenses generally increased over the periods presented, primarily due to higher payroll-related costs to support growth.

Adjusted EBITDA

Adjusted EBITDA fluctuated across the periods presented, reflecting the impact of revenue seasonality, continued investment in operating expenses and changes in gross margin. Adjusted EBITDA improved through the second half of 2025 as revenue growth, improved gross margins and operating leverage more than offset increases in operating expenses. Adjusted EBITDA declined in the first quarter of 2026 compared to the fourth quarter of 2025, remained relatively consistent in the second quarter of 2026, and declined further in the third quarter of 2026, primarily reflecting continued investment in operating expenses to support commercial growth. Variability across the periods presented was also impacted by discrete items, including a milestone payment to Xeris in the fourth quarter of 2024 and quality system remediation expenses beginning in the fourth quarter of 2025 and continuing through 2026.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. To date, research and development, market development and commercial launch activities have accounted for a significant portion of our overall operating expenses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the commercialization of Mint, our patch pump, and further develop the bihormonal system of the iLet.

To date, we have funded our operations primarily through equity financings, including our IPO completed in January 2025 and our follow-on public offering in September 2026, as well as revenue generated from the sale of the iLet and related single-use

products. We have also received payments under collaboration agreements and government grants. As of September 30, 2026, we had cash, cash equivalents and short-term and long-term investments of $373.6 million.

Cash Flows

The following table summarizes our cash flows for the periods presented:

	Nine Months Ended September 30,	
	2026	2025
	(in thousands)	
Net cash used in operating activities	$ (50,741)	$ (42,298)
Net cash used in investing activities	(65,308)	(163,463)
Net cash provided by financing activities	166,024	213,814
Net increase in cash, cash equivalents and restricted cash	$ 49,975	$ 8,053

Operating Activities

Net cash used in operating activities was $50.7 million for the nine months ended September 30, 2026, compared to $42.3 million for the nine months ended September 30, 2025. The increase in net cash used of $8.4 million was primarily driven by a higher net loss in the current period and the absence of a $12.5 million non-cash adjustment for the change in fair value of warrant liabilities recorded in the prior-year period, as the warrants were net exercised in connection with our IPO in January 2025. These impacts were partially offset by higher stock-based compensation expense, favorable changes in the amortization of premiums and discounts on investments and higher depreciation expense. Working capital activity also partially offset the increase in cash used, primarily due to favorable changes in inventories and prepaid expenses and other current assets reflecting the timing of payments on software licenses and prepaid inventory, partially offset by unfavorable changes in accounts receivable and accounts payable, with the increase in accounts receivable primarily reflecting higher sales activity late in the quarter for amounts not yet due, and the change in accounts payable reflecting the timing of vendor payments on inventory and capital purchases.

Investing Activities

Net cash used in investing activities was $65.3 million for the nine months ended September 30, 2026, compared to net cash used of $163.5 million for the nine months ended September 30, 2025. The decrease of $98.1 million in net cash used in investing activities was primarily driven by a $192.8 million decrease in purchases of short-term investments and a $20.0 million increase in proceeds from maturities and redemptions of short-term investments. These decreases in cash used were partially offset by a $113.4 million increase in purchases of long-term investments, primarily from investing a portion of the proceeds from our September 2026 follow-on public offering, and a $1.3 million increase in purchases of property and equipment to support further development of Mint.

Financing Activities

In September 2026, we completed a follow-on public offering of common stock and a pre-funded warrant to purchase common stock. Net cash provided by financing activities was $166.0 million for the nine months ended September 30, 2026, compared to $213.8 million for the nine months ended September 30, 2025. The decrease of $47.8 million was primarily due to the higher proceeds from IPO-related financing activities in the prior-year period, which included $195.4 million of cash proceeds from our IPO, which, after $5.0 million of offering costs paid in prior periods, resulted in $190.4 million of net proceeds, and $15.6 million from the concurrent private placement, compared with $161.8 million of cash proceeds from the follow-on public offering, after underwriting discounts, commissions and offering expenses, in the current period. This decrease was partially offset by a $1.4 million increase in proceeds from stock option exercises and employee stock purchase plan issuances.

Future Funding Requirements

We expect our expenses to increase gradually in connection with our ongoing activities. The timing and amount of our funding requirements will depend on many factors, including:

- the cost of maintaining FDA clearance for the iLet as an automated insulin dosing system cleared for the treatment of T1D in adults and children six years of age and older, including updates and revisions to our quality system;
- the cost of maintaining FDA clearance for Mint, our patch pump, including costs associated with ongoing regulatory requirements and future product modifications;

- the cost of obtaining and maintaining FDA marketing authorization or clearance for other future indications or other product candidates, including for the iLet for T1D using both insulin and glucagon (a bihormonal system), and the iLet for T2D;
- future revenue generated by sales of the iLet and Mint, and any future product candidates, if approved or cleared;
- costs associated with scaling up and expanding our manufacturing capacity, including in preparation for the commercial launch of Mint;
- costs associated with building and expanding our sales and marketing efforts in the United States, including the commercialization of Mint and, in the future, internationally;
- costs associated with conducting research and development efforts for future improvements to the iLet or Mint, our patch pump;
- costs associated with conducting research and development efforts for future product offerings, such as bihormonal system of the iLet;
- the cost of complying with regulatory requirements;
- costs associated with capital expenditures;
- the costs associated with hiring additional personnel as our business grows;
- the costs of operating as a public company;
- costs associated with any future litigation;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the impact of geopolitical and macroeconomic events, including tariffs or other trade measures, future bank failures, increased geopolitical tensions and conflict, global pandemics, global economic conditions including changes in monetary and fiscal policy, U.S. political developments and other sources of instability that may impact our ability to access capital on acceptable terms, if at all.

Based on our current operating plans, we believe that our existing cash, cash equivalents and short-term and long-term investments, as well as cash generated from sales of our products, will be sufficient to fund our projected operating expenses and capital expenditure requirements for the foreseeable future. This assessment is based on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

We expect to finance our operations through product revenue. We may also seek additional capital in the future through equity or debt financing, collaborations or strategic alliances. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations or strategic alliances with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or investigational devices, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market products that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Other Commitments

Leases

We have entered into various non-cancelable operating leases for certain office, laboratory and manufacturing space. The leases have varying initial lease terms of approximately one to six years. For additional information, see Notes 2 and 14 of our unaudited condensed financial statements included elsewhere in this Quarterly Report.

Research and Development Costs

In May 2024, in connection with research and development activities, we entered into an exclusive worldwide Collaboration and License Agreement with Xeris which contains a number of contractual obligations. In consideration for the licenses and other rights granted to us under the Collaboration and License Agreement, we paid Xeris a one-time, non-refundable payment of $0.5 million and a one-time, non-refundable milestone payment of $3.0 million for the achievement of certain developmental milestones. In connection with entering into Phase 2 of the collaboration, we ordered and paid for clinical material totaling $0.9 million. In May 2026, we entered into a letter agreement under the Clinical Supply Agreement with Xeris for additional Phase 2 clinical material, including a one-time non-refundable payment of $0.5 million and reimbursement of certain internal and travel costs. In connection with entering into Phase 3 of the collaboration, we expect to incur development and manufacturing costs, including ordering clinical materials and technical transfer, development, and testing of the product, totaling $5.1 million. As of September 30, 2026, we have completed payments totaling $4.0 million. The payments were initially recognized in prepaid expense and other current assets in the balance sheets and a portion of the payment was expensed to research and development related to the services completed. In addition, we are required to pay tiered royalties of low double-digit percentages based on net sales of glucagon products, subject to certain reductions. We may continue to incur costs as we progress into Phase 2 and Phase 3 clinical trials. For additional information, see "Business—License and Collaboration Agreements" in our Annual Report on Form 10-K for the year ended December 31, 2025. We expect to continue to incur costs as development activities progress.

Royalty Obligations

In connection with the development, production and sale of the iLet, we have entered into certain agreements that obligate us to pay royalties based on specific production or net sales metrics. Among other obligations, certain license agreements with BU require us to pay quarterly royalties of a mid-single-digit percentage based on net sales (and royalties of a low double-digit percentage of net sales by sublicensees), of any products licensed under the agreements, which royalties are creditable against the minimum royalty amount. For additional information on these license agreements with BU, see "Business—License and Collaboration Agreements" in our Annual Report on Form 10-K for the year ended December 31, 2025. As of September 30, 2026, we have not identified any material changes to these agreements or the related royalty obligations described above.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities, that would have been established to facilitate off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed financial statements, which are prepared in accordance with GAAP. The preparation of our unaudited condensed financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our unaudited condensed financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Part I. Item 1. Note 2 to our unaudited condensed financial statements included elsewhere in this Quarterly Report, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our unaudited condensed financial statements.

Revenue Recognition

Our revenue from contracts with customers is generated from the iLet and single-use products that are used together with the iLet, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body. Our primary customers are distributors and pharmacy partners who sell our products to insulin-requiring PWD. We recognize revenue when we transfer control of the promised goods or services to customers in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services, net of estimated returns and estimated variable consideration. Variable consideration related to pharmacy rebates and chargebacks is accounted for as a reduction in revenue and is estimated based on contractual arrangements, actual sales of products qualifying for rebates or chargebacks, and historical payments made related to pharmacy rebates and chargebacks. Estimates associated with pharmacy rebates and chargebacks on products sold are the most

significant component of our variable consideration estimates and most at risk for material adjustment because of the time delay between the recording of the provision and its ultimate settlement, an interval that generally ranges from 30 to 90 days. Due to this time lag, in any given period, our adjustments to reflect actual amounts can incorporate changes of estimates related to prior periods. The amount of variable consideration that is included in the transaction price is estimated and is included in revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If the actual amounts of consideration that we receive differ from estimates, we adjust these estimates, which affects reported revenue, in the period that such variances become known or at the end of each reporting period.

We have identified the ability for a customer to access the mobile application and our promise to provide firmware upgrades to the iLet through the mobile application as distinct performance obligations, as access and support is provided throughout the standard four-year warranty period of the device. Accordingly, revenue related to the mobile application and firmware upgrades are deferred and recognized ratably over a four-year period. Given that access to the mobile application and unspecified software updates follow the same pattern of transfer to the customer and are provided over the same four-year period, we recognize revenue for these performance obligations as if they were a single performance obligation. As there is no observable standalone selling price for access to the mobile application or promise to provide firmware upgrades, we estimate standalone selling price by applying the expected cost plus a margin approach.

Stock-Based Compensation

We measure stock options and employee stock purchase plan purchase rights based on their fair value on the date of grant using the Black-Scholes option pricing model. We measure restricted stock units based on the fair value of our common stock on the date of grant. Stock-based compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award for employees and directors and the period during which services are performed for non-employees. Stock-based compensation expense for non-employee awards is recognized in the same manner as if we had paid cash in exchange for the goods or services, which is generally the vesting period of the award. We have issued awards with only service-based vesting conditions and record the expense for these awards using the straight-line method. We have not issued any stock-based awards with performance-based or market-based vesting conditions.

We determined the assumptions for the Black-Scholes option pricing model as discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

- *Fair Value of Our Common Stock*—The fair value of stock-based awards is determined based on the market price of our common stock on the date of grant.
- *Expected Volatility—E*xpected volatility is derived from the average historical stock volatilities of several public companies within our industry that we consider to be comparable to our business over a period equivalent to the expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term for our stock options was calculated based on the weighted-average vesting term of the awards and the contract period, or the simplified method.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to expected term of the stock options.
- *Expected Dividend Yield*—The expected dividend is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.

Forfeitures are accounted for as they occur.

See Part I. Item 1. Note 11 of our unaudited condensed financial statements included elsewhere in this Quarterly Report for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. Certain of these assumptions involve inherent uncertainties and generally require significant analysis and judgment to develop. Changes in these assumptions can materially impact the fair value and ultimately how much stock-based compensation expense is recognized.

Recent Accounting Pronouncements

A description of recently issued accounting standards that may potentially impact our financial position, results of operations, and cash flows is included in Part I. Item 1. Note 2 to our unaudited condensed financial statements included elsewhere in this Quarterly Report.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups (JOBS) Act. For as long as we remain an "emerging growth company", we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to: (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act; (ii) reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and (iii) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period, and therefore, we are not subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies; however, we may adopt certain new or revised accounting standards early. We may use these provisions until the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We are no longer a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act because our annual revenue exceeded $100.0 million during the most recently completed fiscal year. However, we may continue to take advantage of certain of the scaled disclosures available to smaller reporting companies through the end of the year ended December 31, 2026 and until our Form 10-Q for the quarter ended March 31, 2027. If we are a smaller reporting company or are otherwise eligible to take advantage of the scaled disclosure available to smaller reporting companies at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of unaudited condensed financial statements in our Quarterly Report on Form 10-Q and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are eligible to take advantage of the scaled disclosures available to "smaller reporting company" as defined by Item 10(f)(1) of Regulation S-K. Accordingly, we are not required to provide the information required by this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of September 30, 2026, management, with the participation of our principal executive officer and our principal financial officer, have evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report. Based on such evaluation, our principal executive officer and our principal financial officer have concluded that as of September 30, 2026, our disclosure controls and procedures were effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2026, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. In September 2026, a purported stockholder of our company filed a securities class action against our company and certain of our executive officers in the United States District Court for the Central District of California, captioned *Holtzman vs. Beta Bionics, Inc. et al.*, Case No. 8:26-cv-2612-JWH (KESx). The complaint alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and SEC Rule 10b-5 promulgated thereunder, by making material misstatements or omissions concerning the safety, efficacy, and commercial success of iLet. The complaint seeks, on behalf of the putative class, unspecified damages, pre- and post-judgment interest, attorneys' fees, expert fees and costs, as well as class certification and such other relief as the court may deem just and proper. We intend to vigorously defend against the claims in this action. Any potential loss arising from this claim is not currently probable or estimable.

Item 1A. Risk Factors.

Refer to the "Item 1A. Risk Factors" section in our Annual Report on Form 10-K for the year ended December 31, 2025 for a discussion of risks to which our business, financial condition, results of operations and cash flows are subject. Other than as described below, there have been no material changes to the risk factors disclosed in the aforementioned Annual Report.

Risks Related to Our Limited Commercial History, Financial Position and Need for Additional Capital

We may need to raise additional funds in the future, and these funds may not be available on acceptable terms, if at all.

The development of medical devices is capital-intensive. Our operations have consumed substantial amounts of cash since inception. As of September 30, 2026, our cash, cash equivalents and short-term investments were $240.3 million. In January 2025, we completed our initial public offering and a concurrent private placement, pursuant to which we received aggregate net proceeds of approximately $190.4 million and approximately $15.6 million, respectively, in each case after deducting underwriting discounts, commissions, and other offering expenses. In September 2026, we completed a follow-on public offering of common stock and a pre-funded warrant to purchase common stock, resulting in net proceeds of approximately $161.3 million after underwriting discounts, commissions and offering expenses. Based on our current and planned use of the net proceeds of these offerings and our current cash, cash equivalents and short-term investments, we estimate that our funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for the foreseeable future. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control.

We expect our expenses to increase gradually in connection with our ongoing activities. The timing and amount of our funding requirements, will depend on many factors, including:

- the cost of maintaining FDA clearance for the iLet as an automated insulin dosing system cleared for the treatment of T1D in adults and children six years of age and older, including updates and revisions to our quality system;
- the cost of maintaining FDA clearance for Mint, our patch pump, including costs associated with ongoing regulatory requirements and future product modifications;
- the cost of obtaining and maintaining FDA marketing authorization or clearance for other future indications or other product candidates, including for the iLet for T1D using both insulin and glucagon (a bihormonal system) and the iLet for T2D;
- the cost of commercializing our Mint patch pump;
- future revenue generated by sales of the iLet and Mint and any future product candidates, if approved or cleared;
- costs associated with scaling up and expanding our manufacturing capacity, including in preparation for the commercial launch of Mint;
- costs associated with building and expanding our sales and marketing efforts in the United States, including the commercialization of Mint, and, in the future, internationally;
- costs associated with conducting research and development efforts for future improvements to the iLet or Mint, our patch pump;

- costs associated with conducting research and development efforts for future product offerings, such as bihormonal system of the iLet;
- the cost of complying with regulatory requirements;
- costs associated with capital expenditures;
- the costs associated with hiring additional personnel as our business grows;
- the costs of operating as a public company;
- costs associated with any future litigation;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the impact of geopolitical and macroeconomic events, including tariffs or other trade measures, future bank failures, increased geopolitical tensions and conflict, global pandemics, global economic conditions including changes in monetary and fiscal policy, U.S. political developments and other sources of instability that may impact our ability to access capital on acceptable terms, if at all.

We may require additional capital beyond the proceeds of these offerings, which we may raise through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties. Furthermore, we expect to incur additional costs associated with operating as a public company. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development, manufacturing and commercialization efforts.

Our ability to raise additional funds may also be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from geopolitical tensions, such as the ongoing war in Ukraine, the Israel and Palestine conflict, government actions implemented as a result of either of the foregoing, as well as tensions with and economic uncertainty in China, tariffs and other trade measures, inflation, interest rates, liquidity concerns at, and failures of, banks and other financial institutions, changes in monetary and fiscal policy and U.S. political developments and other sources of instability. If the equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Market volatility may further adversely impact our ability to access capital as and when needed.

If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs or manufacturing or commercialization efforts. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Business, Strategy and Industry

We may not be able to successfully commercialize Mint, our patch pump, on the timeline we anticipate or at all, and Mint may not achieve market acceptance among patients, healthcare providers, or payors, which would adversely affect our business, financial condition, and results of operations.

In September 2026, we announced that the FDA had cleared Mint, our patch pump. Our future growth depends in significant part on our ability to successfully commercialize Mint, and we have no experience launching a patch pump. Mint is a new product with a different form factor from the iLet, which is currently our only commercialized product and source of revenue. Our strategy for Mint therefore requires us to execute on the risks described below, many of which are outside our control.

We currently expect to commercially launch Mint in the United States by the end of the first quarter of 2027. This timeline has changed before, and we may not meet it. Our ability to launch depends on, among other things:

- completing scale-up and validation of manufacturing processes, including those of our contract manufacturers and component suppliers;
- building sufficient inventory;
- obtaining and maintaining quality system compliance;

- training and expanding our sales, clinical support, and customer service organizations;
- developing training, onboarding, and technical support for a new product category; and
- completing any remaining regulatory, software, or cybersecurity activities required for launch.

Any delay in these activities, or any product quality, reliability, or supply issue, could postpone the launch, increase our costs, harm our reputation, or lead to recalls, corrective actions, or field safety notices.

Risks Related to the Development, Regulatory Approval and Commercialization of our iLet Bionic Pancreas and Product Candidates

We are highly dependent on the success of our iLet and Mint for the treatment of T1D, which are cleared by the FDA for commercial sale in the United States for the treatment of T1D. If we are unable to obtain and maintain regulatory clearance or approval for planned modifications to the iLet or Mint or for new indications, or for any current or future development-stage products, such as 3D Intelligence, iLet 3D and Mint 3D, or if we are unsuccessful in our efforts to continue to commercialize our cleared products, our business will be materially harmed.

We currently have one commercialized device, the iLet, which is an automated insulin dosing system cleared for the treatment of T1D in adults and children six years of age and older. Our business primarily depends on the successful commercialization of the iLet. In September 2026, we announced FDA clearance of Mint, our patch pump featuring a transformative reusable and disposable architecture, for the treatment of T1D in adults and children six years of age and older, and our expected initiation of full commercialization of Mint in the United States in the first quarter of 2027. We currently have no other products cleared for sale and may never be able to develop other marketable products. Additionally, in September 2026, we announced our submission of a 510(k) application to the FDA for 3D Intelligence, our anticipated next-generation insulin dosing algorithm and, subject to and following regulatory clearance by the FDA, our expectation for 3D Intelligence to power both iLet 3D and Mint 3D, our investigational next-generation automated insulin delivery platforms. In October 2026, pursuant to discussion with FDA, we voluntarily withdrew the 510(k) notification for 3D Intelligence, and intend to revise and resubmit it mid-fourth quarter of 2026. Our iLet will require additional clinical development, testing and marketing authorization or regulatory clearance before we are permitted to commercialize it in a bihormonal system for the treatment of T1D or for any future indications we may pursue. Further, as we develop a bihormonal system of the iLet, which is designed to use both insulin and glucagon for the treatment of T1D, we will separately need to develop and obtain approval for our glucagon product candidate as a drug via an NDA submission in order to successfully commercialize our iLet in a bihormonal system. We expect that the bihormonal system will require completion of clinical trials and submission of a 510(k) for both the infusion pump and algorithm. In addition, we expect that the single hormone and bihormonal algorithms will require separate studies to be performed in T1D and T2D populations in order to seek clearance in these patient populations. Our iLet and Mint will also require additional marketing authorization or regulatory clearance before we are permitted to commercialize them with 3D Intelligence as iLet 3D and Mint 3D, respectively. However, there can be no assurance that we will be able to revise and timely resubmit 3D Intelligence or that the FDA will clear the 3D intelligence or any other application on the anticipated timeline, or at all, that we will ultimately be able to market and commercialize 3D Intelligence, iLet 3D or Mint 3D, or that we will be able to scale our manufacturing processes sufficiently to meet anticipated demand at launch. The future regulatory and commercial success of 3D Intelligence, iLet and Mint, including versions powered by 3D Intelligence, and any other product candidate is subject to a number of risks, including the following:

- completion of preclinical studies with favorable results;
- successful enrollment in, and completion of, planned and future clinical trials with favorable results;
- sufficiency of our financial and other resources to complete the necessary clinical trials and regulatory activities;
- successful patient enrollment in clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile in the intended populations;
- whether we are required by the FDA to conduct additional clinical trials or to modify the design of current or planned trials to support any future application seeking marketing authorization or clearance of the iLet in a bihormonal system for the treatment of T1D or for other indications we may pursue, or seeking initial marketing authorization or clearance for any of our other product candidates;
- receipt and maintenance of marketing authorizations or clearances from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity, including for our iLet;
- making arrangements with third-party manufacturers and ensuring such third-party manufacturers supply sufficient quantities of components of our products and product candidates;

- scaling up our manufacturing capabilities, for both commercial and clinical supplies of our products and product candidates;
- entry into collaborations to further the development of capabilities;
- expanding sales, marketing and distribution capabilities as we continue our commercialization efforts of the iLet, whether alone or in collaboration with others;
- successfully launching and driving commercial sales of our existing products and any other product candidate, if authorized for marketing or cleared;
- acceptance of our products by PWD, the medical community and third-party payors;
- maintaining a continued acceptable safety profile following marketing authorization or clearance, including in respect of our post-market surveillance order issued by the FDA for our iLet;
- managing and responding to voluntary or mandatory recalls, including our four open recalls;
- maintaining regulatory compliance;
- effectively competing with other treatment options and the availability, perceived advantages, relative cost, relative safety and relative effectiveness of alternative and competing treatments;
- the emergence of competing technologies and other adverse market developments, and our need to enhance existing products and/or develop new products to maintain market share in response to such competing technologies or market developments;
- maintaining healthcare coverage and adequate reimbursement from third-party payors;
- continuing to build and maintain an organization of people who can successfully develop our products; and
- enforcing and defending intellectual property rights and claims.

Many of these risks are beyond our control, including the risks related to clinical development, the regulatory submission, oversight and review processes, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are not successful in commercializing our iLet or Mint, or in obtaining marketing authorization or clearance for the iLet in its bihormonal system for the treatment of T1D or for the iLet or Mint in other indications, such as T2D, the investigational glucagon product, or any other product candidate, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

Furthermore, even though we have received clearance for our iLet for insulin-only delivery for the treatment of T1D, any other configuration for the treatment of T1D such as a bihormonal system using both insulin and glucagon or other indications we may pursue for which we receive marketing authorization or clearance may be subject to limitations on the patient populations for which we may market the product. Even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that we will successfully develop, obtain marketing authorization or clearance for, and commercialize our iLet in its bihormonal system for the treatment of T1D or for any future indication we may pursue, the investigational glucagon product, or any other development-stage products. If we are unable to continue commercializing the iLet or Mint for T1D, or if we are unable to develop, or obtain marketing authorization or clearance for, or, if authorized for marketing or cleared, successfully commercialize the iLet or Mint for the treatment of any future indications, we may not be able to generate sufficient revenue to continue our business.

Our future growth depends on the continued success, enhancement, and expanded use of the iLet as well as the development and commercial release of the patch pump, Mint. If we fail to advance the iLet platform, the Mint platform or expand their indications, our business may be adversely affected.

It is important to our business and our long-term growth that we continue to develop and enhance the iLet, including in a bihormonal system, as well as expand our product portfolio, including our patch pump, Mint. For example, we have completed over 20 pre-pivotal trials testing the algorithms in order to enhance its learning capabilities. We intend to continue to invest in research and development activities focused on improvements and enhancements to the iLet. Additionally, we intend to pursue marketing authorization or clearance for other indications in the United States in the future.

Developing enhancements to the iLet and developing Mint has, and will continue to be expensive and time-consuming and has, and may continue to, divert management's attention away from the commercialization of the iLet and Mint and divert financial resources from other operations. The success of any new products or new product enhancements, including marketing authorization or clearance for additional indications, will depend on several factors, including our ability to:

- properly identify and anticipate physician and patient needs, and develop enhancements to meet those needs;
- demonstrate, if required, the safety and effectiveness of new enhancements to our products, including additional indications, with data from preclinical studies and clinical trials;
- obtain in a timely manner the necessary marketing authorization or clearance for new enhancements to the iLet, product modifications or expanded indications;
- avoid infringing upon the intellectual property rights of third parties;
- comply with all applicable laws and regulations, including those governing the marketing of new devices or modified products;
- develop an effective and dedicated sales and marketing team to provide adequate education and training to potential users of the iLet; and
- receive adequate coverage and reimbursement for procedures performed with the iLet.

While we have commercialized the iLet as an automated insulin dosing system cleared for the treatment of T1D in adults and children six years of age and older, we may not be successful in expanding the configurations or indications and developing and commercializing new products or product enhancements. This could negatively impact our ability to achieve and maintain market share and increase our revenue, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Manufacturing and Our Reliance on Third Parties

We are substantially dependent on various third parties for the continued development of our iLet and product candidates. Certain of our current and future collaborators may control aspects of our clinical trials, which could result in delays or other obstacles in the development of the investigational devices or other development-stage candidates, such as glucagon, we develop. If our collaborations are terminated or are not successful, our ability to further enhance our iLet and product candidates may be adversely affected.

Our iLet is currently only compatible with DexCom's G6 and G7 iCGM devices and Abbott's FreeStyle Libre 3 Plus CGM sensor. In September 2026, we announced a partnership to integrate the iLet with Senseonics Holdings, Inc.'s Eversense 365 CGM. Although we are actively working to expand the compatibility of our iLet with other iCGM models, there is no assurance we will be successful in our efforts. Our development agreement with DexCom provides us with non-exclusive licenses to integrate the currently available generation of DexCom's iCGM technology with our iLet. Under our current commercialization agreement with DexCom, we and DexCom have agreed to commercialize an AID system comprised of our iLet and DexCom's G6 or G7 iCGM. We also have a development and commercialization agreement with Abbott, under which we and Abbott have agreed to commercialize an AID system comprised of our iLet and Abbott's iCGM. These agreements may be terminated by the other party upon certain conditions. If our existing agreements are terminated and/or DexCom or Abbott enter into an exclusive partnership with one of our competitors, our ability to commercialize the iLet would be disrupted, which would have a material adverse impact on our business, financial condition and results of operations, negatively impact our ability to compete and cause the price of our common stock to decline.

Additionally, we entered into an exclusive collaboration and license agreement with Xeris to facilitate the development of a dual-hormone pump for PWD, whereby Xeris will develop a glucagon drug product candidate utilizing Xeris' XeriSol technology for use in our iLet in its bihormonal system (if such configuration is authorized for marketing). We will be responsible for obtaining regulatory approval of such glucagon product candidate. We also entered into collaboration agreements with certain third-party producers of insulin, pursuant to which we have agreed to work with such parties to support the development of the iLet by researching and incorporating certain proprietary insulins in our iLet. Although we have been successful in obtaining clearance of our iLet with the use of these insulins, we are dependent upon the continued cooperation and collaboration of these parties. If any of these agreements are terminated, we would be required to purchase the applicable party's approved insulin and fill empty insulin cartridges fitted for the iLet to evaluate such party's insulin in trials, which would increase our costs and could delay the timing of trials. Although there are other producers of insulin, there is no assurance we could enter into agreements with them on commercially reasonable terms, if at all, and receive marketing authorizations or clearances for the use of their insulin in the iLet. Our current collaboration agreements pose, and potential future collaborations involving our iLet may pose, the following risks to us:

- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development and commercialization of our products;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our iLet;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the investigational device, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may experience financial difficulties;
- our collaborators may experience legal difficulties with respect to FDA regulations or regulations of other government agencies that jeopardize their ability to continue supporting the development and commercialization of our products;
- collaborators could terminate our existing or future agreements or allow them to expire, which would delay the development and may increase the cost of developing our products;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new investigational devices.

If we enter into collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to any investigational device or other development-stage product we develop could delay the development and commercialization of our investigational devices or other development-stage products, which would harm our business prospects, financial condition and results of operations.

Risks Related to Government Regulation

We and our suppliers are subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once we obtain marketing authorization or clearance for FDA-regulated products, such as our iLet and any future products, we and such products will be subject to continued and pervasive regulatory review, oversight, requirements, and periodic inspections by the FDA and other domestic and foreign regulatory bodies governing, among other things, the manufacture, marketing, advertising, reporting, sale, promotion, import, export, registration, and listing of our products. For example, medical device manufacturers must submit periodic reports to the FDA as a condition of obtaining marketing authorization or clearance. These reports include information about failures and certain adverse events associated with the device after its marketing authorization or clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation. In particular, unless exempt, we and our suppliers are required to comply with the FDA's QMSR for medical device products and cGMPs for any approved drug products, such as glucagon if it is ultimately approved, and other regulations enforced outside the United States which cover the manufacture of our products and the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of medical devices. Regulatory bodies, such as the FDA, enforce the QMSR and cGMPs and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions and/or other negative consequences:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notification, or orders for repair, replacement or refunds;
- voluntary or mandatory recall or seizure of our current or future products;
- administrative detention by the FDA of medical devices believed to be adulterated or misbranded;
- operating restrictions, suspension or shutdown of production;

- refusing our requests for marketing authorization or clearance of new products, or new intended uses or modifications to the iLet;
- suspending or withdrawing marketing authorizations or clearances that have already been granted; and
- criminal prosecution.

If any of these actions were to occur, our reputation would be harmed and our product sales and profitability would be adversely impacted. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to manufacture our products on a timely basis and in the required quantities, if at all. Later discovery of previously unknown problems with our products, including manufacturing problems, or failure to comply with regulatory requirements such as the QMSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

In addition, the FDA may change its marketing authorization or clearance policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization or clearance of any product candidate under development or impact our ability to modify any products authorized for market on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain marketing authorizations or clearances, increase the costs of compliance or restrict our ability to maintain any marketing authorizations or clearances we have obtained. For example, in February 2024, the FDA issued a final rule to amend and replace the former Quality System Regulation, which set forth the FDA's current good manufacturing practice requirements for medical devices, to align more closely with the International Organization for Standardization standards. Specifically, this final rule, which went into effect on February 2, 2026, established the QMSR, which among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the former Quality System Regulation, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise negatively affect our business. If we are unable to comply with the QMSR or with any other changes in the laws or regulations enforced by the FDA or comparable regulatory authorities, we may be subject to enforcement action, which could have an adverse effect on our business, financial condition and results of operations. Additionally, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability, which would harm our business, financial condition, results of operations and prospects.

In addition, even after we have obtained marketing authorization or clearance for a product, the FDA has the power to require us to conduct post marketing studies, such as under a 522 Order, which is an order by the FDA to conduct a post-market study of an authorized or cleared medical device. We are subject to a post-market surveillance order issued by the FDA for our iLet. If the FDA determines that our iLet does not perform as anticipated, or if the FDA identifies new concerns related to the safety and effectiveness of the device, we may need to make changes to or recall or withdraw the iLet from the field, which could harm our business. These studies can be very expensive and time-consuming to conduct. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if marketing authorization or clearance is withdrawn, it would have a material adverse effect on our business, financial condition and results of operations.

In June 2025, the FDA conducted an inspection of our Irvine, California facility. Following the inspection, the FDA issued a Form 483. We initiated remediation activities and followed our communicated plan to address the FDA's observations. We submitted our response and provided multiple updates to the FDA regarding the status of our remediation efforts. On January 29, 2026, we received a Warning Letter from the FDA following such inspection. In the Warning Letter, the FDA cited deficiencies in the response letters we sent to the FDA following the FDA's issuance of the Form 483. The Warning Letter highlights non-conformities observed by the FDA in relation to our Quality Management System, Medical Device Reporting, and Correction and Removals, which were previously communicated by the FDA in the Form 483. The Warning Letter does not restrict our ability to produce, market, manufacture or distribute our products, nor does it restrict our ability to seek FDA 510(k) clearance of new products. We take the observations described in the Warning Letter seriously and have been regularly updating the FDA on the progress we have made in improving our quality management system in the areas outlined by the FDA in the Warning Letter. We intend to continue providing

these regular updates to the FDA until the Warning Letter is resolved. We cannot provide assurances that the FDA will be satisfied with our response or an expected timeline for resolutions of the matters included in the Warning Letter. Until the deficiencies cited in the Warning Letter are resolved to the FDA's satisfaction, additional legal or regulatory action may be taken without further notice. We do not expect the Warning Letter to materially impact our previously disclosed guidance that we expect to fully commercialize Mint by the end of the first quarter of 2027.

The FDA can also publish Safety Communications or Letters to Health Care Providers when the agency becomes aware of new issues involving a specific product or, more broadly, a product family. These communications are posted on the FDA's website and describe the FDA's analysis of a current issue and provide specific regulatory approaches and clinical recommendations for patient management. If such communications occur it may harm our reputation and prevent us from generating revenue.

General Risk Factors

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because medical device companies have experienced significant stock price volatility in recent years. For example, in September 2026, a purported stockholder of our company filed a securities class action against our company and certain of our executive officers in the United States District Court for the Central District of California, captioned *Holtzman v. Beta Bionics, Inc. et al.*, Case No. 8:26-cv-2612-JWH (KESx), alleging violations of certain federal securities laws related to certain statements made with respect to the safety, efficacy and commercial success of iLet. We intend to vigorously defend ourselves in this matter. If we are not successful in defense of these claims or any other claims we may face in the future, we may have to make significant payments to, or other settlements with, our stockholders and their attorneys. Even if such claims are not successful, this litigation has resulted in additional costs to us and this litigation and any other claims we may face in the future could result in further substantial costs and diversion of our management's attention and resources in the future, which could have a material adverse effect on our business, operating results or financial condition. Additionally, the increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Plan

During the three months ended September 30, 2026, the following officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated the contracts, instructions or written plans for the purchase or sale of securities of our company set forth in the table below.

Name and Position	Action	Date	Rule 10b5-1*	Total Shares to be Sold	Expiration Date
Stephen Feider, Chief Financial Officer	Adoption	July 31, 2026	X	80,000	October 29, 2027
Sean Saint, President and Chief Executive Officer	Adoption	August 20, 2026	X	320,000	December 31, 2027
Maria Palasis, Director	Adoption	August 25, 2026	X	13,994	June 30, 2027
* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.					

Item 6. Exhibits.

Exhibit Number	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-42491	3.1	01/31/25	
3.2	Amended and Restated Bylaws of the Registrant.	S-1	333-284147	3.4	01/06/25	
4.1	Form of Common Stock Certificate.	S-1/A	333-284147	4.1	01/22/25	
4.2	Amended and Restated Investor Rights Agreement, dated November 8, 2024, by and among the Registrant and certain of its stockholders.	S-1	333-284147	4.2	01/06/25	
4.3	Form of Pre-Funded Warrant	8-K	001-42491	4.1	09/17/26	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document–the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents					X
104	Cover page formatted as Inline XBRL and contained in Exhibit 101					X

+ The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certification will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

BETA BIONICS, INC.

Date: October 27, 2026

By: /s/ Sean Saint
Sean Saint
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Stephen Feider
Stephen Feider
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sean Saint, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Beta Bionics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 27, 2026

/s/ Sean Saint
Sean Saint
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen Feider, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Beta Bionics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 27, 2026

/s/ Stephen Feider
Stephen Feider
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Sean Saint, President, Chief Executive Officer and Director of Beta Bionics, Inc. (the "Company"), and Stephen Feider, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2026, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 27, 2026

In Witness Whereof, the undersigned have set their hands hereto as of October 27, 2026.

/s/ Sean Saint	/s/ Stephen Feider
Sean Saint	Stephen Feider
President, Chief Executive Officer and Director	Chief Financial Officer
(Principal Executive Officer)	(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.