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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 6, 2025

Biomea Fusion, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	001-40335	82-2520134
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Biomea Fusion, Inc.
1599 Industrial Road
San Carlos, California 94070
(Address of principal executive offices, including zip code)

(650) 980-9099
(Telephone number, including area code, of agent for service)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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	BMEA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Item 8.01 Other Events

On October 6, 2025, Biomea Fusion, Inc. (the "Company") reported new 52-week results from Phase II COVALENT-111 study in Type 2 diabetes.

COVALENT-111 Study Design and Results

COVALENT-111 is a double-blind, randomized, placebo-controlled trial that enrolled adult patients diagnosed with type 2 diabetes ("T2D") within the last 7 years. Eligible participants had HbA1c levels between 7.0% and 10.5%, and a body mass index (BMI) between 25 and 40 kg/m². At baseline, all participants were treated with lifestyle management, including diet and exercise, with or without antidiabetic medications and had inadequate glycemic control despite treatment with up to three antidiabetic medications.

The study evaluated icovamenib in three dosing regimens: Arm A at 100mg QD (once daily) for 8 weeks, Arm B at 100mg QD for 12 weeks, and Arm C at 100 mg QD for 8 weeks and 100mg BID (twice daily) for 4 weeks. A total of 267 patients received at least one dose of icovamenib and were considered evaluable for the modified intent-to-treat ("mITT") population. As previously reported, dosing was interrupted an interim clinical hold imposed by the U.S. Food and Drug Administration ("FDA"). The topline efficacy analysis presented here includes the patient population (N=163) who had completed at least 80% of their planned dosing prior to the clinical hold (without other significant protocol deviations) and who, at baseline, were treated with one or more antihyperglycemic agents. As prespecified in the statistical analysis plan, outcomes were prospectively evaluated by diabetes phenotype using the Ahlqvist algorithm.

The study showed positive results, while exploratory, through Week 52 across multiple subgroups, with certain groups demonstrating statistically significant and clinically meaningful reductions in HbA1c, the gold standard for assessing glycemic control in T2D, observed nine months after dosing. In the 26-week analysis, 8 weeks of dosing was found to be less effective than 12. Accordingly, the 52-week readout primarily focused on patients in Arms B and C who received 12 weeks of treatment (n=10). Among these severe insulin-deficient patients, icovamenib achieved a durable HbA1c reduction of 1.2% (p=0.01) sustained through Week 52. The strongest performing arm for this prespecified population was Arm B (n=6; 100mg QD for 12 weeks), with a mean HbA1c reduction of 1.5% (p=0.01). Severe insulin-deficient diabetes is characterized by impaired insulin secretion, the lowest beta cell function among T2D subtypes, and rapid disease progression. This group was prospectively defined prior to unblinding and represents a population with substantial unmet need.

The 52-week analysis also showed clinically meaningful benefit in study participants who were receiving a GLP-1-based therapy but had not achieved glycemic targets at study entry (all arms n=11). In this subgroup, 8 or 12 weeks of icovamenib resulted in a 1.3% reduction in HbA1c (p=0.05) with effects sustained through Week 52.

Icovamenib maintained a favorable safety profile throughout the 52-week observation period. There were no treatment-related serious adverse events or discontinuations due to adverse events. Across all dosing arms, icovamenib was generally well tolerated.

Planned Next Steps

- Food Effect Study (COVALENT-121) is ongoing, to optimize the dosing criteria for icovamenib, and expected to be completed by December 2025
- Phase IIb trial (COVALENT-211) in severe insulin-deficient type 2 diabetes patients, is expected to be initiated in the fourth quarter of 2025

- Phase II trial (COVALENT-212) with GLP-1 based therapy in type 2 diabetes patients, is expected to be initiated in the fourth quarter of 2025
- Phase I trial (GLP-131) Biomea's oral GLP-1 RA (BMF-650) in obese, otherwise healthy volunteers, initiation is ongoing, and data anticipated in the first half of 2026

Forward-Looking Statements

Statements in this Current Report on Form 8-K (this "Current Report") may include statements which are not historical facts and are considered forward-looking statements within the meaning of 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"). These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this Current Report that are not statements of historical fact, including statements regarding the clinical and therapeutic potential of the Company's product candidates and development programs, including icovamenib and the potential of icovamenib as a treatment for T1D and T2D, and the Company's expectations regarding the optimal dose and target patient population; the Company's research, development and regulatory plans; the mechanism of action of our product candidates and development programs; the progress and initiation of the Company's ongoing and upcoming clinical trials, including our Food Effect Study (COVALENT-121), the initiation of the Company's Phase IIb trial (COVALENT-211) in severe insulin-deficient type 2 diabetes patients, to initiate in fourth quarter of 2025 and the initiation of the Company's Phase II trial with GLP-1 therapy (COVALENT-212) in type 2 diabetes patients, in the fourth quarter of 2025; the anticipated availability of data from the Company's clinical trials; the Company's planned interactions with regulators, and the timing of such events may be deemed to be forward-looking statements.. The Company intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and are making this statement for purposes of complying with those safe harbor provisions. Any forward-looking statements in this Current Report are based on the Company's current expectations, estimates and projections only as of the date hereof and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, including the risk that preliminary or interim results of preclinical studies or clinical trials may not be predictive of future or final results in connection with future clinical trials and the risk that the Company may encounter delays in preclinical or clinical development, patient enrollment, and in the initiation, conduct and completion of the Company's ongoing and clinical trials and other research and development activities. These risks concerning the Company's business and operations are described in additional detail in its periodic filings with the U.S. Securities and Exchange Commission ("SEC"), including its most recent periodic report filed with the SEC and subsequent filings thereafter. The Company explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

SIGNATURES

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

Biomea Fusion, Inc.

Date: October 6, 2025

By: /s/ Michael J.M. Hitchcock

Michael J.M. Hitchcock
Interim Chief Executive Officer, Director
(Principal Executive Officer)