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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15b-16 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the month of September 2026

Commission File Number: 001-41359

Belite Bio, Inc

(Exact name of registrant as specified in its charter)

Not Applicable
(Translation of Registrant´s name into English)

12750 High Bluff Drive Suite 475,
San Diego, CA 92130
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

On September 8, 2026, Belite Bio, Inc issued a press release entitled “Belite Bio Announces Submission of New Drug Application to the Ministry of Health, Labour, and Welfare in Japan under the Sakigake Designation System for Tinlarebant for the Treatment of Stargardt Disease Type 1”. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

This Report on Form 6-K shall be deemed to be incorporated by reference into all effective registration statements filed by the registrant under the Securities Act of 1933, and shall be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

EXHIBIT INDEX

SIGNATURE

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.

Belite Bio, Inc

By: /s/ Yu-Hsin Lin
Name: Yu-Hsin Lin
Title: Chief Executive Officer and Chairman

Date: September 8, 2026

Exhibit 99.1

Belite Bio Announces Submission of New Drug Application to the Ministry of Health, Labour, and Welfare in Japan under the Sakigake Designation System for Tinlarebant for the Treatment of Stargardt Disease Type 1

- *U.S. Food and Drug Administration accepted the New Drug Application with Priority Review for tinlarebant for the treatment of Stargardt disease type 1; Prescription Drug User Fee Act target action date of February 12, 2027*
- *If approved, tinlarebant would be the first-ever approved treatment for Stargardt Disease Type 1 and could become the first Sakigake pharmaceutical product for ophthalmology disease in Japan*

SAN DIEGO, Sept. 8, 2026 (GLOBE NEWSWIRE) - Belite Bio, Inc (NASDAQ: BLTE) ("Belite Bio®" or the "Company"), a clinical-stage drug development company focused on advancing novel therapeutics targeting degenerative retinal diseases that have significant unmet medical needs, today announced the submission of a New Drug Application (NDA) to the Ministry of Health, Labour, and Welfare (MHLW) in Japan for tinlarebant in Stargardt disease type 1 (STGD1). Tinlarebant is an investigational, once-daily oral therapy for the treatment of STGD1, a rare, inherited retinal disease caused by mutations in the *ABCA4* gene that leads to progressive and irreversible vision loss. STGD1 affects an estimated 9,500 people in Japan alone, and there are currently no approved treatment options for the disease.

Tinlarebant has been designated a SAKIGAKE pharmaceutical product for accelerated review and the NDA in Japan was filed side-by-side with the United States NDA to enable simultaneous early access for patients in both regions. Tinlarebant will be reviewed under the Sakigake Designation System - Japan's expedited regulatory pathway for innovative medical products. If approved, it could become the first Sakigake pharmaceutical product for ophthalmology disease in Japan.

"The NDA submission in Japan under Sakigake designation reflects the significant unmet need for people living with STGD1 and is backed by our robust data showing tinlarebant's ability to slow the growth rate of retinal lesions compared to placebo. This is another important milestone as we continue to make rapid progress against our goal to bring tinlarebant to STGD1 patients around the world," said Dr. Tom Lin, Chairman and Chief Executive Officer of Belite Bio. "I'd like to sincerely thank everyone in Japan who participated in or helped facilitate our clinical trials, as well as our entire team who helped make this submission possible. We look forward to working closely with the MHLW as they review our application."

Sakigake designation was established by MHLW to accelerate the drug approval process in Japan for innovative drugs with prominent effectiveness targeting serious diseases, in order to make them available to patients in Japan ahead of the rest of the world, by providing (a) prioritized consultation, (b) pre-application consultation, (c) prioritized review, (d) assignment of a review partner, and (e) extension of re-examination period.

"Although Stargardt disease was first described nearly 120 years ago, no approved treatment has been established to date. We view our NDA in Japan as an important step toward delivering the first therapeutic option in the country for people living with Stargardt disease," said Kaz Tsunaba, President of Belite Bio Japan. "We extend our sincere gratitude to the patients, their families, and the healthcare professionals who have supported the development of this therapy. As tinlarebant could become the first ophthalmology pharmaceutical product to receive regulatory approval under the SAKIGAKE designation, we remain committed to advancing all necessary preparations to ensure that it can be delivered to patients in Japan as early as possible."

About Tinlarebant (a/k/a LBS-008)

Tinlarebant is a novel oral therapy that is intended to reduce the accumulation of vitamin A-based toxins (known as bisretinoids) that cause retinal disease in Stargardt disease type 1 (STGD1) and also contribute to disease progression in geographic atrophy (GA), or advanced dry age-related macular degeneration (AMD). Bisretinoids are by-products of the visual cycle, which is dependent on the supply of vitamin A (retinol) to the eye. Tinlarebant works by reducing and maintaining levels of serum retinol binding protein 4 (RBP4), the sole carrier protein for retinol transport from the liver to the eye. By modulating the amount of retinol entering the eye, tinlarebant reduces the formation of bisretinoids. Tinlarebant has been granted Breakthrough Therapy Designation, Fast Track Designation, and Rare Pediatric Disease Designation in the U.S., Orphan Drug Designation in the U.S., Europe, Japan, and Switzerland, and Sakigake Designation in Japan for the treatment of STGD1.

About Belite Bio

Belite Bio is a clinical-stage drug development company focused on advancing novel therapeutics targeting degenerative retinal diseases that have significant unmet medical needs, such as Stargardt disease type 1 (STGD1) and geographic atrophy (GA) in advanced dry age-related macular degeneration (AMD), in addition to specific metabolic diseases. Belite Bio's lead candidate, tinlarebant, is an oral therapy intended to reduce the accumulation of bisretinoid toxins in the eye. The Company has completed a Phase 3 trial (DRAGON) in adolescent and adult subjects with STGD1, which met its primary endpoint, and the drug is currently being evaluated in a Phase 2/3 trial (DRAGON II) in adolescent and adult subjects with STGD1 and a Phase 3 trial (PHOENIX) in subjects with GA. For more information, follow us on X, Instagram, LinkedIn, and Facebook, or visit us at www.belitebio.com.

Important Cautions Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to future expectations, plans and prospects, as well as other statements regarding matters that are not historical facts. These statements include but are not limited to statements regarding Belite Bio's advancement of regulatory review process, the ability and efficacy of tinlarebant to treat STGD1 and GA, the potential approval of tinlarebant as the first therapy in the U.S. and Japan for people living with STGD1, Belite's ability to successfully launch and market tinlarebant after its potential approval, as well as any other statements regarding matters that are not historical facts, and any other statements containing the words "may", "will", "expect", "believe", "target", "plan", "intend", "continue", "hope", "potential", "anticipate", "estimate", "look forward", and other similar expressions. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors related to Belite Bio's business, including but not limited to Belite Bio's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or regulatory approval; the timing to complete any ancillary clinical trials and/or to receive the interim/final data of such clinical trials; the timing to communicate with and submit trial data to regulatory authorities for drug approval in various jurisdictions; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Belite Bio's drug candidates; Belite Bio's ability to successfully commercialize tinlarebant, if approved, including its ability to build out commercial infrastructure, achieve market acceptance, and execute a timely product launch, as well as those risks more fully discussed in the "Risk Factors" section in Belite Bio's filings with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Belite Bio, and Belite Bio undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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