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 August 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 August 11, 2026, Belite Bio, Inc issued a press release entitled “Belite Bio Announces U.S. Food and Drug Administration Acceptance and Priority Review of New Drug Application 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the Securities Act of 1933, and shall be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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: August 11, 2026

Exhibit 99.1

Belite Bio Announces U.S. Food and Drug Administration Acceptance and Priority Review of New Drug Application for Tinlarebant for the Treatment of Stargardt Disease Type 1

- *Prescription Drug User Fee Act target action date is February 12, 2027*
- *If approved, tinlarebant would be the first-ever approved treatment for Stargardt Disease Type 1*

SAN DIEGO, August 11, 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 that the U.S. Food and Drug Administration (FDA) has accepted and granted Priority Review designation of the New Drug Application (NDA) for tinlarebant for the treatment of Stargardt Disease Type 1 (STGD1). The FDA has set a Prescription Drug User Fee Act (PDUFA) date of February 12, 2027.

The filing was based on the results from the Phase 3 DRAGON trial, which evaluated tinlarebant for the treatment of STGD1. In the study, tinlarebant demonstrated a statistically significant and clinically meaningful 35.7% reduction in the growth rate of atrophic retinal lesions, measured as definitely decreased autofluorescence (DDAF) by fundus autofluorescence imaging, compared with placebo. Tinlarebant has been generally well tolerated in clinical trials with side effects consistent with its mechanism of action. If approved, tinlarebant would be the first ever FDA-approved treatment option for STGD1, a rare, inherited retinal disease caused by mutations in the ABCA4 gene that leads to progressive and irreversible vision loss and affects an estimated 53,000 people in the U.S. alone.

"The acceptance of our NDA with Priority Review designation underscores the immediate need among the Stargardt disease community for an approved treatment option, and we believe it reinforces the quality and depth of the data that we've generated," said Dr. Tom Lin, Chairman and Chief Executive Officer of Belite Bio. "Stargardt disease typically presents early in life and leads to progressive, irreversible vision loss. We are proud that, if approved, tinlarebant could positively impact the decline in vision that was previously inevitable. We look forward to working with the FDA through its review process and remain focused on our commercial readiness and execution following potential approval."

“The acceptance of our NDA is an important milestone driven by the clinically meaningful results from our Phase 3 DRAGON trial, which showed reduction in atrophic retinal lesion growth rate compared to placebo, supporting tinlarebant's oral, once-daily mechanism,” said Dr. Hendrik Scholl, Chief Medical Officer of Belite Bio. “As a practicing physician, I have treated people living with Stargardt disease for more than 20 years and have seen firsthand the challenges that it brings. As of now, the only options that we have to offer people as their blindness progresses are visual aids, further emphasizing the impact that tinlarebant could have on people living with this debilitating disease, if approved. We continue to see enthusiasm across the Stargardt community at the prospect of this potential treatment.”

About Tinlarebant (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 and also contribute to disease progression in geographic atrophy, 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 Stargardt Disease.

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 the estimated STGD1 patient population in the U.S., Belite Bio's advancement of regulatory milestones and planned commercialization of its product candidates, Belite Bio's commercial preparedness and the timing and execution of a potential product launch following regulatory 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; expectations for the timing of initiation, enrollment and completion of, and data relating to, its clinical trials; 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; timing for Belite Bio to share additional data at upcoming medical meetings; the potential efficacy of tinlarebant to set a new benchmark for future research in inherited retinal disorders, 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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