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 March 2024

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 March 22, 2024, Belite Bio, Inc issued a press release entitled “Belite Bio Announces PMDA Submission of Tinlarebant for Stargardt Disease Clinical Trial in Japan”. 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the Securities Act of 1933, and shall be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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: March 22, 2024

Exhibit 99.1

Belite Bio Announces PMDA Submission of Tinlarebant for Stargardt Disease Clinical Trial in Japan

- Tinlarebant is Belite Bio's orally administered tablet intended to slow disease progression in patients affected with Stargardt Disease (STGD1) and Geographic Atrophy (GA) in advanced Dry Age-related Macular Degeneration (Dry AMD)
- Data from a 24-month Phase 2 trial in adolescent STGD1 subjects showed a sustained lower atrophic lesion growth in Tinlarebant-treated subjects compared to ProgStar participants possessing similar baseline characteristics (aged ≤18 years) ($p<0.001$)
- In the Phase 2 trial, 42% of Tinlarebant-treated subjects (5 out of 12) did not develop atrophic retinal lesions during the 24-month treatment period
- Enrollment of a pivotal global Phase 3 trial of Tinlarebant in adolescent STGD1 subjects ("DRAGON") has been completed with 104 subjects across 11 countries with interim data expected in 4Q 2024
- Tinlarebant has been granted Orphan Drug Designation in Japan for the treatment of STGD1
- A global Phase 3 trial in GA ("PHOENIX") is ongoing

SAN DIEGO, March 22, 2024 - Belite Bio, Inc (NASDAQ: BLTE) ("Belite Bio" or the "Company"), a clinical-stage biopharmaceutical drug development company focused on advancing novel therapeutics targeting degenerative retinal diseases that have significant unmet medical needs, today announces its submission to the Pharmaceuticals and Medical Devices Agency (PMDA) to initiate a clinical trial of Tinlarebant in adolescent STGD1 in Japan ("DRAGON II").

The DRAGON II trial is a combination of Phase 1b open-label study to evaluate the pharmacokinetics and pharmacodynamics of Tinlarebant in Japanese adolescent STGD1 subjects and a Phase 2/3, global, multicenter, double-masked, placebo-controlled, randomized study designed to evaluate the efficacy, safety and tolerability of Tinlarebant in adolescent STGD1 subjects. Approximately 60 subjects, aged 12 to 20 years old, including approximately 10 Japanese subjects, are targeted for enrollment in the Phase 2/3 portion of the trial with a 1:1 randomization (tinlarebant:placebo). The data from Japanese subjects is intended to facilitate future NDA applications in Japan.

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 STGD1 and also contribute to disease progression in GA, or advanced Dry 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 Fast Track Designation and Rare Pediatric Disease designation in the U.S., and Orphan Drug Designation in the U.S., Europe, and Japan for the treatment of STGD1.

Stargardt Disease (STGD1)

STGD1 is the most common inherited retinal dystrophy (causing blurring or loss of central vision) in both adults and children. The disease is caused by mutations in a retina-specific gene (ABCA4), which results in progressive accumulation of bisretinoids leading to retinal cell death and progressive loss of central vision. The fluorescent properties of bisretinoids and the development of retinal imaging systems have helped ophthalmologists identify and monitor disease progression. Currently, there are no FDA approved treatments for STGD1.

Importantly, STGD1 and GA, or advanced Dry AMD, share a similar pathophysiology, which is characterized by the excessive accumulation of bisretinoids, retinal cell death, and progressive loss of vision. Vision loss occurs slowly, despite peripheral expansion of “dead retina,” until the disease reaches the center of the eye (the macula). Therefore, Belite Bio is evaluating safety and efficacy of Tinlarebant in GA patients in a 2-year Phase 3 study (PHOENIX).

GA in advanced Dry Age-related Macular Degeneration (Dry AMD)

Dry AMD is a leading cause of vision loss in older adults. Geographic Atrophy, or GA, is the advanced stage of AMD. Currently, there are no FDA approved orally administered treatments for GA and no FDA approved therapies for the other stages of Dry AMD other than GA. There are an estimated 20 million AMD patients in the U.S. and over 196 million patients worldwide with an estimated global direct healthcare cost of US$255 billion.

About Belite Bio

Belite Bio is a clinical-stage biopharmaceutical drug development company focused on advancing novel therapeutics targeting retinal degenerative eye diseases which have significant unmet medical needs such as (i) atrophic age-related macular degeneration (AMD), commonly known as Geographic Atrophy (GA) in advanced dry AMD, and (ii) autosomal recessive Stargardt disease type 1, or STGD1, in addition to specific metabolic diseases. For more information, follow us on Twitter, Instagram, LinkedIn, Facebook or visit us at www.belitebio.com.

Important Cautions Regarding Forward Looking Statements

This press release contains forward-looking statements about future expectations and plans, as well as other statements regarding matters that are not historical facts. These statements include but are not limited to statements regarding the potential implications of clinical data for patients, and Belite Bio's advancement of, and anticipated preclinical activities, clinical development, regulatory milestones, and commercialization of its product candidates, and any other statements containing the words "expect", "hope" and similar expressions. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, 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 relevant clinical trials and/or to receive the interim/final data of such clinical trials; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Belite Bio's drug candidates; the potential efficacy of Tinlarebant, 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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