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 2022

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)

5820 Oberlin Drive, Suite 101,
San Diego, CA 92121

(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 ☐

Indicate by check mark if the Registrant is submitting this Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):
Yes ☐ No ☒

Indicate by check mark if the Registrant is submitting this Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):
Yes ☐ No ☒

Indicate by check mark whether the registrant by furnishing the information contained in this Form 6-K is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934
Yes ☐ No ☒

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 16, 2022

Exhibit 99.1

Belite Bio Receives Approval of LBS-008 Phase 3 Clinical Trial in China

- LBS-008 (aka Tinlarebant) is Belite Bio's **orally administered tablet** for **early intervention** to maintain the health of retinal tissue in Stargardt disease (STGD1) and Dry AMD patients
- A 2-year Phase 2 trial in adolescent STGD1 and a global Phase 3 trial in adolescent STGD1 are ongoing
- The Phase 3 trial named "DRAGON" is a Multi-center, Randomized, **D**ouble Masked, Placebo Controlled Study to Evaluate the Safety and Efficacy of Tinla**R**ebant in the Treatment of St**A**r**G**ardt Disease in Ad**O**lesce**N**t Subjects has commenced in the U.S., the United Kingdom, Germany, Belgium, Switzerland, Hong Kong, Taiwan, and Australia, with several patients already enrolled
- LBS-008, Belite Bio's lead asset, has been granted Fast Track Designation and Rare Pediatric Disease Designation in the U.S., and Orphan Drug Designation in both the U.S. and Europe for STGD1

SAN DIEGO, September 16, 2022- Belite Bio, Inc (NASDAQ: BLTE), a San Diego based clinical stage biopharmaceutical drug development company targeting currently untreatable eye diseases, today announced the approval from the National Medical Products Administration (NMPA) of China to initiate the Phase 3 clinical trial of LBS-008 in adolescent STGD1 in China.

"We are very pleased with our clinical trial progress and excited to start the DRAGON clinical trial in China to bring this potential treatment to patients afflicted with STGD1." said Dr. Tom Lin, Belite Bio's Chairman and CEO. "With a 1 in 10,000 prevalence rate, STGD1 is the most common inherited retinal dystrophy causing blurring and/or loss of central vision in both adults and children with no approved treatment. We have an early intervention, orally administered treatment which has the potential to maintain the health of retinal tissues and address a large unmet need."

Belite Bio's DRAGON trial is a 2-year Phase 2 trial and a 2-year Phase 3 trial of LBS-008 in adolescent STGD1 subjects which is currently underway. The Phase 2 trial has enrolled a total of 13 subjects at clinical sites in Australia and Taiwan. Preliminary data from the Phase 2 trial at the first 6-month interval shows that 8 of the 13 patients (or 61.5%) recorded a gain in best-corrected visual acuity (BCVA) in at least one eye, including 2 patients who recorded a BCVA gain in both eyes.

In addition, there were no atrophic lesions in any of the 13 subjects at study start and only 1 subject showed evidence of a retinal lesion (~0.3mm^2 in size) at 6-months. Belite expects the next data readout of this Phase 2 trial to occur in the last quarter of 2022 when all subjects have completed 12 months of treatment.

The DRAGON trial is a phase 3, randomized, double-masked, placebo-controlled, global and multi-center study, designed to evaluate the safety and efficacy of LBS-008 in adolescent STGD1 patients. To date, the Company has commenced the DRAGON trial in the U.S., the United Kingdom, Germany, Belgium, Switzerland, Hong Kong, Taiwan, and Australia. Approximately 60 patients are targeted for enrollment in this study with a 2:1 randomization (active:placebo). (For more information, visit clinicaltrials.gov at https://www.clinicaltrials.gov/ct2/show/NCT05244304?term=belite+bio&draw=2&rank=1)

The accumulation of toxic bisretinoids have also been implicated in the progression of Dry AMD, a disease with a huge unmet need, which primarily affects the elderly and shows a pathophysiology that is similar to that of STGD1. This finding has led to the sponsorship and endorsement of LBS-008 by the NIH Blueprint program as a promising first-in-class oral medication to slow or halt the progression of Dry AMD. Belite believes that LBS-008 has the potential to be an effective early intervention treatment to maintain the health of retinal tissues in Dry AMD. Belite plans to initiate a Phase 2/3 clinical trial for Dry AMD in the fourth quarter of 2022.

About LBS-008

LBS-008 is a novel oral therapy intended as an early intervention to prevent the buildup of toxins in the eye that cause STGD1 and contribute to Dry AMD. These toxins are by-products of vitamin A in the visual cycle, which is dependent on the supply of vitamin A (retinol) to the eye. LBS-008 works by reducing and maintaining levels of serum retinol binding protein 4 (RBP4), the sole carrier protein for transport of retinol into the eye. By modulating the amount of retinol entering the eye, LBS-008 reduces the formation of vitamin A-based toxins which have been implicated in STGD1 and Dry AMD in order to maintain the health of retinal tissues. LBS-008 has been granted Fast Track Designation, Rare Pediatric Disease Designation in the U.S., and Orphan Drug Designation in the U.S. and Europe for the treatment of STGD1.

Stargardt Disease

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 a dysfunctional retina-specific gene (ABCA4) which results in massive accumulation of toxic vitamin A byproducts (known as 'bisretinoids') in the retina leading to retinal cell death and progressive loss of central vision. The fluorescent properties of bisretinoids and the development of retinal imaging have helped ophthalmologists identify and monitor disease progression. STGD1 and Dry AMD share a similar pathophysiology characterized by excessive accumulation of cytotoxic bisretinoids, retinal cell death, and loss of vision. Vision loss occurs slowly, despite peripheral expansion of 'dead retina', until the disease reaches the center of the eye (the macula).

Dry Age-related Macular Degeneration

Dry AMD is a leading cause of vision loss in the U.S. There are no approved treatments available for Dry AMD. There are an estimated 11 million Dry 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 San Diego based clinical stage biopharmaceutical drug development company targeting currently untreatable eye diseases, such as atrophic age-related macular degeneration (commonly known as advanced Dry AMD) and Stargardt disease, and 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, including 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. 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 content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Belite Bio's drug candidates; the potential efficacy of LBS-008 on the treatment of Dry AMD, 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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