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 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 ☐

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 ☒

On August 9, 2024, Belite Bio, Inc issued a press release entitled “Belite Bio Reports Second Quarter 2024 Financial Results and Provides a Corporate Update.” 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the Securities Act of 1933 and shall be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 9, 2024

Exhibit 99.1

Belite Bio Reports Second Quarter 2024 Financial Results and Provides a Corporate Update

- *Tinlarebant, a novel oral therapy, is 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)*
- *Phase 1b & 2/3 ("DRAGON II") trial of Tinlarebant in adolescent STGD1 patients has been initiated and have completed enrollment for Phase 1b with six subjects in Japan*
- *Tinlarebant granted Orphan Drug and Sakigake (Pioneer Drug) Designation in Japan for the treatment of STGD1*
- *Pivotal global Phase 3 trial of Tinlarebant in GA subjects ("PHOENIX") is ongoing and approximately 200 subjects have been enrolled*
- *Data from a 24-month Phase 2 trial in adolescents with STGD1 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, five of 12 subjects (42%) with known pathogenic ABCA4 mutations, no incident atrophic (DDAF) lesions were formed during the 24-month treatment period and no change in autofluorescent (QDAF) lesions was observed*
- *Company continues to expect interim analysis from the pivotal global Phase 3 trial of Tinlarebant in adolescent STGD1 subjects ("DRAGON") in 4Q 2024*
- *Company to host conference call and webcast on Monday, August 12, 2024, at 4:30 p.m. EDT*

SAN DIEGO, August 9, 2024 (GLOBE NEWSWIRE) -- Belite Bio, Inc (NASDAQ: BLTE) ("Belite" 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 announced its financial results for the second quarter ended June 30, 2024, and provided a general business update.

"We continued to make meaningful strides in advancing Tinlarebant this quarter. We initiated our DRAGON II trial in adolescent STGD1 patients and have completed the enrollment for its phase 1b portion, and notably, we received Sakigake designation in Japan, a testament to the groundbreaking potential of this drug and the unmet need it stands to address for people living with STGD1. In GA, we are approaching 200 patients enrolled in our pivotal Phase 3 trial," said Dr. Tom Lin, Chairman and CEO of Belite Bio. "In the quarter, we also bolstered our balance sheet, having raised $25 million in gross proceeds in a registered direct offering in April. As we enter the second half of the year, we are well positioned to execute on key milestones and look forward to sharing interim analysis from our pivotal Phase 3 DRAGON trial in the fourth quarter."

Second Quarter 2024 Business Highlights and Upcoming Milestones:

Clinical Highlights

Tinlarebant (LBS-008) is an oral, potent, once daily retinol binding protein 4 (RBP4) antagonist that decreases RBP4 levels in the blood and reduces vitamin A (retinol) delivery to the eye without disrupting systemic retinol delivery to other tissues. Vitamin A is critical to normal vision but can accumulate as toxic byproducts in individuals affected with STGD1 and GA (the advanced form of Dry AMD) leading to retinal cell death and loss of vision.

- **Stargardt disease (STGD1):** Accumulation of cytotoxic vitamin A byproducts (bisretinoids) has been implicated in the onset and progression of STGD1. Tinlarebant has been granted Fast Track Designation and Rare Pediatric Disease Designation in the U.S., Orphan Drug Designation in the U.S., Europe, and Japan, and Sakigake (Pioneer Drug) Designation in Japan for the treatment of STGD1.
    - DRAGON Trial: Ongoing, 24-month, randomized (2:1, active: placebo), double-masked, placebo-controlled, global, multi-center, pivotal Phase 3 trial in adolescent STGD1 subjects
        - Completed enrollment with 104 subjects in 11 countries
        - Primary efficacy endpoint is slowing of atrophic lesion growth rate; safety and tolerability will also be assessed
        - Interim analysis expected in 4Q 2024
    - DRAGON II Trial: Combination of Phase 1b open-label trial to evaluate the pharmacokinetics and pharmacodynamics of Tinlarebant in Japanese adolescent STGD1 subjects and a Phase 2/3, double-masked, placebo-controlled, multicenter, trial in adolescent STGD1 subjects
        - Completed Phase 1b enrollment with six subjects in Japan
        - Company targeting approximately 60 subjects, aged 12 to 20 years old, including approximately 10 Japanese subjects, for enrollment in the Phase 2/3 portion of the trial with a 1:1 randomization, with data from Japanese subjects intended to facilitate future new drug application in Japan
        - Primary efficacy endpoint is slowing of atrophic lesion growth rate; safety and tolerability will also be assessed
- **Geographic Atrophy (GA):** GA is a chronic degenerative disease of the retina that leads to blindness in the elderly. Accumulation of toxic vitamin A byproducts (bisretinoids) has been implicated in the progression of GA. There are currently no FDA approved, orally administered treatments for GA.
    - PHOENIX Trial: Ongoing, 24-month, randomized (2:1, active: placebo; n~430 subjects), double-masked, placebo-controlled, global, multi-center, pivotal Phase 3 trial in patients with GA
        - Primary efficacy endpoint is slowing of atrophic lesion growth rate; safety and tolerability will also be assessed
        - Approximately 200 subjects have been enrolled as of August 9, 2024
        - Company expects to conduct interim analysis at the mid-point of the trial

Corporate Highlights

- Raised $25 million in gross proceeds in a registered direct offering in April 2024

Second Quarter 2024 Financial Results:

Current Assets:

As of June 30, 2024, the Company had $112.3 million in cash, time deposits and U.S treasury bills.

R&D Expenses:

For the three months ended June 30, 2024, research and development expenses were $9.1 million compared to $5.5 million for the same period in 2023. For the six months ended June 30, 2024, research and development expenses were $15.8 million compared to $11.2 million for the same period in 2023. The increase in research and development expenses in both the quarter and year-to-date was primarily attributable to (i) a development milestone payment for completion of a phase 2 trial, and (ii) share-based compensation expense.

G&A Expenses:

For the three months ended June 30, 2024, general and administrative expenses were $1.4 million compared to $1.4 million for the same period in 2023. For the six months ended June 30, 2024, general and administration expenses were $3.0 million compared to $2.5 million for the same period in 2023. The increase year-to-date is primarily from an increase in share-based compensation expense.

Other Income:

For the three months ended June 30, 2024, other income was $1.0 million compared to $0.1 million for the same period in 2023. For the six months ended June 30, 2024, other income was $1.4 million compared to $0.1 million for the same period in 2023. The increase in both the quarter and year-to-date is attributed to accrued interest from time deposits and U.S. treasury bills.

Net Loss:

For the three months ended June 30, 2024, the Company reported a net loss of $9.5 million, compared to a net loss of $6.8 million for the same period in 2023. For the six months ended June 30, 2024, the Company reported a net loss of $17.4 million, compared to a net loss of $13.7 million for the same period in 2023.

Webcast Information

Belite Bio will host a webcast on Monday, August 12, 2024, at 4:30 p.m. Eastern Time to discuss the Company's financial results and provide a business update. To join the webcast, please visit https://wsw.com/webcast/cc/blte4/1422018. A replay will be available for approximately 90 days following the event.

About Belite Bio

Belite Bio is a clinical-stage biopharmaceutical drug development company focused on advancing novel therapeutics targeting retinal degenerative eye diseases that 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.

BELITE BIO, INC
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands of US Dollars, except share and per share amounts)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	**2024**	**2023**	**2024**
Expenses				
Research and development	5,516	9,078	11,239	15,843
General and administrative	1,355	1,393	2,513	2,956
Total operating expenses	6,871	10,471	13,752	18,799
Loss from operations	(6,871)	(10,471)	(13,752)	(18,799)
Other income:				
Total other income, net	62	977	54	1,440
Loss before income tax	(6,809)	(9,494)	(13,698)	(17,359)
Income tax expense	3	-	9	6
Net loss	(6,812)	(9,494)	(13,707)	(17,365)
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of nil tax	(76)	(10)	(60)	(106)
Total comprehensive loss	(6,888)	(9,504)	(13,767)	(17,471)
Weighted average number of ordinary shares used in per share calculation:				
- Basic and Diluted	25,785,147	30,324,132	25,350,949	30,000,653
Net loss per ordinary share				
- Basic and Diluted	$ (0.26)	$ (0.31)	$ (0.54)	$ (0.58)

BELITE BIO, INC
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands of US Dollars, except share amounts)

	December 31, 2023	June 30, 2024
Current assets	$ 89,940	$ 113,858
Other assets	4,702	4,572
TOTAL ASSETS	$ 94,642	$ 118,430
TOTAL LIABILITIES	$ 4,211	$ 3,837
TOTAL SHAREHOLDERS' EQUITY	90,431	114,593
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 94,642	$ 118,430
Ordinary shares authorized	400,000,000	400,000,000
Ordinary shares issued	29,184,475	30,649,321
Ordinary shares outstanding	29,149,444	30,612,359

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