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 May 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 May 20, 2026, Belite Bio, Inc issued a press release entitled “Belite Bio Reports Unaudited First Quarter 2026 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Securities Act of 1933 and shall be a part thereof from the date on which this report is furnished, to the extent not superseded by documents or reports subsequently filed or furnished.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: May 20, 2026

Exhibit 99.1

Belite Bio Reports Unaudited First Quarter 2026 Financial Results and Provides a Corporate Update

- *Initiated a rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for tinlarebant for the treatment of Stargardt disease type 1 (STGD1); submission expected to be completed in the second quarter of 2026*
- *Commercialization preparation for STGD1 underway; hiring of all key commericial leadership positions completed*
- *Cash and cash equivalents, U.S. treasury bills and notes: $798.6 million as of March 31, 2026*
- *Conference call and webcast on Wednesday, May 20, 2026, at 4:30 p.m. ET*

SAN DIEGO, May 20, 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 its unaudited financial results for the first quarter ended March 31, 2026, and provided a business update.

"This has been an exciting start to the year for Belite. In April, we announced the initiation of our rolling NDA submission to the FDA for tinlarebant in STGD1, an important step on our path to becoming a commercial company and potentially bringing the first ever treatment for this devastating disease to patients. We are on track to finalize the NDA submission in the second quarter," said Dr. Tom Lin, Chairman and CEO of Belite Bio. "Initiatives to advance our pre-commercial efforts, including hiring experienced commercial leaders and building out key teams within our organization, are underway. In tandem, we are taking a thoughtful approach to achieving our mission to make this potential treatment available to as many patients as possible worldwide."

First Quarter 2026 Business Highlights and Upcoming Milestones

Clinical Highlights

Tinlarebant is an oral, potent, once-daily, retinol binding protein 4 (RBP4) antagonist that is intended to decrease RBP4 levels in the blood and reduce vitamin A (retinol) delivery to the eye without disrupting systemic retinol delivery to other tissues. Vitamin A is critical for normal vision but can accumulate as toxic byproducts in individuals affected with STGD1 and geographic atrophy (GA), the advanced form of dry age-related macular degeneration (AMD), leading to retinal cell death and loss of vision.

Stargardt disease (STGD1): Accumulation of cytotoxic vitamin A byproducts (bisretinoids) compounds has been implicated in the onset and progression of STGD1, for which there is no approved treatment. Tinlarebant has been granted Breakthrough Therapy, Fast Track, and Rare Pediatric Disease Designations in the U.S.; Orphan Drug Designation in the U.S., Europe, Japan, and Switzerland; and Sakigake (Pioneer Drug) Designation in Japan for the treatment of STGD1.

- DRAGON Trial: Completed, 24-month, 104 subjects, aged 12 to 20 years old, randomized (2:1, active: placebo), double-masked, placebo-controlled, global, multi-center, pivotal Phase 3 trial in adolescent STGD1 patients

  - Initiated a rolling NDA submission under Breakthrough Therapy Designation with the FDA for tinlarebant in STGD1 in April 2026. The NDA submission is expected to be completed in the second quarter of 2026

  - Granted Orphan Drug Status for the treatment of STGD1 by the Swiss Agency for Therapeutic Products (Swissmedic)

- DRAGON II Trial: Combination of a Phase 1b open-label trial to evaluate the pharmacokinetics and pharmacodynamics of tinlarebant in adolescent Japanese STGD1 patients and a Phase 2/3, 24-month, randomized (1:1, active: placebo), double-masked, placebo-controlled, multi-center trial in adolescent STGD1 patients aged 12 to 20 years old across Japan, the U.S., and the United Kingdom.
    - Targeted enrollment of 60 subjects for the Phase 2/3 trial in STGD1 was reached in January 2026, with enrollment extending into early March for screened participants. Enrollment was completed with a total of 73 subjects, including 15 Japanese subjects.
    - Trial design and inclusion of Japanese patients are intended to facilitate a future NDA in Japan.
    - Primary efficacy endpoint is the growth rate of atrophic lesions; 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 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), double-masked, placebo-controlled, global, multi-center, pivotal Phase 3 trial in GA patients
    - Enrollment was completed with 530 subjects.
    - Primary efficacy endpoint is the growth rate of atrophic lesions; safety and tolerability will also be assessed.
    - The Company expects to conduct an interim analysis.

Corporate Highlights

- Commercialization preparation for STGD1 is underway; hiring of all key commercial leadership positions has been completed.

Unaudited First Quarter 2026 Financial Results:

Cash and Cash Equivalents: As of March 31, 2026, the Company had $276.4 million in cash and cash equivalents, compared with $352.9 million on December 31, 2025.

Investments: As of March 31, 2026, the Company had $522.2 million in U.S. treasury bills and U.S. treasury notes, compared to $419.7 million as of December 31, 2025.

Research & Development Expenses:

For the three months ended March 31, 2026, research and development expenses were $15.7 million compared to $9.4 million for the same period in 2025. The increase in research and development expenses in the quarter was primarily attributable to increases in (i) expenses related to the DRAGON II trial, (ii) active pharmaceutical ingredient ("API") manufacturing expense and drug product ("DP") manufacturing expense; and (iii) consultant and professional service fees.

On a non-GAAP basis, excluding share-based compensation expenses, non-GAAP research and development expenses for the three months ended March 31, 2026, were $13.8 million compared to $7.4 million for the same periods in 2025.

Selling, General & Administrative Expenses:

For the three months ended March 31, 2026, selling, general and administrative expenses were $17.0 million compared to $6.1 million for the same period in 2025. The increase in selling, general and administrative expenses in the quarter was primarily due to increases in share-based compensation expenses, professional service fees, and wages and salaries resulting from our team expansion.

On a non-GAAP basis, excluding share-based compensation expenses, non-GAAP selling, general and administrative expenses for the three months ended March 31, 2026, were $5.7 million compared to $1.5 million for the same period in 2025.

Other Income:

For the three months ended March 31, 2026, other income was $5.7 million compared to $1.2 million for the same period in 2025. The increase in the quarter was primarily due to interest income from bank deposits, U.S. treasury bills and U.S. treasury notes.

Net Loss:

For the three months ended March 31, 2026, the Company reported a GAAP net loss of $26.9 million, compared to a GAAP net loss of $14.3 million for the same period in 2025.

On a non-GAAP basis, excluding share-based compensation expenses, the Company reported a non-GAAP net loss of $13.7 million for the three months ended March 31, 2026, compared to a non-GAAP net loss of $7.6 million for the same period in 2025.

Webcast Information

Belite Bio will host a webcast on Wednesday, May 20, 2026, 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://events.q4inc.com/attendee/135456520. A replay of the event will be available on the Investor Relations section of the Company's website for approximately 90 days following the event.

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 need, 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, 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 potential implications of clinical data for patients; Belite Bio's advancement of, and anticipated preclinical activities, clinical development, regulatory milestones, and commercialization of its product candidates; the ability or potential of tinlarebant to treat STGD1 and GA; the timing to complete relevant clinical trials and/or to receive the interim/final data of such clinical trials; the timing of the completion of the NDA submission for tinlarebant; the timing to submit trial data to regulatory authorities for drug approval, the potential benefits of any regulatory designations, the potential for and timing of any interim analysis of ongoing clinical trials; the design of clinical trials intended to facilitate a future NDA in Japan; the Company's commercialization preparation activities and hiring progress, as well as any other statements regarding matters that are not historical facts, and any other statements containing the words "expect", "believe", "anticipate", "intend", "target", "plan", "hope", "potential", "estimate", "project", "may", "will", "could", "should", "on track", 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; the 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; Belite Bio's limited experience in launching and marketing product candidates; Belite Bio's ability to attract, retain and motivate senior management and qualified employees, 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.

Discussion of Non-GAAP Financial Measures

To supplement the Company's unaudited condensed consolidated financial results prepared in accordance with GAAP, the Company discloses certain non-GAAP financial measures that exclude share-based compensation, including research and development (non-GAAP), selling, general and administrative (non-GAAP), total operating expenses (non-GAAP), loss from operations (non-GAAP), net loss (non-GAAP), weighted average number of ordinary shares used in per share (non-GAAP) and net loss per ordinary share basic and diluted (non-GAAP).

The Company believes that these non-GAAP measures provide supplemental information that may be helpful in understanding period-to-period trends in operating expenses and results when considered together with, and not as a substitute for, the corresponding GAAP financial measures. These measures are intended to increase transparency into expense items that may vary from period to period for reasons such as the timing, structure, and valuation of equity awards. These measures are not intended to replace GAAP financial information and are not considered by management to be superior to GAAP measures.

At the Company's current stage of development as a clinical-stage biotechnology company, the primary expenditures relate to the execution of clinical trials, regulatory activities (including preparation for potential NDA submissions), and the management of ongoing operations. In this context, management believes that the supplemental presentation of operating expenses excluding certain non-cash charges, such as share-based compensation, may assist users in understanding the nature and scale of cash-based operating activities by reducing period-to-period volatility from non-cash items. However, these non-GAAP measures are not intended to represent, and should not be viewed as, measures of liquidity, cash burn rate, or cash flows.

Non-GAAP measures have inherent limitations and may differ from similarly titled measures used by other companies. Accordingly, these measures should be viewed as supplemental and evaluated together with the Company's GAAP results and the reconciliations to the most directly comparable GAAP measures presented in this release.

Explanation of Adjustment – Share-based compensation:

Share-based compensation expense consists of non-cash charges related to the fair value of equity awards awarded to employees and other non-employees. The amount recognized in any period may vary based on factors such as grant timing, award structure, and valuation assumptions, which may not be directly correlated with the timing or magnitude of cash payments related to the Company's clinical, regulatory, and operational activities. The exclusion of share-based compensation in the Company's non-GAAP measures is intended to supplementally illustrate operating expense trends and facilitate period-to-period comparisons of cash-based expenditures. The Company recognizes that share-based compensation is an important component of total compensation, and does not view non-GAAP measures as a replacement for GAAP results, which include the full impact of share-based compensation.

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 March 31,	
	2025	**2026**
Expenses		
Research and development	9,396	15,661
Selling, general and administrative	6,121	17,023
Total operating expenses	15,517	32,684
Loss from operations	(15,517)	(32,684)
Other income:		
Total other income, net	1,240	5,746
Loss before income tax	(14,277)	(26,938)
Net loss	(14,277)	(26,938)
Other comprehensive income		
Foreign currency translation adjustments, net of nil tax	18	18
Total comprehensive loss	(14,259)	(26,920)
Weighted average number of ordinary shares used in per share calculation:		
- Basic and Diluted	32,084,106	39,868,666
Net loss per ordinary share		
- Basic and Diluted	$ (0.45)	$ (0.68)

BELITE BIO, INC
RECONCILIATION OF GAAP TO NON-GAAP UNAUDITED OPERATING RESULTS
(Amounts in thousands of US Dollars, except share and per share amounts)

	For the Three Months Ended March 31,	
	2025	**2026**
Expenses		
GAAP Research and development	9,396	15,661
Share-based compensation expense	(2,007)	(1,855)
Non-GAAP research and development	7,389	13,806
GAAP Selling, general and administrative	6,121	17,023
Share-based compensation expense	(4,663)	(11,341)
Non-GAAP selling, general and administrative	1,458	5,682
GAAP Total operating expenses	15,517	32,684
Share-based compensation expense	(6,670)	(13,196)
Non-GAAP Total operating expense	8,847	19,488
GAAP Loss from operations	(15,517)	(32,684)
Share-based compensation expense	6,670	13,196
Non-GAAP Loss from operations	(8,847)	(19,488)
GAAP Net loss	(14,277)	(26,938)
Share-based compensation expense	6,670	13,196
Non-GAAP Net Loss	(7,607)	(13,742)
Weighted average number of ordinary shares used in per share		
Calculation GAAP and Non-GAAP:		
- Basic and Diluted	32,084,106	39,868,666
Net loss per ordinary share		
- Basic and Diluted GAAP	$ (0.45)	$ (0.68)
- Basic and Diluted Non-GAAP	$ (0.24)	$ (0.34)

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

	December 31, 2025	March 31, 2026
Current assets	$ 494,272	$ 521,864
Other assets	286,284	289,407
TOTAL ASSETS	$ 780,556	$ 811,271
TOTAL LIABILITIES	$ 10,070	$ 15,483
TOTAL SHAREHOLDERS' EQUITY	770,486	795,788
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 780,556	$ 811,271
Ordinary shares authorized	400,000,000	400,000,000
Ordinary shares issued	39,353,365	40,144,432
Ordinary shares outstanding	39,339,960	40,085,091

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