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**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 2023**

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

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On March 31, 2023, Belite Bio, Inc issued a press release entitled “Belite Bio Reports Full-Year 2022 Operational Highlights and Financial Results”. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

#### **EXHIBIT INDEX**

[Exhibit 99.1 — Press Release](#)

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**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 31, 2023

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## Belite Bio Reports Full-Year 2022 Operational Highlights and Financial Results

- 12-month interim data from the ongoing 2-year, Phase 2 Stargardt disease (STGD1) study continues to show halting or slowing of lesion growth; 18-month efficacy and safety update expected during the 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting on April 25
- 42 subjects have been enrolled for the pivotal Phase 3 “DRAGON” trial evaluating oral tinlarebant in adolescent STGD1; at least 90 subjects are targeted for enrollment
- The first patient of the pivotal Phase 3 “PHOENIX” trial in Geographic Atrophy (GA) is expected to be enrolled during mid-2023
- Webcast Monday, April 3, 2023, at 4:30 p.m. ET

SAN DIEGO, March 31, 2023- [Belite Bio, Inc](#) (NASDAQ: BLTE) (“Belite” or the “Company”), a San Diego based clinical stage biopharmaceutical drug development company targeting eye diseases with significant unmet medical needs, today announced its financial results for the full-year ended December 31, 2022 and provided a general business update.

“2022 was a transformative year for Belite, with achievements across key clinical and corporate milestones including the closing of our successful initial public offering, enrollment in over 11 countries for our pivotal Phase 3 DRAGON trial, and Phase 2 efficacy data reinforcing the potential for tinlarebant to slow down disease progression in Stargardt disease,” said Dr. Tom Lin, Belite’s Chairman and CEO. “As we look towards 2023, we remain focused on late-stage advancement of tinlarebant with continued enrollment in the DRAGON trial and the first patient of the Phase 3 PHOENIX trial in GA is expected to be enrolled during mid-year. We also expect to present the 18-month efficacy and safety data from our two-year Phase 2 trial in Stargardt disease during ARVO this year. With our balance sheet strengthened, we are well-positioned to execute across our near-term catalysts and work towards our mission of developing oral therapies for eye diseases with significant unmet medical needs.”

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## Full Year 2022 Business Highlights and Upcoming Milestones:

### Clinical Highlights

**Tinlarebant** (LBS-008) is an oral, once daily, retinol binding protein 4 (RBP4) antagonist that decreases RBP4 levels in the blood and selectively lowers vitamin A (retinol) delivery to the eye as a means to potentially reduce the accumulation of toxic vitamin A byproducts within the eye leading to preservation of the retina. Vitamin A is critical for normal vision but it can be converted to toxic byproducts (bisretinoids) in degenerative retinal diseases such as STGD1 and GA leading to photoreceptor cell death and vision loss.

- **Stargardt disease (STGD1):** Accumulation of cytotoxic bisretinoids has been implicated in the onset and progression of STGD1. Tinlarebant has been granted Fast Track and Rare Pediatric Disease (RPD) designations by the U.S. Food and Drug Administration (FDA), and orphan drug designation (ODD) in the U.S. and Europe for STGD1. There are currently no FDA approved treatments for STGD1.
    - Ongoing, open-label, 2-year Phase 2 trial in adolescent STGD1 subjects:
      - o 13 subjects enrolled at clinical sites in Australia and Taiwan.
      - o No atrophic retinal lesions in the 13 subjects at study start; only 1 subject developed bilateral retinal lesions (~0.44 mm<sup>2</sup> mean size) at the 12-month interval.
      - o ARVO 2023, April 25: Expect to present 18-month efficacy and safety data.
    - Pivotal DRAGON Trial: 2-year, randomized, double-masked, placebo-controlled, global, multi-center, pivotal Phase 3 trial in adolescent STGD1 subjects:
      - o Trial initiated in the U.S., the United Kingdom, Germany, Belgium, France, Switzerland, China, Hong Kong, Taiwan, Australia, and the Netherlands, with 42 subjects enrolled; at least 90 subjects are targeted for enrollment.
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- o Upper age range for enrollment increased from 18 to 20 years.
- o Primary efficacy endpoint is slowing of lesion growth rate; safety and tolerability will also be assessed.
- o Mid 2024: Interim efficacy and safety data expected.

**Geographic Atrophy (GA):** GA, an advanced form of Dry Age-Related Macular Degeneration (Dry AMD), 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.

- o Pivotal PHOENIX Trial: initiated; a 2-year prospective, randomized (2:1, active:placebo, n ~430 subjects), double-masked, placebo-controlled, global, multi-center, Phase 3 trial in patients with GA.
- o Primary efficacy endpoint is slowing of lesion growth rate; safety and tolerability will also be assessed.
- o Interim analysis expected at mid-point of the study.
- o Mid 2023: Enrollment of first patient in pivotal Phase 3 PHOENIX trial expected

### **Corporate Highlights**

Completed initial public offering in April 2022. Belite Bio (NASDAQ: BLTE) became listed on Nasdaq and raised net proceeds of approximately \$38.0 million including the overallocation. The Company expects to use the net proceeds to fund the Phase 3 clinical trial of Tinalrebant for STGD1 and GA, working capital and other general corporate purposes.

### **Full Year 2022 Financial Results:**

**Cash and Cash Equivalents:** As of December 31, 2022, the Company had \$42.1 million in cash.

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**R&D Expenses:**

For the year ended December 31, 2022, research and development expenses were \$8.9 million compared to \$7.4 million for the same period in 2021. Research and development expense increase was primarily attributable to an increase in wages and salaries due to our R&D team expansion and increased share-based compensation expenses.

**G&A Expenses:**

For the year ended December 31, 2022, general and administration expenses were \$4.0 million compared to \$2.4 million for the same period in 2021. General and Administration expenses increased by approximately \$1.6 million from the year ended December 31, 2021, to the year ended December 31, 2022, which was primarily due to an increase in professional service fees incurred, an increase of D&O insurance expense, and increase of wages and salaries.

**Net Loss:**

For the year ended December 31, 2022, the Company reported a net loss of \$12.6 million, compared to a net loss of \$9.7 million for the same period in 2021.

**Webcast Information**

Belite Bio will host a webcast to discuss the Company's financial results and provide a business update. The call is scheduled for Monday, April 3, 2023, at 4:30 p.m. Eastern Time. To join the live webcast please click [here](#). A replay will be available approximately two hours after the event for 90 days.

**About Belite Bio**

Belite Bio is a San Diego based clinical stage biopharmaceutical drug development company targeting eye diseases with significant unmet medical needs, such as advanced dry age-related macular degeneration (commonly known as Geographic Atrophy, or advanced Dry AMD), Stargardt disease, and metabolic diseases. For more information, follow us on [Twitter](#), [Instagram](#), [LinkedIn](#), [Facebook](#) or visit us at [www.belitebio.com](http://www.belitebio.com).

**Important Cautions Regarding Forward Looking Statements**

*This press release contains forward-looking statements about future expectations, plans and prospects, as well as any 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, clinical development, regulatory milestones, and commercialization of its product candidates, and any other statements containing the words "expect", "will", "believe", "target", and other 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 content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Belite Bio's drug candidates; the potential efficacy of Tnlarebant, 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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BELITE BIO, INC

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Amounts in thousand US Dollars, except share and per share amounts)

	For the Years Ended December 31,		
	2020	2021	2022
<b>Expenses</b>			
Research and development	3,688	7,419	8,869
General and administrative	2,055	2,378	3,952
Total operating expenses	5,743	9,797	12,821
<b>Loss from operations</b>	(5,743)	(9,797)	(12,821)
<b>Other income (expense):</b>			
Total other (expense) income, net	(9)	131	173
<b>Loss before income tax</b>	(5,752)	(9,666)	(12,648)
Income tax expense	(1)	—	—
<b>Net loss</b>	(5,753)	(9,666)	(12,648)
<b>Other comprehensive income (loss)</b>			
Foreign currency translation adjustments, net of nil tax	6	(152)	(196)
<b>Total comprehensive loss</b>	\$ (5,747)	\$ (9,818)	(12,844)
<b>Weighted average number of ordinary shares used in per share calculation:</b>			
- Basic and Diluted	8,790,397	9,569,932	19,976,596
<b>Net loss per ordinary share</b>			
- Basic and Diluted	\$ (0.65)	\$ (1.01)	\$ (0.63)





SELECTED CONSOLIDATED BALANCE SHEET

(Amounts in thousand US Dollars)

	December 31	
	2021	2022
Current assets	\$ 17,431	\$ 42,807
Other assets	917	1,466
<b>TOTAL ASSETS</b>	<b>\$ 18,348</b>	<b>\$ 44,273</b>
<b>TOTAL LIABILITIES</b>	<b>\$ 1,635</b>	<b>\$ 2,772</b>
Total convertible preferred shares	31,806	—
Total shareholders' (deficit) equity	(15,093)	41,501
<b>TOTAL LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' (DEFICIT) EQUITY</b>	<b>\$ 18,348</b>	<b>\$ 44,273</b>
<b>SUPPLEMENTAL DISCLOSURE</b>		
Ordinary shares authorized	492,179,086	492,179,086
Ordinary shares issued and outstanding	10,274,403	24,898,908

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