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

August 13, 2026

- *U.S. Food and Drug Administration (FDA) accepted the New Drug Application (NDA) with Priority Review for tinlarebant for the treatment of Stargardt disease type 1 (STGD1); Prescription Drug User Fee Act (PDUFA) target action date of February 12, 2027*
- *Company presented additional positive secondary endpoint data from the Phase 3 DRAGON trial of tinlarebant at the American Society of Retina Specialists (ASRS) Annual Meeting with quantitative autofluorescence (qAF) showing a marked divergence between treatment groups*
- *Conference call and webcast on Thursday, August 13, 2026, at 4:30 p.m. ET*

SAN DIEGO, Aug. 12, 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 financial results for the second quarter ended June 30, 2026, and provided a business update.

"We continue to make significant strides in advancing tinlarebant in Stargardt disease. The FDA's acceptance of our NDA is a pivotal milestone for Belite Bio and the STGD1 community, bringing us meaningfully closer to potentially delivering the first ever approved treatment for STGD1. We believe the Priority Review status reflects the strength of our data and recognizes the tremendous unmet need for people living with this debilitating retinal disease," said Dr. Tom Lin, Chairman and Chief Executive Officer of Belite Bio. “Simultaneously, our launch preparations are well underway, including continuing our team expansion and building out our commercial and operational infrastructures. We believe we will be well positioned for both a strong launch and long-term success."

Second Quarter 2026 Business Highlights and Upcoming Milestones:

Clinical Highlights

STGD1 Disease

- 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 and adult STGD1 patients.
  - The FDA had accepted the NDA submission and granted Priority Review, with an assigned PDUFA target action date of February 12, 2027.
  - Additional positive secondary endpoint data from the Phase 3 DRAGON trial was given in an oral presentation at the ASRS 2026 Annual Meeting, highlighting that quantitative autofluorescence (qAF), a marker of toxic bisretinoid accumulation, showed a marked divergence between treatment groups. Specifically, at month 25, qAF values in tinlarebant-treated subjects remained stable to slightly decreased from baseline (approximately 2%), whereas placebo-treated subjects showed an approximate 20% increase from baseline, further strengthening the clinical body of evidence showing the efficacy of tinlarebant in STGD1.
- 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 and adult STGD1 patients aged 12 to 20 years old across Japan, the U.S., and the United Kingdom.
  - Completed enrollment with 73 subjects, including 15 Japanese subjects for the Phase 2/3 trial in STGD1.
  - The trial design and inclusion of Japanese patients are intended to facilitate a potential future NDA in Japan.
  - The primary efficacy endpoint is the growth rate of atrophic lesions; safety and tolerability will also be assessed.

Geographic Atrophy (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.
    - Completed enrollment 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, and the Company is planning a Commercial Day in September to provide an update.

Second Quarter 2026 Financial Results:

Cash and Cash Equivalents: As of June 30, 2026, the Company had $279.9 million in cash and cash equivalents, compared with $352.9 million on December 31, 2025.

Investments: As of June 30, 2026, the Company had $500.1 million in U.S. treasury bills and U.S. treasury notes, compared to $419.7 million as of December 31, 2025.

Research and Development (R&D) Expenses:

For the three months ended June 30, 2026, R&D expenses were $18.2 million compared to $11.0 million for the same period in 2025. The increase in R&D expenses in the quarter was primarily attributable to a royalty payment for an additional milestone achieved under the license agreement.

For the six months ended June 30, 2026, R&D expenses were $33.9 million compared to $20.4 million for the same period in 2025. The increase in R&D expenses year-to-date was primarily attributable to (i) a royalty payment for an additional milestone achieved under the license agreement, (ii) increases in active pharmaceutical ingredient (“API”) and drug product (“DP”) manufacturing expenses and (iii) increases in consultant fees.

On a non-GAAP basis, excluding share-based compensation expenses, non-GAAP R&D expenses for the three months ended June 30, 2026, were $17.2 million compared to $8.6 million for the same period in 2025. For the six months ended June 30, 2026, non-GAAP R&D expenses were $31.0 million compared to $16.0 million for the same period in 2025.

Selling, General, and Administrative (SG&A) Expenses:

For the three months ended June 30, 2026, SG&A expenses were $16.7 million compared to $6.5 million for the same period in 2025. The increase in SG&A expenses in the quarter was primarily attributable to increases in professional service fees, and wages and salaries resulting from our team expansion.

For the six months ended June 30, 2026, SG&A expenses were $33.7 million compared to $12.7 million for the same period in 2025. The increase in SG&A expenses year-to-date was primarily attributable to increases in professional service fees, share-based compensation expenses, and wages and salaries resulting from our team expansion.

On a non-GAAP basis, excluding share-based compensation expenses, non-GAAP SG&A expenses for the three months ended June 30, 2026, were $10.9 million compared to $1.3 million for the same period in 2025. For the six months ended June 30, 2026, non-GAAP SG&A expenses were $16.6 million compared to $2.8 million for the same period in 2025.

Other Income:

For the three months ended June 30, 2026, other income was $6.6 million compared to $1.3 million for the same period in 2025. For the six months ended June 30, 2026, other income was $12.3 million compared to $2.5 million for the same period in 2025. The increase in other income in the quarter and year-to-date was primarily attributable to interest income from bank deposits, U.S. treasury bills and U.S. treasury notes.

Net Loss:

For the three months ended June 30, 2026, the Company reported a net loss of $28.4 million, compared to a net loss of $16.3 million for the same period in 2025. For the six months ended June 30, 2026, net loss was $55.4 million compared to $30.6 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 $21.6 million for the three months ended June 30, 2026, compared to a non-GAAP net loss of $8.7 million for the same period in 2025. For the six months ended June 30, 2026, non-GAAP net loss was $35.3 million compared to $16.3 million for the same period in 2025.

Webcast Information

Belite Bio will host a webcast on Thursday, August 13, 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 click here. 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 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 Stargardt disease type 1 (STGD1) and also contribute to disease progression in geographic atrophy (GA), or advanced dry age-related macular degeneration (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 Breakthrough Therapy Designation, Fast Track Designation, and Rare Pediatric Disease Designation in the U.S., Orphan Drug Designation in the U.S., Europe, Japan, and Switzerland, and Sakigake Designation in Japan for the treatment of STGD1.

About Stargardt Disease

STGD1 is the most common inherited macular dystrophy 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 high-resolution retinal imaging systems have helped ophthalmologists identify and monitor disease progression. Currently, there are no approved treatments for STGD1.

About 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.

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 needs, 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, which met its primary endpoint, 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 Belite Bio's advancement of regulatory review process, the ability and efficacy of tinlarebant to treat STGD1 and GA, the potential approval of tinlarebant as the first therapy for people living with STGD1, Belite's ability to successfully launch and market tinlarebant after its potential approval, as well as any other statements regarding matters that are not historical facts, and any other statements containing the words "may", "will", "expect", "believe", "target", "plan", "intend", "continue", "hope", "potential", "anticipate", "estimate", "look forward", 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; Belite Bio's ability to successfully commercialize tinlarebant, if approved, including its ability to build out commercial infrastructure, achieve market acceptance, and execute a timely product launch; 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, 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.

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,	
	2025	**2026**	**2025**	**2026**
Expenses				
Research and development	11,049	18,213	20,445	33,874
Selling, general and administrative	6,547	16,694	12,668	33,717
Total operating expenses	17,596	34,907	33,113	67,591
Loss from operations	(17,596)	(34,907)	(33,113)	(67,591)
Other income:				
Total other income, net	1,276	6,550	2,516	12,296
Loss before income tax	(16,320)	(28,357)	(30,597)	(55,295)
Income tax expense	-	55	-	55
Net loss	(16,320)	(28,412)	(30,597)	(55,350)
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of nil tax	128	10	146	28
Total comprehensive loss	(16,192)	(28,402)	(30,451)	(55,322)
Weighted average number of ordinary shares used in per share calculation:				
- Basic and Diluted	32,585,043	40,182,310	32,335,958	40,026,354
Net loss per ordinary share				
- Basic and Diluted	$ (0.50)	$ (0.70)	$ (0.95)	$ (1.38)

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 June 30,		For the Six Months Ended June 30,	
	2025	**2026**	**2025**	**2026**
Expenses				
GAAP Research and development	11,049	18,213	20,445	33,874
Share-based compensation expense	(2,410)	(1,023)	(4,417)	(2,878)
Non-GAAP research and development	8,639	17,190	16,028	30,996
GAAP Selling, general and administrative	6,547	16,694	12,668	33,717
Share-based compensation expense	(5,206)	(5,758)	(9,869)	(17,099)
Non-GAAP selling, general and administrative	1,341	10,936	2,799	16,618
GAAP Total operating expenses	17,596	34,907	33,113	67,591
Share-based compensation expense	(7,616)	(6,781)	(14,285)	(19,977)
Non-GAAP Total operating expense	9,980	28,126	18,828	47,614
GAAP Loss from operations	(17,596)	(34,907)	(33,113)	(67,591)
Share-based compensation expense	7,616	6,781	14,285	19,977
Non-GAAP Loss from operations	(9,980)	(28,126)	(18,828)	(47,614)
GAAP Net loss	(16,320)	(28,412)	(30,597)	(55,350)
Share-based compensation expense	7,616	6,781	14,285	19,977
Non-GAAP Net Loss	(8,704)	(21,631)	(16,312)	(35,373)
Weighted average number of ordinary shares used in per share				
Calculation GAAP and Non-GAAP:				
- Basic and Diluted	32,585,043	40,182,310	32,335,958	40,026,354
Net loss per ordinary share				
- Basic and Diluted GAAP	$ (0.50)	$ (0.70)	$ (0.95)	$ (1.38)

- Basic and Diluted Non-GAAP	$ (0.27)	$ (0.54)	$ (0.50)	$ (0.88)

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

	December 31, 2025	June 30, 2026
Current assets	$ 494,272	$ 501,600
Other assets	286,284	289,982
TOTAL ASSETS	$ 780,556	$ 791,582
TOTAL LIABILITIES	$ 10,070	$ 14,946
TOTAL SHAREHOLDERS' EQUITY	770,486	776,636
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 780,556	$ 791,582
Ordinary shares authorized	400,000,000	400,000,000
Ordinary shares issued	39,353,365	40,344,713
Ordinary shares outstanding	39,339,960	40,272,144

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