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

November 12, 2026

- New Drug Application (NDA) for tinlarebant in Stargardt disease type 1 (STGD1) granted priority review by the U.S. Food and Drug Administration (FDA) in August 2026 with Prescription Drug User Fee Act (PDUFA) target action date of February 12, 2027
- Company has been informed by the FDA that it will not convene an advisory committee meeting to discuss the NDA for tinlarebant in STGD1
- Submitted NDA for tinlarebant to Japan's Ministry of Health, Labour and Welfare under Sakigake designation (J-NDA)
- Submitted Marketing Authorization Applications for tinlarebant in Singapore, the United Kingdom, and Switzerland via the Access Consortium pathway
- Company uplisted to the Nasdaq Global Select Market
- Conference call and webcast on Thursday, November 12, 2026, at 4:30 p.m. ET

SAN DIEGO, Nov. 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 third quarter ended September 30, 2026, and provided a business update.

"As we advance toward our PDUFA target action date of February 12, 2027, we remain focused on commercial readiness and are energized by the potential to bring a first-ever treatment to people living with STGD1," said Dr. Tom Lin, Chairman and Chief Executive Officer of Belite Bio. "The third quarter also marked meaningful progress in our efforts to bring tinlarebant to people living with STGD1 globally. Following the FDA's acceptance of our NDA with Priority Review, we submitted a J-NDA in Japan under Sakigake designation and filed marketing authorization applications in Singapore, the United Kingdom, and Switzerland through the Access Consortium, as we seek to expand the potential reach of tinlarebant in this rare degenerative retinal disease."

Third Quarter 2026 Business Highlights and Upcoming Milestones:

Clinical Highlights

Stargardt disease type 1 (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.
  - In August 2026, the FDA accepted the NDA for tinlarebant in STGD1 and granted Priority Review, with an assigned PDUFA target action date of February 12, 2027.
  - The Company has been informed by the FDA that it will not convene an advisory committee meeting to discuss the NDA for tinlarebant in STGD1. The FDA's review of the NDA for tinlarebant in STGD1 is still ongoing.
  - The Company submitted a J-NDA to the Ministry of Health, Labour and Welfare (MHLW) in Japan for tinlarebant in STGD1 in September 2026. Tinlarebant has been granted Sakigake designation in Japan, which provides for prioritized consultation, pre-application consultation, prioritized review, assignment of a review partner, and an extended re-examination period.
  - The Company also submitted Marketing Authorization Applications for tinlarebant in STGD1 to Singapore's Health Sciences Authority, the United Kingdom's Medicines and Healthcare Products Regulatory Agency, and Swissmedic in October 2026 through the Access Consortium framework, a collaborative initiative comprised of multiple regulatory authorities.
  - In July 2026, Belite Bio reported additional, positive secondary endpoint data from the DRAGON trial. Notably, the presentation reported that quantitative autofluorescence (qAF), a marker of toxic bisretinoid accumulation, showed a marked divergence between treatment groups. At month 25, in subjects treated with tinlarebant, qAF values remained stable to slightly decrease from baseline (approximately 2%), whereas placebo-treated subjects showed an approximate 20% increase in qAF from baseline. As previously announced, the Phase 3 DRAGON trial met its

primary efficacy endpoint, demonstrating a statistically significant and clinically meaningful 35.7% reduction in the growth rate of retinal lesions, measured as definitely decreased autofluorescence (DDAF) by fundus autofluorescence imaging, compared with placebo. Tinlarebant was well tolerated throughout the trial.
    - Belite Bio also presented encore data at various medical congresses, including at the Schweizerische Ophthalmologische Gesellschaft (SOG) Annual Congress, the 19th Asia-Pacific Vitreo-retina Society (APVRS) Congress, EURETINA 2026, Innovate Retina, and the American Academy of Ophthalmology (AAO) 2026 Annual Meeting.
- 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.
    - Target enrollment is completed with a total of 73 subjects, including 15 Japanese subjects for the Phase 2/3 trial in STGD1.
    - Trial design and inclusion of Japanese patients are intended to supplement the J-NDA submission in Japan.
    - 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

- Belite Bio hosted a Commercial Day in September 2026 featuring members of management, leading ophthalmology experts and people living with STGD1, which provided an overview of STGD1, the significant unmet need for treatment options and the current treatment landscape, as well as the Company's prelaunch preparedness strategies and the potential commercial opportunity for tinlarebant in STGD1, if approved by the FDA.
- Belite Bio launched the disease website for STGD1 in October 2026 (https://seestargardtdisease.com/).
- Belite Bio also recently announced the uplisting of the Company's securities from the Nasdaq Capital Market to the Nasdaq Global Select Market, with trading beginning on October 19, 2026, under the existing ticker symbol "BLTE."

Third Quarter 2026 Financial Results:

Cash and Cash Equivalents: As of September 30, 2026, the Company had $271.3 million in cash and cash equivalents, compared with $352.9 million on December 31, 2025.

Investments: As of September 30, 2026, the Company had $502.7 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 September 30, 2026, R&D expenses were $15.5 million compared to $10.3 million for the same period in 2025. The increase in R&D expenses in the quarter was primarily attributable to increases in (i) active pharmaceutical ingredient ("API") manufacturing expense and drug product ("DP") manufacturing expense, (ii) consultant fees, and (iii) sponsorship funding. For the nine months ended September 30, 2026, R&D expenses were $49.4 million compared to $30.8 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 in the second quarter of 2026, (ii) an increase in API and DP manufacturing expenses, and (iii) an increase in consultant fees.

On a non-GAAP basis, excluding share-based compensation expenses, non-GAAP R&D expenses for the three months ended September 30, 2026, were $14.7 million compared to $8.0 million for the same period in 2025. For the nine months ended September 30, 2026, non-GAAP R&D expenses were $45.7 million compared to $24.1 million for the same period in 2025.

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

For the three months ended September 30, 2026, SG&A expenses were $21.4 million compared to $12.7 million for the same period in 2025. The increase in SG&A expenses in the quarter was primarily attributable to an increase in professional service fees. For the nine months ended September 30, 2026, SG&A expenses were $55.1 million compared to $25.4 million for the same period in 2025. The increase in SG&A year-to-date was primarily attributable to increases in (i) professional service fees, and (ii) 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 September 30, 2026, were $16.3 million compared to $2.1 million for the same period in 2025. For the nine months ended September 30, 2026, non-GAAP SG&A expenses were $32.9 million compared to $4.9 million for the same period in 2025.

Other Income:

For the three months ended September 30, 2026, other income was $6.7 million compared to $1.3 million for the same period in 2025. For the nine

months ended September 30, 2026, other income was $18.9 million compared to $3.8 million for the same period in 2025. The increase in other income in the quarter and year-to-date was attributed to interest income from bank deposits, U.S. treasury bills and U.S. treasury notes.

Net Loss:

For the three months ended September 30, 2026, the Company reported a net loss of $30.3 million, compared to a net loss of $21.7 million for the same period in 2025. For the nine months ended September 30, 2026, net loss was $85.6 million compared to $52.3 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 $24.3 million for the three months ended September 30, 2026, compared to a non-GAAP net loss of $8.8 million for the same period in 2025. For the nine months ended September 30, 2026, non-GAAP net loss was $59.7 million compared to $25.1 million for the same period in 2025.

Webcast Information

Belite Bio will host a webcast on Thursday, November 12, 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 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 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 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 approval of tinlarebant as the first-ever treatment to patients living with STGD1, the potential implications of clinical data for patients; Belite Bio's advancement of, and anticipated 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 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 supplement J-NDA in Japan; the Company's progress and efforts in commercialization preparation, the Company's pre-launch preparedness strategies and the potential commercial opportunity for tinlarebant in STGD1, 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", "remain", "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, FDA's regulatory decisions on the NDA for tinlarebant in STGD1, the outcome and timing of the review of the J-NDA for tinlarebant in STGD1 by the MHLW and of the marketing authorization applications for tinlarebant in STGD1 by the Health Sciences Authority, the Medicines and Healthcare Products Regulatory Agency and Swissmedic; Belite Bio's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, including the results of any interim analysis of the PHOENIX trial, 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; 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 September 30,		For the Nine Months Ended September 30,	
	2025	**2026**	**2025**	**2026**
Expenses				
Research and development	10,307	15,482	30,753	49,356
Selling, general and administrative	12,711	21,428	25,378	55,145
Total operating expenses	23,018	36,910	56,131	104,501
Loss from operations	(23,018)	(36,910)	(56,131)	(104,501)
Other income:				
Total other income, net	1,328	6,650	3,844	18,946
Loss before income tax	(21,690)	(30,260)	(52,287)	(85,555)
Income tax expense	-	13	-	68
Net loss	(21,690)	(30,273)	(52,287)	(85,623)
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of nil tax	82	23	228	51
Total comprehensive loss	(21,608)	(30,250)	(52,059)	(85,572)
Weighted average number of ordinary shares used in per share calculation:				
- Basic and Diluted	33,223,232	40,415,114	32,634,966	40,157,365
Net loss per ordinary share				
- Basic and Diluted	$ (0.65)	$ (0.75)	$ (1.60)	$ (2.13)

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 September 30,		For the Nine Months Ended September 30,	
	2025	2026	2025	2026
Expenses				
GAAP Research and development	10,307	15,482	30,753	49,356
Share-based compensation expense	(2,278)	(773)	(6,695)	(3,651)
Non-GAAP research and development	8,029	14,709	24,058	45,705
GAAP Selling, general and administrative	12,711	21,428	25,378	55,145
Share-based compensation expense	(10,640)	(5,168)	(20,509)	(22,267)
Non-GAAP selling, general and administrative	2,071	16,260	4,869	32,878
GAAP Total operating expenses	23,018	36,910	56,131	104,501
Share-based compensation expense	(12,918)	(5,941)	(27,204)	(25,918)
Non-GAAP Total operating expense	10,100	30,969	28,927	78,583
GAAP Loss from operations	(23,018)	(36,910)	(56,131)	(104,501)
Share-based compensation expense	12,918	5,941	27,204	25,918
Non-GAAP Loss from operations	(10,100)	(30,969)	(28,927)	(78,583)
GAAP Net loss	(21,690)	(30,273)	(52,287)	(85,623)
Share-based compensation expense	12,918	5,941	27,204	25,918
Non-GAAP Net Loss	(8,772)	(24,332)	(25,083)	(59,705)
Weighted average number of ordinary shares used in per share				
Calculation GAAP and Non-GAAP:				
- Basic and Diluted	33,223,232	40,415,114	32,634,966	40,157,365
Net loss per ordinary share				
- Basic and Diluted GAAP	$ (0.65)	$ (0.75)	$ (1.60)	$ (2.13)
- Basic and Diluted Non-GAAP	$ (0.26)	$ (0.60)	$ (0.77)	$ (1.49)

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

	December 31, 2025	September 30, 2026
Current assets	$ 494,272	$ 498,346
Other assets	286,284	291,392
TOTAL ASSETS	$ 780,556	$ 789,738
TOTAL LIABILITIES	$ 10,070	$ 18,678
TOTAL SHAREHOLDERS' EQUITY	770,486	771,060
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 780,556	$ 789,738
Ordinary shares authorized	400,000,000	400,000,000
Ordinary shares issued	39,353,365	40,750,271
Ordinary shares outstanding	39,339,960	40,614,160

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