

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): January 11, 2026

EXELIXIS[®]

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

000-30235

(Commission File Number)

04-3257395

(IRS Employer Identification No.)

**1851 Harbor Bay Parkway
Alameda, California 94502**

(Address of principal executive offices) (Zip Code)

(650) 837-7000

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock \$0.001 Par Value per Share	EXEL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On January 11, 2026, Exelixis, Inc. (Exelixis or the Company) issued a press release announcing its preliminary unaudited financial results for the fiscal year ended January 2, 2026, providing financial guidance for the fiscal year ending January 1, 2027, and delivered an update on its business. A copy of such press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference. The preliminary unaudited financial results contained in the press release do not present all information for an understanding of Exelixis' financial condition as of January 2, 2026 and its results of operations for the fiscal year ended January 2, 2026. The audit of Exelixis' financial statements for the fiscal year ended January 2, 2026 is ongoing and could result in changes to the information in the press release. The press release also announced that Exelixis will report its audited financial results for the fiscal year ended January 2, 2026 on February 10, 2026.

The information in this report, including the exhibit hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this report and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission (SEC) made by Exelixis, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Exhibit Description</u>	
99.1	Press Release dated January 11, 2026	
104	Cover Page Interactive Data File	The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

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 hereunto duly authorized.

EXELIXIS, INC.

January 12, 2026

Date

/s/ Brenda Hefti

Brenda Hefti

Executive Vice President and General Counsel

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Exelixis Announces Preliminary Fiscal Year 2025 Financial Results, Provides 2026 Financial Guidance and Outlines Key Priorities and Milestones for 2026

– Cabozantinib franchise achieves approximately \$2.123 billion in preliminary U.S. net product revenues for fiscal year 2025

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– Fiscal year 2026 net product revenues guidance of \$2.325 billion - \$2.425 billion –

– Presentation and webcast at J.P. Morgan 2026 Healthcare Conference tomorrow, Monday, January 12th at 5:15 p.m. PT / 8:15 p.m. ET –

ALAMEDA, Calif. – January 11, 2026 – Exelixis, Inc. (Nasdaq: EXEL) today announced its preliminary unaudited financial results for the fiscal year 2025, provided financial guidance for fiscal year 2026 and delivered an update on its business. Exelixis anticipates 2026 will be a significant year of clinical, regulatory and commercial progress as the company grows its current cabozantinib business, works toward building a potential second commercial franchise with zanzalintinib and moves its earlier stage pipeline forward. As outlined at its December 2025 R&D Day, the company seeks to leverage its diverse pipeline and key clinical collaborations to build next-generation oncology franchises that can improve standards of care for patients with cancer.

Preliminary Fiscal Year 2025 Financial Results & 2026 Financial Guidance

Exelixis is providing the following preliminary unaudited 2025 financial results and financial guidance for 2026. Net product and total revenues guidance do not currently reflect any revenues resulting from a potential U.S. regulatory approval and commercial launch of zanzalintinib for the treatment of patients with previously treated metastatic colorectal cancer (CRC). The U.S. Food and Drug Administration (FDA) is currently reviewing Exelixis' New Drug Application (NDA) for this proposed indication, when used in combination with atezolizumab (Tecentriq®).

	Fiscal Year 2025	Fiscal Year 2026 Guidance
Total revenues	~ \$2.320 billion	\$2.525 billion - \$2.625 billion
Net product revenues	~ \$2.123 billion	\$2.325 billion - \$2.425 billion ⁽¹⁾
Cost of goods sold, % of net product revenues	~ 3.7%	3.5% - 4.5%
Research and development expenses	~ \$825 million ⁽²⁾	\$875 million - \$925 million ⁽³⁾
Selling, general and administrative expenses	~ \$520 million ⁽⁴⁾	\$575 million - \$625 million ⁽⁵⁾
Effective tax rate	n/a ⁽⁶⁾	21% - 23%
Ending cash and marketable securities ⁽⁷⁾	~ \$1.65 billion	n/p

⁽¹⁾ Exelixis' 2026 net product revenues guidance range includes the impact of a U.S. wholesale acquisition cost increase of 3.0% for both CABOMETYX® and COMETRIQ® effective on January 1, 2026.

⁽²⁾ Includes \$40.8 million of non-cash stock-based compensation expense.

⁽³⁾ Includes \$50.0 million of non-cash stock-based compensation expense.

⁽⁴⁾ Includes \$72.2 million of non-cash stock-based compensation expense.

⁽⁵⁾ Includes \$75.0 million of non-cash stock-based compensation expense.

⁽⁶⁾ Preliminary results not yet available.

⁽⁷⁾ Cash and marketable securities are composed of cash, cash equivalents and marketable securities. Fiscal year 2026 guidance not provided (n/p).

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The preliminary 2025 financial information presented in this press release has not been audited and is subject to change. The complete Exelixis Fourth Quarter and Fiscal Year 2025 Financial Results are planned for release after market on Tuesday, February 10, 2026.

“Exelixis enters 2026 with a strong and growing commercial business, the opportunity to bring a potential second oncology franchise to market and an exciting pipeline of novel small molecules and biotherapeutics,” said Michael M. Morrissey, Ph.D., President & CEO, Exelixis. “Our momentum accelerated throughout 2025, driven by the continued strong commercial performance of CABOMETYX in renal cell carcinoma and advanced neuroendocrine tumors. We also achieved major milestones with the first positive pivotal data readout and subsequent U.S. regulatory filing for zanzalintinib, our next potential franchise molecule, and drove meaningful pipeline progress.”

Dr. Morrissey continued: “To achieve our goal of becoming a top-5 solid tumor oncology company, Exelixis is pursuing a multi-franchise approach that fosters innovation, manages risk and maximizes the value of our portfolio for all our stakeholders. Building on the cabozantinib experience, we aim to establish lasting franchises in renal cell carcinoma, neuroendocrine tumors and colorectal cancer where our products can be successful as monotherapies or in combination, including with other Exelixis pipeline assets. Through careful prioritization and disciplined investments in high-value opportunities, we are confident we can drive sustained near- to mid-term growth while returning capital to shareholders and improving the standards of care for patients with cancer.”

Anticipated Cabozantinib Milestones

Growth and Acceleration of Cabozantinib Commercial Franchise. Exelixis expects cabozantinib franchise growth to continue in 2026, building on the product's position as the leading tyrosine kinase inhibitor (TKI) and oral therapy in renal cell carcinoma (RCC) and neuroendocrine tumors (NET). As of the third quarter 2025, in RCC, CABOMETYX® (cabozantinib) was the market leader as the number one TKI monotherapy and the most prescribed TKI in combination with immunotherapy (IO). The accelerating uptake in NET builds on the March 2025 U.S. regulatory approval of CABOMETYX for two new NET indications, advanced pancreatic and extra-pancreatic NET (pNET and epNET), based on results from the CABINET study. As of the third quarter 2025, CABOMETYX was the leading oral therapy in the second-or-later line (2L+) NET market, with broad uptake across 2L+ patient types and practice settings. Based on this success and with additional gastrointestinal (GI) cancer opportunities ahead, Exelixis is expediting the full buildout of its GI sales team to accelerate growth in NET and prepare for potential future indications for zanzalintinib in GI cancers.

Anticipated Zanzalintinib Milestones

Ongoing U.S. Regulatory Review in CRC. Exelixis is preparing for the potential first commercial launch of zanzalintinib for the treatment of patients with previously treated CRC, when used in combination with atezolizumab. The regulatory filing was based on positive results from the phase 3 STELLAR-303 pivotal trial, which met one of its dual primary endpoints, with the combination of zanzalintinib and atezolizumab demonstrating a statistically significant reduction in the risk of death versus regorafenib in the intention-to-treat population at the final analysis. An overall survival (OS) benefit with the combination was consistently observed across pre-specified subgroups, including geographic region, RAS status, liver involvement and prior anti-VEGF therapy.

STELLAR-303 CRC Study Final Analysis of Second Dual Primary Endpoint of OS in Patients without Liver Metastases Expected Mid-2026. In 2025, a prespecified interim analysis of STELLAR-303's other dual primary endpoint, OS in patients without liver metastases (non-liver metastases or NLM), showed a trend favoring the combination; however, these data were immature at the data cutoff. The trial is proceeding to the planned final analysis for this endpoint, which is expected in mid-2026, based on current event rates.

Topline Results for STELLAR-304 Anticipated Mid-2026. STELLAR-304 is a phase 3 pivotal trial evaluating zanzalintinib in combination with nivolumab versus sunitinib in previously untreated patients with advanced non-clear cell RCC. The primary endpoints in the trial are progression-free survival (PFS) and objective response rate (ORR). STELLAR-304 completed enrollment in May 2025. Topline results expected in mid-2026, based on current event rates.

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Enrollment Progress for STELLAR-311 Trial of Zanzalintinib in Advanced NET. Exelixis is actively enrolling patients in the phase 2/3 STELLAR-311 pivotal trial, which is evaluating zanzalintinib versus everolimus as a first oral therapy in patients with advanced NET, regardless of site of origin, who have received up to one prior line of therapy. Initiated in June 2025, STELLAR-311 is the first study to randomize a small molecule against an active control in this setting, with the potential to broadly redefine oral treatment options for these patients. The primary endpoint of the trial is PFS per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 as assessed by Blinded Independent Central Review.

Additional Ongoing and Planned Pivotal Trials for Zanzalintinib. In addition to the ongoing Exelixis-sponsored STELLAR-303, -304, and -311 trials, additional zanzalintinib pivotal trials include:

- **LITESPARK-033**, which is evaluating the combination of zanzalintinib and WELIREG® (belzutifan) versus cabozantinib in first-line advanced RCC following IO administered in the adjuvant setting. LITESPARK-033 was initiated in December 2025 and is the first Merck-sponsored pivotal trial of zanzalintinib and belzutifan in RCC under the companies' clinical development collaboration. A second Merck-sponsored pivotal trial of zanzalintinib and belzutifan in RCC is anticipated to begin in early 2026. Details of this anticipated study are forthcoming.
- **STELLAR-316**, which will evaluate the potential of zanzalintinib, with and without an immune checkpoint inhibitor, to keep patients disease-free in the adjuvant CRC setting. As currently proposed, the study will enroll patients with resected stage II/III CRC who have completed definitive therapy and tested positive for molecular residual disease (MRD), but do not have radiographic evidence of disease. The primary endpoint of STELLAR-316 is disease-free survival, with secondary endpoints including circulating tumor DNA clearance. Exelixis recently announced a collaboration with Natera, a global leader in cell-free DNA and precision medicine, in which Natera will provide its Signatera™ assay to identify MRD-positive patients for enrollment in the trial. Exelixis expects to initiate STELLAR-316 in mid-2026.
- **STELLAR-201**, which will evaluate zanzalintinib in recurrent meningioma, the most common primary intracranial neoplasm for which there are currently no approved systemic therapies. The study is planned to enroll patients with Grade I/II/III meningioma with relapse/progression following radiation/surgery or who are not candidates for radiation/surgery. The proposed primary endpoint of the trial is ORR, with secondary endpoints including duration of response, PFS and OS. Pending favorable results, the trial represents an opportunity for zanzalintinib to become the first and only systemic therapy approved for this form of cancer. Exelixis expects to initiate STELLAR-201 in mid-2026, and a confirmatory phase 3 study is also being planned.

Anticipated R&D Milestones

Progress of Phase 1 Clinical Programs for XL309, XB010, XB628 and XB371. Exelixis is advancing ongoing phase 1 clinical trials for XL309 (USP1 inhibitor), XB010 (5T4-targeting ADC), XB628 (PD-L1 + NKG2A bispecific) and XB371 (TF-targeting ADC). If phase 1 data are supportive, Exelixis plans to progress these molecules into full development as part of its strategy to build next-generation oncology franchises across tumor types and novel combination regimens, including with zanzalintinib and other therapeutic modalities. Combination opportunities of particular development interest highlighted at the December 2025 R&D Day include zanzalintinib plus XB628 in both advanced RCC and CRC.

Two Potential IND Applications in 2026. Exelixis anticipates advancing two programs into clinical development this year:

- **XL557** is an orally bioavailable small molecule Somatostatin Receptor 2 agonist. Somatostatin analogs are widely used in the first- and second-line NET treatment settings, but currently available therapies are administered via injection and pose associated challenges. Exelixis believes XL557 has the potential to become a best-in-class molecule that could serve NET patients across all lines of treatment as a monotherapy and potentially in combination with zanzalintinib.
- **XB773** is an antibody-drug conjugate (ADC) consisting of an exatecan payload conjugated to a monoclonal antibody targeting DLL3, a transmembrane protein that is expressed in neuroendocrine carcinomas such as small cell lung cancer and neuroendocrine prostate cancer. Exelixis believes XB773 could be a best-in-class molecule with better payload delivery compared to competitor ADCs and potential for improved therapeutic benefit, as well as strong combination potential that would facilitate its use in earlier lines and settings.

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Corporate Updates

Stock Repurchase Program (SRP) Update. Since Exelixis' Board of Directors authorized the first SRP in March 2023, Exelixis has repurchased a total of \$2.16 billion of the company's common stock, retiring 76.7 million shares, at an average price of \$28.14 per share, as of the end of fiscal year 2025. In October 2025, Exelixis' Board of Directors authorized the repurchase of up to an additional \$750 million of the company's common stock before December 31, 2026. Exelixis has begun executing stock repurchases under the October 2025 SRP, which is the fifth such program to be undertaken by the company since March 2023. Stock repurchases under this program may be made from time to time through a variety of methods, which may include open market purchases, in block trades, Rule 10b5-1 trading plans, accelerated share repurchase transactions, exchange transactions or any combination of such methods. The timing and amount of any stock repurchases under the SRP will be based on a variety of factors, including ongoing assessments of the capital needs of the business, alternative investment opportunities, the market price of our common stock and general market conditions. The program does not obligate Exelixis to acquire any amount of its common stock, and the SRP may be modified, suspended or discontinued at any time without prior notice.

Presentation and Webcast

Exelixis President and Chief Executive Officer Michael M. Morrissey, Ph.D., will provide a corporate overview and discuss the company's preliminary fiscal year 2025 financial results, 2026 financial guidance and key priorities and milestones for 2026 during the company's presentation at the J.P. Morgan 2026 Healthcare Conference beginning at 5:15 p.m. PT / 8:15 p.m. ET on Monday, January 12, 2026.

To access the webcast link, log onto www.exelixis.com and proceed to the Event Calendar page under the Investors & News heading. A replay will also be available at the same location for at least 30 days.

About Exelixis

Exelixis is a globally ambitious oncology company innovating next-generation medicines and regimens at the forefront of cancer care. Powered by drug discovery and development excellence, we are rapidly evolving our product portfolio to target an expanding range of tumor types and indications with our clinically differentiated pipeline of small molecules and biotherapeutics. This comprehensive approach harnesses decades of robust investment in our science and partnerships to advance our investigational programs and extend the impact of our flagship commercial product, CABOMETYX® (cabozantinib). Exelixis is driven by a bold scientific pursuit to create transformational treatments that give more patients hope for the future. For information about the company and its mission to help cancer patients recover stronger and live longer, visit www.exelixis.com, follow [@ExelixisInc](https://twitter.com/ExelixisInc) on X (Twitter), like [Exelixis, Inc.](https://www.facebook.com/Exelixis,Inc) on Facebook and follow [Exelixis](https://www.linkedin.com/company/exelixis) on LinkedIn.

Forward-Looking Statements and Preliminary Financial Results

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' anticipation that 2026 will be a significant year of clinical, regulatory and commercial progress as the company grows its current cabozantinib business, works toward building a potential second commercial franchise with zanzalintinib and moves its earlier stage pipeline forward; Exelixis' 2026 financial guidance; Exelixis' goal to build next-generation oncology franchises that can improve standards of care for patients with cancer and to become top 5 solid tumor oncology company; Exelixis' goal to establish lasting franchises in RCC, NET and CRC while driving sustained near to mid-term growth, returning capital to shareholders and improving the standards of care for patients with cancer; Exelixis' belief in the continued strong commercial performance of the cabozantinib franchise, with expected growth and acceleration in RCC and NET in 2026, including plans to buildout its GI sales team to accelerate growth in NET and prepare for future indications for zanzalintinib in GI cancers; the regulatory review process with respect to Exelixis' NDA for zanzalintinib for the treatment of patients with previously metastatic CRC, when used in combination with atezolizumab; Exelixis' plans for the potential first commercial launch of zanzalintinib in combination with atezolizumab for the treatment of patients with previously treated CRC; Exelixis' upcoming development milestones, including expansion and acceleration of the zanzalintinib pivotal trial program; Exelixis' expectation for clinical data readouts from STELLAR-303 and STELLAR-304; clinical progress and priorities for STELLAR 311 and LITESPARK-033; Exelixis' plans to initiate STELLAR-316 and STELLAR-301 in 2026; Exelixis plans to progress XL309, XB010, XB628 and XB371 into full development as part of its strategy to build next-generation oncology franchises across tumor types and novel

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combination regimens, including with zanzalintinib and other therapeutic modalities, if phase 1 data are supportive; Exelixis' anticipated discovery milestones, including the advancement into clinical development of XL557 and XB773; the timing, amount, and completion of any stock repurchase programs; and Exelixis' scientific pursuit to create transformational treatments that give more patients hope for the future; and other statements that are not historical facts. Any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements and are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the degree of market acceptance of CABOMETYX and other Exelixis products in the indications for which they are approved and in the territories where they are approved, and Exelixis' and its partners' ability to obtain or maintain coverage and reimbursement for these products; the effectiveness of CABOMETYX and other Exelixis products in comparison to competing products; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; Exelixis' ability to maintain and scale adequate sales, marketing, market access and product distribution capabilities for its products or to enter into and maintain agreements with third parties to do so; the availability of data at the referenced times; the potential failure of cabozantinib, zanzalintinib and other Exelixis product candidates, both alone and in combination with other therapies, to demonstrate safety and/or efficacy in clinical testing; uncertainties inherent in the drug discovery and product development process; Exelixis' dependence on its relationships with its collaboration partners, including their pursuit of regulatory approvals for partnered compounds in new indications, their adherence to their obligations under relevant collaboration agreements and the level of their investment in the resources necessary to complete clinical trials or successfully commercialize partnered compounds in the territories where they are approved; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; Exelixis' continuing compliance with applicable legal and regulatory requirements; unexpected concerns that may arise as a result of the occurrence of adverse safety events or additional data analyses of clinical trials evaluating cabozantinib, zanzalintinib and other Exelixis product candidates; Exelixis' dependence on third-party vendors for the development, manufacture and supply of its products and product candidates; Exelixis' ability to protect its intellectual property rights; market competition, including the potential for competitors to obtain approval for generic versions of Exelixis' marketed products; changes in economic and business conditions, including as a result of changing trade policies and tariffs and the related uncertainty thereof; and other factors detailed from time to time under the caption "Risk Factors" in Exelixis' most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and in Exelixis' other future filings with the Securities and Exchange Commission. All forward-looking statements in this press release are based on information available to Exelixis as of the date of this press release, and Exelixis undertakes no obligation to update or revise any forward-looking statements contained herein, except as required by law.

In addition, this press release includes Exelixis' preliminary financial results for the fiscal year ended January 2, 2026. Exelixis is currently in the process of finalizing its financial results for the quarter and fiscal year ended January 2, 2026, and the preliminary financial results presented in this press release are based only upon preliminary information available to Exelixis as of January 11, 2026. Exelixis' preliminary financial results should not be viewed as a substitute for audited financial statements prepared in accordance with U.S. GAAP, and undue reliance should not be placed on Exelixis' preliminary financial results. Exelixis' independent registered public accounting firm has not audited or reviewed the preliminary financial results included in this press release or expressed any opinion or other form of assurance on such preliminary financial results. In addition, items or events may be identified or occur after the date of this press release due to the completion of operational and financial closing procedures, final audit adjustments and other developments may arise that would require Exelixis to make material adjustments to the preliminary financial results included in this press release. Therefore, the preliminary financial results included in this press release may differ, perhaps materially, from the financial results that will be reflected in Exelixis' audited consolidated financial statements for the fiscal year ended January 2, 2026.

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TECENTRIQ (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

*WELIREG® is a registered trademark of Merck Sharp & Dohme LLC,
a subsidiary of Merck & Co., Inc., Rahway, N.J., USA.*

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