

**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): February 7, 2023**

---

**EXELIXIS<sup>®</sup>**

**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>
<b>Common Stock \$.001 Par Value per Share</b>	<b>EXEL</b>	<b>The Nasdaq Stock Market LLC</b>

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 February 7, 2023, Exelixis, Inc. ("Exelixis") issued a press release announcing its financial results for the quarter and full year ended December 30, 2022, and providing a corporate update. A copy of such press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

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 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	<a href="#">Press Release issued February 7, 2023</a>	
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.

February 7, 2023

\_\_\_\_\_  
Date

/s/ Jeffrey J. Hessekiel

\_\_\_\_\_  
**Jeffrey J. Hessekiel**  
Executive Vice President, General Counsel  
and Secretary



**Contacts:**  
Chris Senner  
Chief Financial Officer  
Exelixis, Inc.  
650-837-7240  
[csenner@exelixis.com](mailto:csenner@exelixis.com)

Susan Hubbard  
EVP, Public Affairs & Investor Relations  
Exelixis, Inc.  
650-837-8194  
[shubbard@exelixis.com](mailto:shubbard@exelixis.com)

**EXELIXIS ANNOUNCES FOURTH QUARTER AND FULL YEAR 2022 FINANCIAL RESULTS  
AND PROVIDES CORPORATE UPDATE**

- **Total Revenues of \$423.9 million for the Fourth Quarter of 2022, \$1.61 billion for the Full Year 2022 -**
- **Cabozantinib franchise achieved \$1.40 billion in U.S. Net Product Revenues for the Full Year 2022, including \$377.4 million for the Fourth Quarter 2022 -**
- **GAAP Diluted EPS of \$(0.09) for the Fourth Quarter of 2022, \$0.56 for the Full Year 2022 -**
- **Non-GAAP Diluted EPS of \$(0.03) for the Fourth Quarter of 2022, \$0.82 for the Full Year 2022 -**
- **Conference Call and Webcast Today at 5:00 PM Eastern Time -**

**ALAMEDA, Calif. - February 7, 2023** - Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the fourth quarter and full year of 2022 and provided an update on progress toward achieving key corporate objectives, as well as commercial, clinical and pipeline development milestones.

“Exelixis had a productive fourth quarter and full year 2022 as we continued to grow the cabozantinib commercial franchise and significantly advanced our growing product pipeline,” said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. “The strong performance of CABOMETYX® resulted in U.S. net product revenues exceeding \$1.4 billion for cabozantinib in 2022, further reinforcing the franchise’s status as a leading therapy for forms of renal, liver, and thyroid cancer. The team also continued to execute across our clinical development, discovery and business development functions. We had clinical data readouts for cabozantinib, next-generation tyrosine kinase inhibitor zanzalintinib, tissue factor-targeting antibody drug conjugate XB002, and selective and irreversible CDK7 inhibitor XL102. We progressed three promising biotherapeutics, XB010, XB014 and XB628, from internal discovery into preclinical development. And we signed multiple new collaborations, including exclusive clinical development collaboration and option agreements with Cybrexa and Sairopa in the fourth quarter to advance the CBX-12 and ADU-1805 programs, respectively.”

Dr. Morrissey continued: “In 2023, Exelixis is focused on advancing our diverse, high-impact pipeline of biotherapeutics and small molecules for oncology fueled by the continued commercial success of the cabozantinib franchise. Throughout the year we expect to initiate the next wave of phase 3 studies of zanzalintinib, move XB002 into full development, report data from three pivotal trials of cabozantinib and continue to add new agents to our portfolio from internal discovery and collaborative efforts. Importantly, we’ll continue to pursue additional in-licensing and strategic opportunities for near-clinical- and clinical-stage assets

- more -

to enhance the breadth and depth of our pipeline. I'd like to thank the Exelixis team for all their hard work and continued dedication toward advancing our mission to help cancer patients recover stronger and live longer.”

#### **Fourth Quarter and Full Year 2022 Financial Results**

**Total revenues** for the quarter and year ended December 31, 2022 were \$423.9 million and \$1,611.1 million, respectively, as compared to \$451.1 million and \$1,435.0 million for the comparable periods in 2021.

Total revenues for the quarter and year ended December 31, 2022 included net product revenues of \$377.4 million and \$1,401.2 million, respectively, as compared to \$302.7 million and \$1,077.3 million for the comparable periods in 2021. The increases in net product revenues were primarily due to increases in sales volume, which were partially offset by higher discounts and allowances, driven primarily by chargebacks related to the 340B Drug Pricing Program.

Collaboration revenues, composed of license revenues and collaboration services revenues, were \$46.5 million and \$209.8 million for the quarter and year ended December 31, 2022, respectively, as compared to \$148.5 million and \$357.7 million for the comparable periods in 2021. The decreases in collaboration revenues were primarily related to decreases in the recognition of milestone-related revenues and in development cost reimbursements earned, which were partially offset by higher royalty revenues for the sales of cabozantinib outside of the U.S. generated by Exelixis' collaboration partners, Ipsen Pharma SAS (Ipsen) and Takeda Pharmaceutical Company Limited (Takeda).

**Research and development expenses** for the quarter and year ended December 31, 2022 were \$336.8 million and \$891.8 million, respectively, as compared to \$222.3 million and \$693.7 million for the comparable periods in 2021. The increases in research and development expenses were primarily related to increases in license and other collaboration costs, personnel expenses, consulting and outside services costs, and clinical trial costs.

**Selling, general and administrative expenses** for the quarter and year ended December 31, 2022 were \$119.3 million and \$459.9 million, respectively, as compared to \$99.3 million and \$401.7 million for the comparable periods in 2021. The increases in selling, general and administrative expenses were primarily related to increases in personnel expenses, business technology initiatives, rent expenses and marketing costs.

**Provision for (benefit from) income taxes** for the quarter and year ended December 31, 2022 was \$(1.3) million and \$52.1 million, respectively, as compared to \$22.9 million and \$63.1 million for the comparable periods in 2021, primarily due to a decrease in pre-tax income.

**GAAP net income (loss)** for the quarter ended December 31, 2022 was \$(30.2) million, or \$(0.09) per share, basic and diluted, as compared to GAAP net income of \$95.2 million, or \$0.30 per share, basic and \$0.29 per share diluted, for the comparable period in 2021. GAAP net income for the year ended December 31, 2022 was \$182.3 million, or \$0.57 per share, basic and \$0.56 per share, diluted, as compared to GAAP net income of \$231.1 million, or \$0.73 per share, basic and \$0.72 per share, diluted, for the comparable period in 2021.

**Non-GAAP net income (loss)** for the quarter ended December 31, 2022 was \$(10.2) million, or \$(0.03) per share, basic and diluted, as compared to non-GAAP net income of \$113.3 million, or \$0.36 per share, basic and \$0.35 per share, diluted, for the comparable period in 2021. Non-GAAP net income for the year ended December 31, 2022 was \$265.4 million, or \$0.83 per share, basic and \$0.82 per share, diluted, as compared to non-GAAP net income of \$324.2 million, or \$1.03 per share, basic and \$1.01 per share, diluted, for the comparable period in 2021.

- more -

### Non-GAAP Financial Measures

To supplement Exelixis' financial results presented in accordance with U.S. Generally Accepted Accounting Principles (GAAP), Exelixis presents non-GAAP net income (and the related per share measures), which excludes from GAAP net income (and the related per share measures) stock-based compensation expense, adjusted for the related income tax effect for all periods presented.

Exelixis believes that the presentation of these non-GAAP financial measures provides useful supplementary information to, and facilitates additional analysis by, investors. In particular, Exelixis believes that these non-GAAP financial measures, when considered together with its financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare Exelixis' results from period to period, and to identify operating trends in Exelixis' business. Exelixis has excluded stock-based compensation expense, adjusted for the related income tax effect, because it is a non-cash item that may vary significantly from period to period as a result of changes not directly or immediately related to the operational performance for the periods presented. Exelixis also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate its business and to make operating decisions.

These non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. Exelixis encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP financial information and the reconciliation between these presentations, to more fully understand Exelixis' business. Reconciliations between GAAP and non-GAAP results are presented in the tables of this release.

### 2023 Financial Guidance

Exelixis is maintaining the previously provided financial guidance for fiscal year 2023:

Total revenues	\$1.775 billion - \$1.875 billion
Net product revenues	\$1.575 billion - \$1.675 billion
Cost of goods sold	4.0% - 5.0% of net product revenues
Research and development expenses <sup>(1)</sup>	\$1,000 million - \$1,050 million
Selling, general and administrative expenses <sup>(2)</sup>	\$475 million - \$525 million
Effective tax rate	20% - 22%

<sup>(1)</sup> Includes \$45 million of non-cash stock-based compensation expense.

<sup>(2)</sup> Includes \$55 million of non-cash stock-based compensation expense.

### Cabozantinib Highlights

**Cabozantinib Franchise Net Product Revenues and Royalties.** Net product revenues generated by the cabozantinib franchise in the U.S. were \$377.4 million during the fourth quarter of 2022, with net product revenues of \$372.6 million from CABOMETYX® (cabozantinib) and \$4.9 million from COMETRIQ® (cabozantinib). For the year ended December 31, 2022, net product revenues generated by the cabozantinib franchise in the U.S. were \$1,401.2 million, with net product revenues of \$1,375.9 million from CABOMETYX and \$25.3 million from COMETRIQ. In 2022, global cabozantinib franchise net product revenues generated by Exelixis and its partners exceeded \$1.9 billion. Based upon cabozantinib-related net product revenues generated by Exelixis' collaboration partners during the quarter and year ended December 31, 2022, Exelixis earned \$33.9 million and \$121.4 million, respectively, in royalty revenues.

- more -

**Cabozantinib Data at the 2023 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU 2023).** Next week, cabozantinib will be the subject of multiple data presentations at ASCO GU 2023, which is being held in a hybrid virtual/in-person format from February 16-18. Notable presentations include: 44-month median follow-up data and biomarker analyses from CheckMate -9ER, the phase 3 pivotal trial of cabozantinib in combination with nivolumab; outcomes by International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) risk score in COSMIC-313, the phase 3 pivotal trial of cabozantinib, nivolumab and ipilimumab; and extended follow-up results from a non-clear cell renal cell carcinoma (nccRCC) cohort of COSMIC-021, the ongoing phase 1b trial of cabozantinib in combination with atezolizumab.

### **Pipeline Highlights**

**Expanded Clinical Trial Collaboration and Supply Agreement with Bristol Myers Squibb (BMS) to Include Fixed-Dose Combination of Nivolumab and Relatlimab in Combination with Zanzalintinib (formerly XL092) in Phase 1b STELLAR-002 Trial.** In October 2022, Exelixis announced the expansion of its June 2021 Clinical Trial Collaboration and Supply Agreement with BMS to include the use of the fixed-dose combination of nivolumab and relatlimab in the ongoing phase 1b STELLAR-002 clinical trial, which is evaluating zanzalintinib in combination with multiple immune checkpoint inhibitors in advanced solid tumors. Relatlimab is a lymphocyte activation gene-3 (LAG-3)-blocking antibody. LAG-3 is an inhibitory immune checkpoint expressed on the surface of T-cells. Exelixis has established a recommended dose of 100 mg for zanzalintinib in combination with nivolumab, and we have begun enrolling expansion cohorts for patients with clear cell RCC. Enrollment and dosing in the dose-escalation stage of STELLAR-002 is ongoing to determine the recommended dose in patients with advanced solid tumors for each of the other combination therapy regimens, including: zanzalintinib, nivolumab and ipilimumab; and zanzalintinib and the fixed-dose combination of nivolumab and relatlimab. The novel triplet combination of zanzalintinib and the fixed-dose combination of nivolumab and relatlimab has the potential to be used in multiple expansion cohorts.

**Presentation of Promising Initial Results from Phase 1 JEWEL-101 Trial Evaluating XB002 in Patients with Advanced Solid Tumors at the 34<sup>th</sup> EORTC-NCI-AACR (ENA) Symposium.** In October 2022, Exelixis presented promising initial results from the ongoing dose-escalation stage of JEWEL-101, a phase 1 study evaluating Exelixis' XB002 next-generation tissue factor-targeting antibody drug conjugate (ADC), at the 34<sup>th</sup> ENA Symposium. The data demonstrated that XB002 was well-tolerated across multiple dose levels and pharmacokinetic analyses showed that XB002 remains stable after infusion with low levels of free payload in the circulation. The dose-escalation stage of the study is currently ongoing and will progress to the cohort-expansion stage once the recommended dose and/or maximum tolerated dose for XB002 have been determined. The company also plans to advance additional combination cohorts in the study to identify sensitive tumor types. In 2023, Exelixis intends to accelerate the development of XB002 both as a monotherapy and in combination with immuno-oncology (IO) and other targeted therapies, across a wide range of tumor types, and expects to move into full development by year-end.

**Presentation of Initial Dose-Escalation Results from First-in-Human Phase 1 QUARTZ-101 Trial Evaluating XL102 in Patients with Advanced Solid Tumors at the 2022 San Antonio Breast Cancer Symposium (SABCS).** In December 2022, Exelixis presented initial results from the ongoing dose-escalation stage of QUARTZ-101, a phase 1 clinical trial evaluating XL102, a potent, selective, irreversible and orally bioavailable small molecule cyclin-dependent kinase 7 (CDK7) inhibitor, at the 2022 SABCS. The data demonstrated that XL102 was well-tolerated at evaluated dose levels with a pharmacokinetic analysis showing rapid absorption of XL102 and an elimination half-life of 5-9 hours. Exelixis expects to evaluate the anti-tumor activity and efficacy of XL102 in additional patients in the single-agent dose-escalation cohorts, in the tumor-specific cohort-expansion stage and in planned combination cohorts. In the cohort-expansion stage of QUARTZ-101, XL102 will be evaluated in patients with certain types of ovarian, breast and prostate cancers.

- more -

**Initiation of the STELLAR-304 Phase 3 Pivotal Trial Evaluating Zanzalintinib in Patients with Advanced Non-Clear Cell Kidney Cancer.** In December 2022, Exelixis announced the initiation of STELLAR-304, a phase 3 pivotal trial evaluating zanzalintinib in combination with nivolumab versus sunitinib in patients with advanced nccRCC. The primary objective of the study is to evaluate the efficacy of the combination, as measured by progression-free survival and objective response rate per Response Evaluation Criteria in Solid Tumors (RECIST) v. 1.1 as assessed by the Blinded Independent Radiology Committee. The secondary endpoint is overall survival (OS). STELLAR-304 is the second phase 3 pivotal trial initiation for zanzalintinib. In 2023, the company plans to expand the pivotal development program for zanzalintinib with multiple new phase 3 pivotal trial initiations. As previously stated, Exelixis intends to develop zanzalintinib as a backbone therapy in novel combination regimens across a broad array of future potential indications, including those where cabozantinib has demonstrated anti-tumor activity.

### **Corporate Updates**

**Exclusive Collaboration Agreement with Cybrexa Therapeutics (Cybrexa) Providing Exelixis the Right to Acquire CBX-12, a First-in-Class Peptide-Drug Conjugate (PDC) of Exatecan.** In November 2022, Exelixis and Cybrexa entered into an exclusive collaboration agreement providing Exelixis the right to acquire CBX-12 (alphalex™ exatecan), a clinical-stage, first-in-class PDC that utilizes Cybrexa's proprietary alphalex technology to enhance delivery of exatecan to tumor cells. CBX-12 is designed to increase the efficacy and reduce the toxicity of topoisomerase I inhibition by delivering exatecan, a highly potent, second-generation topoisomerase I inhibitor, directly to the tumor cells using a target independent approach activated by the acidic microenvironment of solid tumors. Under the terms of the agreement, Exelixis has the right to acquire CBX-12 upon evaluation of a pre-specified clinical data package that includes certain phase 1 results.

**Established Exclusive Clinical Development Collaboration and Option Agreement with Sairopa B.V. (Sairopa) to Develop ADU-1805, a Potentially Best-in-Class Monoclonal Antibody Targeting SIRPα.** In November 2022, Exelixis and Sairopa entered into an exclusive clinical development and option agreement for ADU-1805, a potentially best-in-class monoclonal antibody that targets SIRPα to block the SIRPα-CD47 checkpoint. Blocking SIRPα has the potential to improve the immune system's ability to attack tumors by addressing a significant immune-suppressive component of the tumor microenvironment. ADU-1805 is active against all human alleles of SIRPα, which may allow it to address a broader patient population than other SIRPα-directed therapies, and has been optimized to bind preferentially to SIRPα vs. other SIRP family members, which may enhance its ability to stimulate immune cells. Under the terms of the agreement, Exelixis has the option to obtain an exclusive, worldwide license to develop and commercialize ADU-1805 and other anti-SIRPα antibodies upon review of data from prespecified phase 1 clinical studies of ADU-1805 to be completed by Sairopa during the option period. Exelixis expects its partner Sairopa to file an Investigational New Drug application (IND) for ADU-1805 in the first quarter of 2023.

**New License Agreement with Catalent, Inc. (Catalent) for Three ADC Programs with the Potential to Accelerate Exelixis' Biologics Pipeline.** In November 2022, Exelixis and Catalent established a new license agreement under which Catalent's Redwood Bioscience subsidiary will grant Exelixis an exclusive license to three target programs with lead antibody and/or ADC candidates. The ADC candidates have been developed using Catalent's proprietary SMARTag® technology, and each of the licensed antibodies has potential for development as an ADC or other biologic therapy using a variety of technologies to which Exelixis has access through its partnership network. Under the terms of the agreement, Exelixis will fund the development work conducted by Catalent until development candidate (DC) selection is complete, after which Exelixis will assume responsibility for conducting preclinical, clinical, and commercial activities.

**Announcement of Key Priorities and Anticipated Milestones for 2023.** In January 2023, Exelixis announced its key priorities and anticipated milestones for 2023, including: pivotal data readouts from the ongoing phase 3

- more -



studies evaluating the combination of cabozantinib with atezolizumab in patients with forms of metastatic castration-resistant prostate cancer (CONTACT-02) and RCC (CONTACT-03), and the next OS analysis from the phase 3 COSMIC-313 pivotal study for cabozantinib; expansion of the pivotal development program for zanzalintinib with multiple new phase 3 pivotal trial initiations; acceleration of the XB002 clinical program into full development by year-end; advancement of the XL102 QUARTZ-101 phase 1 study into the tumor-specific cohort-expansion stage and in planned combination cohorts; in collaboration with partner Cybrexa, progression of phase 1 clinical study for CBX-12, including dose-expansion cohorts; expected IND filing for ADU-1805 in the first quarter of 2023 by partner Sairopa; advancement of DCs XB010, XB014 and XB628 toward IND filings; and progress up to five new DCs into preclinical development across biotherapeutics and small molecules. Exelixis presented the details of its key priorities and anticipated milestones at the 41<sup>st</sup> Annual J.P. Morgan Healthcare Conference.

**Cabozantinib Abbreviated New Drug Application (ANDA) Litigation Against MSN Pharmaceuticals, Inc. (MSN).** In January 2023, the U.S. District Court for the District of Delaware (the Delaware District Court) ruled in Exelixis' favor in the ANDA lawsuit against MSN (MSN I), rejecting MSN's challenge to the cabozantinib compound patent (U.S. Patent No. 7,759,473). Additionally, the District Court ruled that MSN's proposed ANDA product does not infringe Exelixis' N-2 polymorph patent (U.S. Patent No. 8,877,776), expiring in October 2030. The decision in MSN I does not address the validity of the '776 patent, which was not contested by MSN, and the Delaware District Court entered judgment that any final FDA approval of MSN's ANDA shall not be a date earlier than August 14, 2026, the expiration date of the '473 patent. In addition, this ruling in MSN I does not impact Exelixis' separate and ongoing suit against MSN (MSN II) concerning four different Orange Book-listed patents related to cabozantinib, which expire between January 15, 2030, and February 10, 2032. A bench trial in MSN II is scheduled to begin in October 2023 in the U.S. District Court for the District of Delaware.

### **Basis of Presentation**

Exelixis has adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31<sup>st</sup>. For convenience, references in this press release as of and for the fiscal periods ended December 30, 2022 are indicated as being as of and for the periods ended December 31, 2022.

### **Conference Call and Webcast**

Exelixis management will discuss the company's financial results for the fourth quarter and full year of 2022 and provide a general business update during a conference call beginning at 5:00 p.m. ET / 2:00 p.m. PT today, Tuesday, February 7, 2023.

To access the webcast link, log onto [www.exelixis.com](http://www.exelixis.com) and proceed to the News & Events / Event Calendar page under the Investors & Media heading. Please connect to the company's website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be required to listen to the webcast. Alternatively, please call [888-338-9509](tel:888-338-9509) (domestic) or [412-902-4281](tel:412-902-4281) (international) and ask to be joined into the Exelixis conference call to participate by phone.

A telephone replay will be available until 8:00 p.m. ET on Thursday, February 9, 2023. Access numbers for the telephone replay are: [877-344-7529](tel:877-344-7529) (domestic) and [412-317-0088](tel:412-317-0088) (international); the passcode is 7374267. A webcast replay will also be archived on [www.exelixis.com](http://www.exelixis.com) for one year.

### **About Exelixis**

Exelixis is a globally ambitious oncology company innovating next-generation medicines and regimens at the forefront of cancer care. Powered by bi-coastal centers of discovery and development excellence, we are rapidly

- more -

evolving our product portfolio to target an expanding range of tumor types and indications with our clinically differentiated pipeline of small molecules, antibody drug conjugates and other 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](http://www.exelixis.com), follow @ExelixisInc on Twitter, like [Exelixis, Inc.](https://www.facebook.com/Exelixis) on Facebook and follow [Exelixis](https://www.linkedin.com/company/exelixis) on LinkedIn.

### **Forward-Looking Statements**

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' plans for 2023 to be focused on advancing its diverse, high-impact pipeline of biotherapeutics and small molecules for oncology fueled by the continued commercial success of the cabozantinib franchise; Exelixis' research and development expectations for 2023, including initiating the next wave of phase 3 studies of zanzalintinib, moving XB002 into full development, reporting data from three pivotal trials of cabozantinib and continuing to add new agents to its portfolio from internal discovery and collaborative efforts; Exelixis' plans to continue to pursue additional in-licensing and strategic opportunities for near-clinical- and clinical-stage assets to enhance the breadth and depth of its pipeline; Exelixis' 2023 financial guidance; planned data presentations for cabozantinib at ASCO GU 2023; the potential for the novel triplet combination of zanzalintinib and the fixed-dose combination of nivolumab and ipilimumab to be used in multiple expansion cohorts in the STELLAR-002 trial; Exelixis' development plans for XB002, including advancing additional combination cohorts in the JEWEL-101 study to identify sensitive tumor types and accelerating the development of XB002, both as a monotherapy and in combination with IO and other targeted therapies, across a wide range of tumor types, with an expectation that XB002 will move into full development by year-end 2023; Exelixis' development plans for XL102; Exelixis' plans for expanding its late-stage development program for zanzalintinib, specifically the initiation of multiple new phase 3 pivotal trials in 2023, and Exelixis' intention to develop zanzalintinib as a backbone therapy in novel combination regimens across a broad array of future potential indications, including those where cabozantinib has demonstrated anti-cancer activity; Exelixis' immediate and future financial and other obligations under its agreements with Cybrea, Sairopa and Catalent; the clinical and therapeutic potential of ADU-1805, including its potential to be a best-in-class monoclonal antibody that targets SIRP $\alpha$  to block the SIRP $\alpha$ -CD47 checkpoint, a process with the potential to improve the immune system's ability to attack tumors, and Exelixis' belief that ADU-1805 may address a broader patient population than other SIRP $\alpha$ -directed therapies; Exelixis' expectation that its partner Sairopa will file an IND for ADU-1805 in the first quarter of 2023; the potential to develop each of the licensed antibodies from Catalent as an ADC or other biologic therapy; Exelixis' additional key priorities and anticipated milestones for 2023, including progressing the phase 1 clinical study for CBX-12 with dose-expansion cohorts, advancing DCs XB010, XB014 and XB628 toward IND filings, and progressing up to five new DCs into preclinical development across biotherapeutics and small molecules; Exelixis' expectation that the bench trial in MSN II will begin in October 2023 as scheduled; and Exelixis' scientific pursuit to create transformational treatments that give more patients hope for the future. 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; 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

- more -

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 and other Exelixis products; 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 the COVID-19 pandemic and other global events; and other factors discussed under the caption "Risk Factors" in Exelixis' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 1, 2022, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' Annual Report on Form 10-K expected to be filed with the SEC on February 7, 2023. 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.

*Exelixis, the Exelixis logo, CABOMETYX and COMETRIQ are registered trademarks of Exelixis, Inc.*

*SMARTag is a registered trademark of Catalent, Inc.*

*alphalex is a trademark of Cybrexa, Inc.*

-see attached financial tables-

- more -

**EXELIXIS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF INCOME**  
(in thousands, except per share amounts)  
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
<b>Revenues:</b>				
Net product revenues	\$ 377,419	\$ 302,679	\$ 1,401,243	\$ 1,077,256
License revenues	38,079	133,094	162,056	249,956
Collaboration services revenues	8,419	15,367	47,763	107,758
Total revenues	423,917	451,140	1,611,062	1,434,970
<b>Operating expenses:</b>				
Cost of goods sold	15,920	12,917	57,909	52,873
Research and development	336,824	222,268	891,813	693,716
Selling, general and administrative	119,251	99,311	459,856	401,715
Total operating expenses	471,995	334,496	1,409,578	1,148,304
Income (loss) from operations	(48,078)	116,644	201,484	286,666
Interest income	16,988	1,441	33,065	7,672
Other expense, net	(337)	(64)	(197)	(184)
Income (loss) before income taxes	(31,427)	118,021	234,352	294,154
Provision for (benefit from) income taxes	(1,254)	22,855	52,070	63,091
Net income (loss)	\$ (30,173)	\$ 95,166	\$ 182,282	\$ 231,063
<b>Net income (loss) per share:</b>				
Basic	\$ (0.09)	\$ 0.30	\$ 0.57	\$ 0.73
Diluted	\$ (0.09)	\$ 0.29	\$ 0.56	\$ 0.72
<b>Weighted-average common shares outstanding:</b>				
Basic	323,256	317,567	321,526	314,884
Diluted <sup>(1)</sup>	323,256	323,187	324,556	322,359

<sup>(1)</sup> The dilutive effect of shares related to employee stock plans are not included in the calculation of GAAP diluted loss per share in the fourth quarter of 2022 as the effect would be anti-dilutive.

**EXELIXIS, INC.**  
**RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME**  
(in thousands, except per share amounts)  
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
GAAP net income (loss)	\$ (30,173)	\$ 95,166	\$ 182,282	\$ 231,063
Adjustments:				
Stock-based compensation - research and development expenses <sup>(1)</sup>	10,464	9,104	45,350	46,654
Stock-based compensation - selling, general and administrative expenses <sup>(1)</sup>	15,392	14,062	62,224	73,166
Income tax effect of the above adjustments	(5,897)	(5,013)	(24,411)	(26,668)
Non-GAAP net income (loss)	<u>\$ (10,214)</u>	<u>\$ 113,319</u>	<u>\$ 265,445</u>	<u>\$ 324,215</u>
GAAP net income (loss) per share:				
Basic	\$ (0.09)	\$ 0.30	\$ 0.57	\$ 0.73
Diluted	\$ (0.09)	\$ 0.29	\$ 0.56	\$ 0.72
Non-GAAP net income (loss) per share:				
Basic	\$ (0.03)	\$ 0.36	\$ 0.83	\$ 1.03
Diluted <sup>(2)</sup>	\$ (0.03)	\$ 0.35	\$ 0.82	\$ 1.01
Weighted-average common shares outstanding:				
Basic	323,256	317,567	321,526	314,884
Diluted <sup>(2)</sup>	323,256	323,187	324,556	322,359

<sup>(1)</sup> Non-cash stock-based compensation expense used for GAAP reporting in accordance with Accounting Standards Codification Topic 718, *Compensation—Stock Compensation*.

<sup>(2)</sup> The dilutive effect of shares related to employee stock plans are not included in the calculation of Non-GAAP diluted loss per share in the fourth quarter of 2022 as the effect would be anti-dilutive.