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): May 9, 2023

EXELIXIS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**000-30235**	**04-3257395**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock $.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 May 9, 2023, Exelixis, Inc. (“Exelixis”) issued a press release announcing its financial results for the quarter ended March 31, 2023, 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.

Exhibit Number	Exhibit Description	
99.1	Press Release issued May 9, 2023	
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.

May 9, 2023	/s/ Jeffrey J. Hessekiel
Date	**Jeffrey J. Hessekiel** Executive Vice President, General Counsel and Secretary

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Exelixis Announces First Quarter 2023 Financial Results and Provides Corporate Update

- Total Revenues of $408.8 million, Cabozantinib Franchise U.S. Net Product Revenues of $363.4 million -
- GAAP Diluted EPS of $0.12, Non-GAAP Diluted EPS of $0.16 -
- Conference Call and Webcast Today at 5:00 PM Eastern Time -

ALAMEDA, Calif. – May 9, 2023 - Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the first quarter of 2023 and provided an update on progress toward achieving key corporate objectives, as well as commercial, clinical and pipeline development milestones.

“The Exelixis team continued to execute on our key priorities and made significant progress in advancing our commercial business and our growing pipeline,” said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. “CABOMETYX® maintained its status as the leading tyrosine kinase inhibitor in renal cell carcinoma in the first quarter, driven by its use in combination with nivolumab in the first-line setting. We’ve made important progress across our pipeline programs, including advancing the STELLAR-303 and STELLAR-304 phase 3 trials for zanzalintinib, as well as single-agent and combination dose-escalation cohorts of the phase 1 trial of XB002. We are on track to initiate additional pivotal studies for zanzalintinib in 2023 and are focused on accelerating XB002 into full development by year-end.”

Dr. Morrissey continued: “Our collaborations with Cybrexa and Sairopa also made steady progress. Sairopa received clearance of its Investigational New Drug application for ADU-1805 from the U.S. Food and Drug Administration in February and subsequently initiated the phase 1 study in March. Cybrexa is planning to present updated phase 1 data for CBX-12 at the ASCO Annual Meeting in June. In March, we announced a share repurchase program for up to $550 million of our common stock before the end of 2023, which reflects continued confidence in our long-term prospects and the strength of our balance sheet and reinforces our commitment to deliver value to shareholders. I’d like to thank the entire Exelixis team for their collective hard work and dedication to improving the standard-of-care for patients while driving sustainable, long-term value for shareholders as we advance our mission to help cancer patients recover stronger and live longer.”

First Quarter 2023 Financial Results

Total revenues for the quarter ended March 31, 2023 were $408.8 million, as compared to $356.0 million for the comparable period in 2022.

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Total revenues for the quarter ended March 31, 2023 included net product revenues of $363.4 million, as compared to $310.3 million for the comparable period in 2022. The increase in net product revenues was primarily due to an increase in sales volume and an increase in average net selling price.

Collaboration revenues, composed of license revenues and collaboration services revenues, were $45.4 million for the quarter ended March 31, 2023, as compared to $45.7 million for the comparable period in 2022. The decrease in collaboration revenues was primarily related to a decrease in development cost reimbursements earned, which was offset by higher royalty revenues for the sales of cabozantinib outside of the U.S. generated by Exelixis' collaboration partners, Ipsen Pharma SAS and Takeda Pharmaceutical Company Limited.

Research and development expenses for the quarter ended March 31, 2023 were $234.2 million, as compared to $156.7 million for the comparable period in 2022. The increase in research and development expenses was primarily related to increases in license and other collaboration costs, personnel expenses and manufacturing costs to support our development candidates, which were partially offset by lower stock-based compensation expense.

Selling, general and administrative expenses for the quarter ended March 31, 2023 were $131.4 million, as compared to $102.9 million for the comparable period in 2022. The increase in selling, general and administrative expenses was primarily related to an increase in personnel expenses.

Provision for income taxes for the quarter ended March 31, 2023 was $8.3 million, as compared to $16.7 million for the comparable period in 2022, primarily due to a decrease in pre-tax income.

GAAP net income for the quarter ended March 31, 2023 was $40.0 million, or $0.12 per share, basic and diluted, as compared to GAAP net income of $68.6 million, or $0.21 per share, basic and diluted, for the comparable period in 2022.

Non-GAAP net income for the quarter ended March 31, 2023 was $52.8 million, or $0.16 per share, basic and diluted, as compared to non-GAAP net income of $83.9 million, or $0.26 per share, basic and diluted, for the comparable period in 2022.

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 [(1)]	$1,000 million - $1,050 million
Selling, general and administrative expenses [(2)]	$475 million - $525 million
Effective tax rate	20% - 22%

[(1)] Includes $45 million of non-cash stock-based compensation expense.
[(2)] 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 $363.4 million during the first quarter of 2023, with net product revenues of $361.8 million from CABOMETYX® (cabozantinib) and $1.6 million from COMETRIQ® (cabozantinib). Based upon cabozantinib-related net product revenues generated by Exelixis' collaboration partners during the quarter ended March 31, 2023, Exelixis earned $32.7 million in royalty revenues.

Cabozantinib Data at the 2023 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium (ASCO GU 2023). In February, cabozantinib was the subject of multiple data presentations at ASCO GU 2023, held from February 16-18, 2023. Notable presentations included: 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 (RCC) cohort of COSMIC-021, the ongoing phase 1b trial of cabozantinib in combination with atezolizumab.

Cabozantinib Data Presentations at the 2023 ASCO Annual Meeting. In June 2023, cabozantinib will be the subject of 22 presentations at this year's ASCO Annual Meeting, which is being held from June 2-6 in Chicago. Notable presentations will include results from the CONTACT-03 phase 3 trial evaluating the combination of cabozantinib and atezolizumab vs. cabozantinib alone in metastatic RCC patients who have progressed following treatment with an immune checkpoint inhibitor therapy, and three-year quality-of-life follow-up data from CheckMate -9ER.

Corporate Updates

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 studies evaluating the combination of cabozantinib with atezolizumab in patients with forms of metastatic castration-resistant prostate cancer (CONTACT-02) and RCC (CONTACT-03), the latter of which has subsequently occurred, and the next overall survival(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 the phase 1 clinical study for CBX-12, including dose-expansion cohorts; expected filing of an Investigational New Drug application (IND) for ADU-1805 with the U.S. Food and Drug Administration (FDA) in the first quarter of 2023 by partner Sairopa B.V. (Sairopa), which has subsequently occurred; advancement of development candidates (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 41st 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.

Announcement of $550 Million Share Repurchase Program. In March, Exelixis announced that the company's Board of Directors authorized the repurchase of up to $550 million of the company's common stock before the end of 2023. Share repurchases under the program may be made from time to time through a variety of methods, which may include open market purchases, in block trades, accelerated share repurchase transactions, exchange transactions, or any combination of such methods. The timing and amount of any share repurchases under the share repurchase program 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 Exelixis' common stock and general market conditions.

Pipeline Highlights

Exelixis and Sairopa Announce FDA Clearance of IND for ADU-1805 in Patients with Advanced Solid Tumors. In February, Exelixis and Sairopa announced FDA clearance of Sairopa's IND to evaluate the safety and pharmacokinetics in a Phase 1 clinical trial of ADU-1805 in adults with advanced solid tumors, which has since been initiated. As a monoclonal antibody active against all human alleles of SIRPα, ADU-1805 has the potential to address a broader patient population than other SIRPα-directed therapies. By blocking SIRPα, a significant immune-suppressive component of the tumor microenvironment, ADU-1805 has the potential to improve the immune system's ability to attack tumors. Under the terms of the clinical development and option agreement announced in November 2022, 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 to be completed by Sairopa during the option period. This IND clearance triggered a $35.0 million milestone payment to Sairopa, paid in the first quarter of 2023.

Basis of Presentation

Exelixis has adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31st. For convenience, references in this press release as of and for the fiscal period ended April 1, 2022 is indicated as being as of and for the period ended March 31, 2022.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the first quarter of 2023 and provide a general business update during a conference call beginning at 5:00 p.m. ET / 2:00 p.m. PT today, Tuesday, May 9, 2023.

To access the conference call, please register using this link. Upon registration, a dial-in number and unique PIN will be provided to join the call. To access the live webcast link, log onto 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. A webcast replay of the conference call will also be archived on 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 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, follow @ExelixisInc on Twitter, like Exelixis, Inc. on Facebook and follow Exelixis on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' research and development expectations for 2023, including initiating additional pivotal studies for zanzalintinib and, by year-end, accelerating XB002 into full development; Exelixis' expectation that updated phase 1 data for CBX-12 will be presented at the ASCO Annual Meeting in June 2023; Exelixis' plan to repurchase up to $550 million of its common stock before the end of 2023 as part of its commitment to deliver value to shareholders; Exelixis' 2023 financial guidance; planned data presentations for cabozantinib at the 2023 ASCO Annual Meeting; Exelixis' additional key priorities and anticipated milestones for 2023, including issuing pivotal data readouts from CONTACT-02 and the next OS analysis from COSMIC-313, advancing the XL102 QUARTZ-101 phase 1 study into the tumor-specific cohort-expansion stage and in planned combination cohorts, progressing the phase 1 clinical study for CBX-12 with dose-expansion cohorts, advancing of 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; the clinical and therapeutic potential of ADU-1805, including its 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 SIRPα-directed therapies; 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 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 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 the COVID-19 pandemic and other global events; and other factors discussed under the caption "Risk Factors" in Exelixis' Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 7, 2023, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' Quarterly Report on Form 10-Q expected to be filed with the SEC on May 9, 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.

-see attached financial tables-

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

	Three Months Ended March 31,	
	2023	**2022**
Revenues:		
Net product revenues	$ 363,400	$ 310,298
License revenues	38,292	32,067
Collaboration services revenues	7,096	13,615
Total revenues	408,788	355,980
Operating expenses:		
Cost of goods sold	14,315	13,203
Research and development	234,246	156,671
Selling, general and administrative	131,397	102,863
Total operating expenses	379,958	272,737
Income from operations	28,830	83,243
Interest income	19,502	1,822
Other income (expense), net	(54)	164
Income before income taxes	48,278	85,229
Provision for income taxes	8,250	16,656
Net income	$ 40,028	$ 68,573
Net income per share:		
Basic	$ 0.12	$ 0.21
Diluted	$ 0.12	$ 0.21
Weighted-average common shares outstanding:		
Basic	324,420	319,582
Diluted	326,279	323,289

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

	Three Months Ended March 31,	
	2023	**2022**
GAAP net income	$ 40,028	$ 68,573
Adjustments:		
Stock-based compensation - research and development expenses [(1)]	3,252	8,899
Stock-based compensation - selling, general and administrative expenses [(1)]	13,409	10,860
Income tax effect of the above adjustments	(3,861)	(4,439)
Non-GAAP net income	$ 52,828	$ 83,893
GAAP net income per share:		
Basic	$ 0.12	$ 0.21
Diluted	$ 0.12	$ 0.21
Non-GAAP net income per share:		
Basic	$ 0.16	$ 0.26
Diluted	$ 0.16	$ 0.26
Weighted-average common shares outstanding:		
Basic	324,420	319,582
Diluted	326,279	323,289

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