EXELIXIS®

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May 17, 2024

VIA EDGAR

Vanessa Robertson, Staff Accountant
Kevin Vaughn, Senior Associate Chief Accountant
Securities and Exchange Commission
Division of Corporation Finance
100 F Street, N.E.
Washington, D.C. 20549

RE: Exelixis, Inc. Form 10-K for the Fiscal Year Ended December 29, 2023 — File Number: 000-30235

Dear Ms. Robertson and Mr. Vaughn,

On behalf of Exelixis, Inc. (the "Company", "we", "our", or "us"), this letter is being submitted in response to the Staff's comments transmitted telephonically to Mr. Chris Senner on April 15, 2024 ("April 15 Comments") and May 10, 2024 ("May 10 Comments"). The staff's comments followed the Company's letters, dated April 8, 2024 and April 29, 2024 regarding the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2023 (the "2023 Form 10-K"). The April 15 Comments, as summarized by us, are below in bold italics.

- ***Please confirm whether the Company can provide further detail beyond external clinical trial costs by scientific modalities, small molecule and biotherapeutics programs. To the extent you track external clinical trial costs on a project-by project basis, revise to provide a breakdown of the expenses tracked by project.***

- ***Please provide us with your proposed disclosure and the timing with which you will provide the revised disclosure.***

Response:

The Company respectfully advises the Staff that the Company groups its research and development (R&D) expenses into three categories: (1) development; (2) drug discovery; and (3) other R&D. Within these three categories, we provide substantive details on certain of the expense classifications that constitute significant portions of the cost of our R&D for each category. We provide this level of detail through tabular and narrative disclosure. Investors in our industry frequently make their investment decisions by evaluating the effectiveness and efficiency of company R&D processes that contribute to the likelihood that a company's product candidates will eventually be approved by regulatory authorities for marketing and sale to treat human illness, ultimately resulting in product revenue opportunities. We believe our current disclosures provide investors with insight as to these R&D processes, known trends, and events and uncertainties that are reasonably likely to have a material effect on our operating performance. In addition, we provide certain forward-looking statements as to our expected future R&D costs, and the nature and timing of those expectations. We believe the quantitative and qualitative disclosures for each of these categories provide important management perspective that enhances the information available to investors in our consolidated financial statements.

The Company does not track total R&D expenses by product or product candidate because internal R&D costs, including salaries and personal expenses, facilities overhead expenses and certain external consulting and outside services are shared across R&D categories. The Company does track external clinical trial costs at the product and product candidate level in addition to clinical trial costs by scientific modality.

In consideration of the Staff's comment, in future filings beginning with the quarter ended June 28, 2024, the Company proposes to enhance its disclosure to include a tabular presentation regarding Clinical trial costs by scientific modalities, small molecule and biotherapeutics programs, including the costs by product and product candidate in the Management Discussion and Analysis of Financial Condition and Results of Operations section of its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q. The Company will also include narrative disclosure to accompany the table that will discuss the underlying reasons for material changes from period to period.

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Set forth below is an illustrative example of the disclosure enhancements described above, using the relevant disclosure in our Annual Report on Form 10-K for the fiscal year ended December 29, 2023 (changes that are in response to the Staff's comments are marked).

Research and Development Expenses

We do not track fully burdened research and development expenses on a project-by-project basis. We group our research and development expenses into three categories: (1) development; (2) drug discovery; and (3) other research and development. Our development group leads the development and implementation of our clinical and regulatory strategies and prioritizes disease indications in which our compounds are being or may be studied in clinical trials. Development expenses include license and other collaboration costs, primarily comprised of upfront license fees, development milestones and other payments associated with our clinical-stage in-licensing collaboration programs, clinical trial costs, personnel expenses, consulting and outside services and other development costs, including manufacturing costs of our drug development candidates. Our drug discovery group utilizes a variety of technologies, including in-licensed technologies, to enable the rapid discovery, optimization and extensive characterization of lead compounds and biotherapeutics such that we are able to select development candidates with the best potential for further evaluation and advancement into clinical development. Drug discovery expenses include license and other collaboration costs primarily comprised of upfront license fees, research funding commitments, development milestones and other payments associated with our in-licensing collaboration programs in preclinical development stage. Other drug discovery costs include personnel expenses, consulting and outside services and laboratory supplies. Other research and development expenses include the allocation of general corporate costs to research and development services and development cost reimbursements in connection with certain of our collaboration arrangements.

Research and development expenses by category were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2023	2022	
Development:			
Clinical trial costs	$ 281,338	$ 253,519	11 %
Personnel expenses	167,879	137,831	22 %
License and other collaboration costs	80,036	49,500	62 %
Consulting and outside services	43,586	35,651	22 %
Other development costs	96,401	45,121	114 %
Total development	669,240	521,622	28 %
Drug discovery:			
License and other collaboration costs	92,970	154,412	-40 %
Other drug discovery costs	122,115	95,301	28 %
Total drug discovery	215,085	249,713	-14 %
Stock-based compensation	34,320	45,350	-24 %
Other research and development	125,426	75,128	67 %
Total research and development expenses	$ 1,044,071	$ 891,813	17 %

In addition, we track our external clinical trial costs by product and product candidate and by scientific modalities, which are categorized as small molecule and biotherapeutics programs. Small molecule clinical development for the reported periods was primarily composed of cabozantinib and zanzalintinib. Biotherapeutics clinical development for the reported periods was composed of XB002.

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Clinical trial costs by scientific modalities, by product and by product candidate were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2023	2022	
Small molecules:			
Zanzalintinib	$ 136,383	$ 64,258	112 %
Cabozantinib	105,318	161,807	-35 %
Other small molecules	9,115	14,365	-37 %
Total small molecules	250,816	240,430	4 %
Biotherapeutics:	30,522	13,089	133 %
Total clinical trial costs	$ 281,338	$ 253,519	11 %

The increase in research and development expenses for the year ended December 31, 2023, as compared to 2022, was primarily related to manufacturing costs to support Exelixis' development candidates (presented as part of other development costs), personnel expenses, clinical trial costs and other research and development expenses, partially offset by decreases in license and other collaboration costs and stock-based compensation expense. Personnel expenses increased primarily due to an increase in headcount to support our discovery and development organization. Clinical trial costs, which include services performed by third-party contract research organizations and other vendors who support our clinical trials, increased primarily due to higher costs associated with studies evaluating zanzalintinib and XB002, partially offset by decreases in costs associated with cabozantinib studies. Other research and development costs increased primarily related to technology costs, including our investments in digital transformation initiatives to support productivity and efficiency in our organization, and an increase in facility expenses. License and other collaboration costs decreased primarily due to lower upfront payments from new in-licensing collaboration arrangements, partially offset by higher development milestone achievement. Stock-based compensation expense decreased primarily due to higher forfeitures.

In addition to reviewing the three categories of research and development expenses described above, we principally consider qualitative factors in making decisions regarding our research and development programs. These factors include enrollment in clinical trials for our product candidates, preliminary data and final results from clinical trials, the potential market indications and overall clinical and commercial potential for our product candidates, and competitive dynamics. We also make our research and development decisions in the context of our overall business strategy.

We project that clinical trial costs may continue to increase with higher costs associated with various studies evaluating zanzalintinib, XB002 and XL309, partially offset by decreases in costs associated with cabozantinib studies. We continue our development efforts with cabozantinib to maximize the therapeutic and commercial potential of this compound. Notable ongoing company-sponsored cabozantinib studies include: CONTACT-02, for which Roche is sharing the development costs and providing atezolizumab free of charge; and COSMIC-313, for which BMS is providing nivolumab and ipilimumab free of charge.

To continue growing our pipeline, we are prioritizing investment in new molecules that are clinically differentiated with the potential to improve the standard of care for our cancer patients, including current and planned clinical trial programs evaluating zanzalintinib, XB002 and XL309. We are also working to expand our oncology product pipeline through drug discovery efforts, which encompass our diverse biotherapeutics and small molecule programs exploring multiple modalities and mechanisms of action. As part of our strategy, our drug development activities have included and continue to include research collaborations, in-licensing arrangements and other strategic transactions that collectively incorporate a wide range of technology platforms and assets and increase our probability of success. We will continue to engage in pipeline expansion initiatives with the goal of acquiring and in-licensing promising oncology assets and then further characterize and develop them utilizing our established preclinical and clinical development infrastructure.

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We project our research and development expenses may decrease in fiscal year 2024, as compared to 2023, primarily driven by decreases in license and collaboration expenses and personnel expenses that result from the implementation of a corporate restructuring plan announced in January 2024 to prioritize the advancement of clinical and near-clinical programs, partially offset by higher manufacturing costs to support development candidates and clinical trial costs, including the current and planned trials evaluating zanzalintinib, XB002 and XL309.

A discussion of the risks and uncertainties with respect to our research and development activities, and the consequences to our business, financial position, and growth prospects can be found in "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

Should you have additional questions or comments regarding the foregoing, please contact the undersigned at (650) 837-7240.

Sincerely,

/s/ CHRISTOPHER J. SENNER

Christopher J. Senner
Executive Vice President and Chief Financial Officer

cc: Jeffrey J. Hessekiel, Executive Vice President, General Counsel and Secretary
Rick Shunn, Ernst & Young LLP
Raquel Fox, Skadden, Arps, Slate, Meagher, Flom & LLP