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April 29, 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: Telephonic Comments Transmitted April 15, 2024 relating to 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"). The staff's comments followed the Company's letter, dated April 8, 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 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. As to external clinical trial costs, the Company is concerned that the disclosure of external clinical trial costs at the product level, rather than at the level of scientific modality as previously proposed, has the potential risk of misleading investors because at the product candidate level, the relative costs associated with product development vary widely based on a large number of factors that are generally beyond the company's control and are not directly related to the effectiveness and efficiency of company R&D processes. For example, development costs are substantially affected by changes in the regulatory requirements for clinical trials in the various countries where the trials are conducted and by the costs and availability of comparator drug substances proposed to be used in individual trials The cost and sourcing impact of these expense factors are not directly related to the likelihood of an individual product candidate's success. Furthermore, we believe such disclosure may provide an incomplete picture of the R&D costs of each of our product candidates for investors.

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Moreover, the Company is also concerned that public disclosure of this information would result in competitive harm to the Company in a variety of ways, adversely impacting our competitive position, and as a result, our shareholders. For instance, we believe that such disclosure may weaken our competitive advantage in negotiating competitive terms with external vendors with whom we may contract from time to time for services in support of our clinical trials because they may be able to deduce the amounts we pay for certain work related to a product candidate and leverage this commercially sensitive information against us in the negotiation of contractual terms. This may negatively impact the Company's ability to secure agreements with them on optimal terms or could even make certain proposed arrangements commercially prohibitive to the Company. Furthermore, while certain of our product candidates are the result of internal discovery efforts, others have been in-licensed from other companies. The market for high-potential product candidate in-licensing opportunities is very competitive. Disclosure of expenses associated with external clinical trial costs of our product candidates would place the Company at an unfair competitive disadvantage by making accessible to potential licensors expense details that would weaken our negotiating strength within this critical market for new product candidate assets. Additionally, if we provide product candidate level information, it could negatively impact our ability to negotiate arrangements for the co-funding of development costs for our product candidates. Co-funding through collaboration and license agreements is an important part of our financing and risk management strategy, and we anticipate that providing this level of information may put us at an unfair competitive disadvantage in these negotiations as well.

The Company respectfully advises the staff that the disclosure of external clinical trial costs by scientific modality, as proposed in our prior response letter, dated April 8, 2024, when taken together with our existing disclosure across the three R&D categories, is a more meaningful level of disclosure for investors. By disclosing the aggregate level of external clinical trials costs within the categories of small molecule or biotherapeutics programs, investors will be able to assess the relative effectiveness and efficiency of these company programs; meaning whether these programs are able to produce approved drug products that result in revenue over time. This level of expense tracking also facilitates the Company's effective financial planning and analysis, enabling evaluation of the relative success of different scientific approaches and appropriate prioritization towards identifying targets that the Company believes have the greatest chance of yielding impactful cancer medicines. The Company has been working to expand its oncology product pipeline exploring these two modalities and multiple mechanisms of action. This approach provides a high degree of flexibility with respect to target selection and allows us to prioritize those targets that we believe have the greatest chance of yielding impactful therapeutics.

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, 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.

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.

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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 scientific modalities, which are categorized as small molecule and biotherapeutics programs. Small molecule clinical development for the reported periods was primarily composed of Cabozantinib, Zanzalintinib and XL309. Biotherapeutics clinical development for the reported periods was composed of XB002.

Clinical trial costs by scientific modalities were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2023	2022	
Clinical trial costs:			
Small molecules	$ 250,816	$ 240,430	4%
Biotherapeutics	30,522	13,059	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 our biotherapeutics program ~~studies~~ and to a lesser extent our small molecule program. The increase in small molecule clinical trial costs was attributed to increases in costs for studies evaluating zanzalintinib including STELLAR-303, STELLAR-002, and STELLAR-304~~XB002~~, partially offset by decreases in costs associated with cabozantinib studies, primarily CONTACT-02 and COSMIC-312. 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.

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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.

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

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