



## Exelixis Announces Second Quarter 2021 Financial Results and Provides Corporate Update

August 5, 2021

**- Total Revenues of \$385.2 Million, Cabozantinib Franchise Revenues of \$284.2 Million -**

**- GAAP Diluted EPS of \$0.30, Non-GAAP Diluted EPS of \$0.37 -**

**- Raised Net Product Revenue Guidance to \$1,050 - \$1,150 Million and Total Revenue Guidance to \$1,300 - \$1,400 Million -**

**- Conference Call and Webcast Today at 5:00 PM Eastern Time -**

ALAMEDA, Calif.--(BUSINESS WIRE)--Aug. 5, 2021-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the second quarter of 2021 and provided an update on progress toward achieving key corporate objectives, as well as commercial, clinical and pipeline development milestones.

"In the second quarter of 2021, Exelixis delivered a 59 percent year over year increase in CABOMETYX<sup>®</sup> net product revenue growth and record total revenues, based on the broad adoption of the CABOMETYX and OPDIVO<sup>®</sup> combination regimen as a preferred treatment in first-line renal cell carcinoma," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "Following this strong commercial performance, we are raising our net product and total revenue guidance for 2021. In parallel, we also made significant progress across our development activities, with the filing of a supplemental New Drug Application for cabozantinib in differentiated thyroid cancer based on the COSMIC-311 study, and announcements of top-line results from both the COSMIC-312 trial in first-line advanced hepatocellular carcinoma and the expanded Cohort 6 of the COSMIC-021 trial in patients with advanced prostate cancer. In addition, on the pipeline front, we broadened the development program of XL092 with a new clinical collaboration with Bristol Myers Squibb and initiated the Phase 1 trial for XB002, our first antibody-drug conjugate. I'd like to thank the entire Exelixis team for a very strong first half of 2021 and look forward to providing further updates on our progress in the second half of the year."

### **Second Quarter 2021 Financial Results**

**Total revenues** for the quarter ended June 30, 2021 were \$385.2 million, compared to \$259.5 million for the comparable period in 2020.

Total revenues for the quarter ended June 30, 2021 included net product revenues of \$284.2 million, compared to \$178.7 million for the comparable period in 2020. The increase in net product revenues was primarily related to an increase in sales volume that was driven by strong uptake for the combination therapy of CABOMETYX (cabozantinib) and OPDIVO (nivolumab) following approval by the U.S. Food and Drug Administration (FDA) in January 2021.

Collaboration revenues, composed of license revenues and collaboration services revenues, were \$100.9 million for the quarter ended June 30, 2021, compared to \$80.7 million for the comparable period in 2020. The increase in collaboration revenues was primarily related to increases in development cost reimbursements earned, and 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), which was partially offset by a decrease in the recognition of milestone-related revenues.

**Research and development expenses** for the quarter ended June 30, 2021 were \$148.8 million, compared to \$114.9 million for the comparable period in 2020. The increase in research and development expenses was primarily related to increases in license and other collaboration costs, personnel expenses and stock-based compensation expense, which was partially offset by decreases in clinical trial costs.

**Selling, general and administrative expenses** for the quarter ended June 30, 2021 were \$98.5 million, compared to \$59.8 million for the comparable period in 2020. The increase in selling, general and administrative expenses was primarily related to increases in personnel expenses, marketing costs, corporate giving and stock-based compensation expense.

**Provision for income taxes** for the quarter ended June 30, 2021 was \$28.8 million, compared to \$13.9 million for the comparable period in 2020, primarily due to an increase in pre-tax income.

**GAAP net income** for the quarter ended June 30, 2021 was \$96.1 million, or \$0.31 per share, basic and \$0.30 per share, diluted, compared to GAAP net income of \$66.8 million, or \$0.22 per share, basic and \$0.21 per share, diluted, for the comparable period in 2020.

**Non-GAAP net income** for the quarter ended June 30, 2021 was \$117.9 million, or \$0.38 per share, basic and \$0.37 per share, diluted, compared to non-GAAP net income of \$79.4 million, or \$0.26 per share, basic and \$0.25 per share, diluted, for the comparable period in 2020. Non-GAAP net income excludes stock-based compensation, adjusted for the related income tax effect.

**Cash, cash equivalents, restricted cash equivalents and investments** were \$1.7 billion at June 30, 2021, compared to \$1.5 billion at December 31, 2020.

### **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.

## **2021 Financial Guidance**

Exelixis is providing the following updated financial guidance for fiscal year 2021:

Total revenues <sup>(1)</sup>	\$1,300 million - \$1,400 million
Net product revenues <sup>(1)</sup>	\$1,050 million - \$1,150 million
Cost of goods sold	Approximately 5% - 6% of net product revenue
Research and development expenses <sup>(1)(2)</sup>	\$650 million - \$700 million
Selling, general and administrative expenses <sup>(3)</sup>	\$375 million - \$425 million
Effective tax rate	20% - 22%
Cash and investments <sup>(1)(4)(5)</sup>	\$1.7 billion - \$1.8 billion

(1) Guidance updated on August 5, 2021 from previously provided guidance on May 6, 2021.

(2) Includes \$45 million of non-cash stock-based compensation expense.

(3) Includes \$60 million of non-cash stock-based compensation expense.

(4) This cash and investments guidance does not include any potential new business development activity.

(5) Cash and investments is composed of cash, cash equivalents, restricted cash equivalents and investments.

## **Cabozantinib Highlights**

**Cabozantinib Franchise Net Product Revenues and Royalties.** Net product revenues generated by the cabozantinib franchise in the U.S. were \$284.2 million during the second quarter of 2021, up 25 percent over the prior quarter, with net product revenues of \$275.6 million from CABOMETYX and \$8.6 million from COMETRIQ<sup>®</sup> (cabozantinib). Exelixis earned \$24.9 million in royalty revenues during the quarter ended June 30, 2021, pursuant to collaboration agreements with our partners, Ipsen and Takeda.

**Announcement of Phase 1b Results from Cohort 6 of COSMIC-021 Trial in Patients with Metastatic Castration-Resistant Prostate Cancer (CRPC).** In May, Exelixis announced results from the metastatic CRPC cohort 6 of COSMIC-021, the phase 1b trial of cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic solid tumors. The analysis included 132 patients, 101 of whom had high-risk disease, defined as measurable visceral and/or extra-pelvic lymph node metastases. Based on these promising results, Exelixis intends to discuss the data with the FDA to determine next steps toward a potential regulatory submission for the combination regimen for patients with high-risk metastatic CRPC and plans to present detailed results at a medical meeting in the second half of 2021.

**Cabozantinib Presentations at the 2021 American Society of Clinical Oncology Annual Meeting (ASCO 2021) Demonstrate Consistent Results in Renal Cell Carcinoma (RCC).** In June, cabozantinib was the subject of multiple RCC data presentations at ASCO 2021, which included: a post-hoc exploratory analysis demonstrating consistent efficacy benefits across subgroups in the phase 3 CheckMate -9ER pivotal trial with CABOMETYX in combination with OPDIVO compared with sunitinib as a first-line treatment for advanced RCC; results from another post-hoc analysis of the CheckMate -9ER trial demonstrating that CABOMETYX in combination with OPDIVO resulted in a statistically significant and clinically meaningful increase in quality-adjusted survival (Q-TWiST) compared with sunitinib; and positive phase 2 results from an investigator-sponsored trial evaluating cabozantinib in combination with nivolumab in patients with advanced or metastatic non-clear cell RCC.

**Detailed Results from Phase 3 COSMIC-311 Pivotal Trial of Cabozantinib in Patients with Previously Treated Radioactive Iodine (RAI)-Refractory Differentiated Thyroid Cancer (DTC) Also Presented at ASCO 2021.** In June, Exelixis and Ipsen announced detailed results from the phase 3 COSMIC-311 pivotal trial of cabozantinib in patients with previously treated RAI-refractory DTC, presented at ASCO 2021. Results from the trial, which met the primary endpoint of demonstrating significant improvement in progression-free survival (PFS) assessed by a blinded independent radiology committee, were recently published in *The Lancet Oncology* and served as the basis for the supplemental New Drug Application (sNDA) submitted to the FDA in June.

**Announcement of Top-line Results of Phase 3 COSMIC-312 Pivotal Trial in Patients with Previously Untreated Advanced Hepatocellular Carcinoma (HCC).** In June, Exelixis and Ipsen announced that COSMIC-312, the ongoing phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab versus sorafenib in patients with previously untreated advanced HCC, met one of the primary endpoints, demonstrating significant improvement in PFS at the planned primary analysis. A prespecified interim analysis for the second primary endpoint of overall survival (OS), conducted at the same time as the primary analysis for PFS, showed a trend favoring the combination of cabozantinib and atezolizumab but did not reach statistical significance. The trial will continue as planned to the final analysis of OS; results are anticipated in early 2022. Exelixis plans to present the trial results at a future medical meeting and intends to discuss the results with the FDA to determine next steps toward a potential regulatory submission for the combination regimen for patients with previously untreated advanced HCC.

**FDA Accepts sNDA for CABOMETYX for Patients with Previously Treated RAI-Refractory DTC.** In August, Exelixis announced that the FDA accepted the company's sNDA for CABOMETYX as a treatment for patients 12 years and older with DTC who have progressed following prior therapy and are RAI-refractory (if RAI is appropriate). The FDA granted Priority Review designation and assigned a Prescription Drug User Fee Act goal date, or target action date, of December 4, 2021.

## **Pipeline Highlights**

**FDA Accepts Investigational New Drug Application (IND) and Phase 1 Trial Initiated for Tissue Factor-Targeting Antibody-Drug Conjugate (ADC) XB002 in Patients with Advanced Solid Tumors.** In April, Exelixis announced that the FDA accepted its IND to evaluate the safety, tolerability, pharmacokinetics and preliminary antitumor activity of XB002 in patients with advanced solid tumors, and in June, a phase 1 trial was initiated. As a next-generation tissue factor-targeting ADC, XB002 has the potential for an improved therapeutic index and may provide a favorable safety profile compared with earlier-generation tissue factor-targeting ADCs. Exelixis in-licensed XB002 from Iconic Therapeutics, Inc. in December 2020 under the companies' May 2019 collaboration agreement.

**Exelixis and Bristol Myers Squibb (BMS) Enter Clinical Trial Collaboration and Supply Agreement to Evaluate XL092 in Combination with Immuno-oncology Therapies in Advanced Solid Tumors.** In June, Exelixis announced a clinical trial collaboration and supply agreement with BMS for STELLAR-002, a new phase 1b trial evaluating XL092 in combination with immuno-oncology therapies in advanced solid tumors. The objective of the study is to evaluate the safety, tolerability and efficacy of XL092, Exelixis' novel next-generation tyrosine kinase inhibitor, in combination with: nivolumab; nivolumab and ipilimumab (YERVOY®); and nivolumab and bempegaldesleukin, an investigational CD122-preferential IL-2-pathway agonist developed by Nektar Therapeutics (Nektar). The trial is anticipated to begin enrolling patients in the second half of 2021. Nektar will supply bempegaldesleukin to BMS through their existing global development and commercialization collaboration, which is evaluating nivolumab in combination with bempegaldesleukin.

#### **Corporate Updates**

**Exelixis Expands its Biotherapeutics Portfolio with Acquisition of Anti-Müllerian Hormone Receptor 2 (AMHR2) Program from GamaMabs Pharma SA (GamaMabs).** In May, Exelixis entered into an asset purchase agreement with GamaMabs under which Exelixis will, upon the closing of the asset purchase and subject to certain conditions, acquire all rights, title and interest in GamaMabs' antibody program directed at AMHR2, a novel oncology target with relevance in multiple forms of cancer. Exelixis believes applying its ADC capabilities to GamaMabs' panel of antibodies against AMHR2 could yield potential additions to the company's biotherapeutics portfolio.

**Exelixis Files Lawsuit to Enforce Its Intellectual Property Rights for CABOMETYX against Abbreviated New Drug Application (ANDA) Filers.** In June, Exelixis filed a patent lawsuit against Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as Teva), along with Teva Pharmaceutical Industries Limited, following receipt of two Paragraph IV certification notice letters from Teva informing Exelixis that it had filed an ANDA with the FDA requesting approval to market a generic version of CABOMETYX tablets. Teva's notice letters included a Paragraph IV certification with respect to three of Exelixis' Orange Book-listed patents: U.S. Patent Nos. 9,724,342 (formulations), 10,034,873 (methods of treatment) and 10,039,757 (methods of treatment), which expire in 2033, 2031 and 2031, respectively. Teva's notice letter did not provide a Paragraph IV certification against any additional CABOMETYX patents. Exelixis is seeking, among other relief, an order that the effective date of any FDA approval of the ANDA would be a date no later than the expiration of all of U.S. Patent Nos. 9,724,342, 10,034,873 and 10,039,757, the latest of which expires on July 9, 2033, and equitable relief enjoining Teva and Teva Pharmaceutical Industries Limited from infringing these patents.

#### **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 July 2, 2021, January 1, 2021 and July 3, 2020 are indicated as being as of and for the periods ended June 30, 2021, December 31, 2020, and June 30, 2020, respectively.

#### **Conference Call and Webcast**

Exelixis management will discuss the company's financial results for the second quarter of 2021 and provide a general business update during a conference call beginning at 5:00 p.m. EDT / 2:00 p.m. PDT today, Thursday, August 5, 2021.

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 855-793-2457 (domestic) or 631-485-4921 (international) and provide the conference call passcode 7296685 to join by phone.

A telephone replay will be available until 8:00 p.m. EDT on August 7, 2021. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 7296685. A webcast replay will also be archived on [www.exelixis.com](http://www.exelixis.com) for one year.

#### **About Exelixis**

Founded in 1994, Exelixis, Inc. (Nasdaq: EXEL) is a commercially successful, oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Following early work in model system genetics, we established a broad drug discovery and development platform that has served as the foundation for our continued efforts to bring new cancer therapies to patients in need. Our discovery efforts have resulted in four commercially available products, CABOMETYX (cabozantinib), COMETRIQ (cabozantinib), COTELLIC® (cobimetinib) and MINNEBRO® (esaxerenone), and we have entered into partnerships with leading pharmaceutical companies to bring these important medicines to patients worldwide. Supported by revenues from our marketed products and collaborations, we are committed to prudently reinvesting in our business to maximize the potential of our pipeline. We are supplementing our existing therapeutic assets with targeted business development activities and internal drug discovery - all to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. Exelixis is a member of the Standard & Poor's (S&P) MidCap 400 index, which measures the performance of profitable mid-sized companies. In November 2020, the company was named to *Fortune's* 100 Fastest-Growing Companies list for the first time, ranking 17<sup>th</sup> overall and the third-highest biopharmaceutical company. For more information about Exelixis, please visit [www.exelixis.com](http://www.exelixis.com), follow [@ExelixisInc](https://twitter.com/ExelixisInc) on Twitter or like [Exelixis, Inc.](https://www.facebook.com/Exelixis,Inc) on Facebook.

#### **Forward-Looking Statements**

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' expectations regarding key development and regulatory milestones in 2021; Exelixis' updated 2021 financial guidance; Exelixis' plans to discuss results from cohort 6 of COSMIC-021 with the FDA to determine next steps towards a potential regulatory submission in a metastatic CRPC indication and present results at a medical meeting in the second half of 2021; Exelixis' expectation it will announce results from COSMIC-312 with respect to the final analysis of OS in early 2022; Exelixis' plans to present results from COSMIC-312 at a future medical meeting and discuss the results with the FDA to determine next steps towards a potential regulatory submission in advanced HCC; the therapeutic potential of XB002; Exelixis' development plans for XL092, including that

STELLAR-002 will begin enrolling patients in the second half of 2021; the potential expansion of Exelixis' biotherapeutics portfolio as a result of the GamaMabs AMHR2 program acquisition; and Exelixis' plans to reinvest in its business to maximize the potential of the company's pipeline, including through targeted business development activities and internal drug discovery. 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 continuing COVID-19 pandemic and its impact on Exelixis' clinical trial, drug discovery and commercial activities; 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 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; and other factors discussed under the caption "Risk Factors" in Exelixis' Quarterly Report on Form 10-Q submitted to the Securities and Exchange Commission (SEC) on May 6, 2021, 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 August 5, 2021. 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.

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OPDIVO and YERVOY are registered trademarks of Bristol-Myers Squibb Company.*

**EXELIXIS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF INCOME**

(in thousands, except per share amounts)  
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Net product revenues	\$ 284,248	\$ 178,730	\$ 511,460	\$ 372,610
License revenues	39,640	59,234	67,168	80,113
Collaboration services revenues	61,289	21,515	76,779	33,671
Total revenues	385,177	259,479	655,407	486,394
Operating expenses:				
Cost of goods sold	14,884	9,221	28,082	18,510
Research and development	148,790	114,933	308,078	216,810
Selling, general and administrative	98,495	59,791	200,846	122,731
Total operating expenses	262,169	183,945	537,006	358,051
Income from operations	123,008	75,534	118,401	128,343
Interest income	1,891	5,162	4,573	12,382
Other income (expense), net	(11)	—	(101)	6
Income before income taxes	124,888	80,696	122,873	140,731
Provision for income taxes	28,796	13,875	25,180	25,298
Net income	\$ 96,092	\$ 66,821	\$ 97,693	\$ 115,433
Net income per share:				
Basic	\$ 0.31	\$ 0.22	\$ 0.31	\$ 0.38
Diluted	\$ 0.30	\$ 0.21	\$ 0.30	\$ 0.36
Weighted-average common shares outstanding:				
Basic	314,117	307,807	313,295	306,598
Diluted	322,941	318,144	322,114	316,992

**EXELIXIS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEET DATA**

(in thousands)  
(unaudited)

**June 30, 2021**      **December 31, 2020**

Cash and investments <sup>(1)</sup>	\$	1,739,086	\$	1,538,842
Working capital	\$	1,337,920	\$	1,240,737
Total assets	\$	2,367,271	\$	2,137,333
Total stockholders' equity	\$	2,043,077	\$	1,879,113

(1) Cash and investments is composed of cash, cash equivalents, restricted cash equivalents and investments.

**EXELIXIS, INC.**  
**RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME**

(in thousands, except per share amounts)  
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
GAAP net income	\$ 96,092	\$ 66,821	\$ 97,693	\$ 115,433
Adjustments:				
Stock-based compensation - research and development expenses <sup>(1)</sup>	13,667	6,112	26,063	11,198
Stock-based compensation - selling, general and administrative expenses <sup>(1)</sup>	14,368	10,042	36,625	18,938
Income tax effect of the above adjustments	(6,235)	(3,609)	(14,024)	(6,789)
Non-GAAP net income	\$ 117,892	\$ 79,366	\$ 146,357	\$ 138,780
GAAP net income per share:				
Basic	\$ 0.31	\$ 0.22	\$ 0.31	\$ 0.38
Diluted	\$ 0.30	\$ 0.21	\$ 0.30	\$ 0.36
Non-GAAP net income per share:				
Basic	\$ 0.38	\$ 0.26	\$ 0.47	\$ 0.45
Diluted	\$ 0.37	\$ 0.25	\$ 0.45	\$ 0.44
Weighted-average common shares outstanding:				
Basic	314,117	307,807	313,295	306,598
Diluted	322,941	318,144	322,114	316,992

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



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