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

November 2, 2021

***- Total Revenues of $328.4 Million, Cabozantinib Franchise Revenues of $263.1 Million -***
***- GAAP Diluted EPS of $0.12, Non-GAAP Diluted EPS of $0.20 -***
***- Conference Call and Webcast Today at 5:00 PM Eastern Time -***

ALAMEDA, Calif.--(BUSINESS WIRE)--Nov. 2, 2021-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the third quarter of 2021 and provided an update on progress toward achieving key corporate objectives, as well as commercial, clinical and pipeline development milestones.

"Exelixis continued to execute across all facets of our business in the third quarter of 2021 with significant progress across our commercial, clinical development and pipeline activities," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. "We are pleased with the growth of CABOMETYX® prescriptions in the third quarter in the face of increasing competition, driven by the continued broad adoption of the CABOMETYX and OPDIVO® combination regimen in first-line renal cell carcinoma. Additionally, in September, CABOMETYX was approved by the U.S. Food and Drug Administration for a differentiated thyroid cancer indication, further expanding the CABOMETYX label to add an important new treatment option for a patient population with significant unmet need. We also made important strides across our clinical pipeline during the quarter, including expanding our XL092 development program and progressing enrollment for our XB002 and XL102 phase 1 studies. More recently, following the FDA's acceptance of the Investigational New Drug application for XL114, we in-licensed the compound from Aurigene. Additionally, we signed a new collaboration agreement with STORM Therapeutics for a novel therapeutic approach to treat cancer. I'd like to thank the Exelixis team for their collective hard work and execution in the third quarter and look forward to providing further updates on our business in the remainder of the year."

## Third Quarter 2021 Financial Results

**Total revenues** for the quarter ended September 30, 2021 were $328.4 million, compared to $231.1 million for the comparable period in 2020.

Total revenues for the quarter ended September 30, 2021 included net product revenues of $263.1 million, compared to $168.6 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 $65.3 million for the quarter ended September 30, 2021, compared to $62.5 million for the comparable period in 2020. The increase in collaboration revenues was primarily related to an increase in recognition of milestone-related revenues 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 development costs reimbursements earned.

**Research and development expenses** for the quarter ended September 30, 2021 were $163.4 million, compared to $176.8 million for the comparable period in 2020. The decrease in research and development expenses was primarily related to decreases in clinical trial costs, license and other collaboration costs and stock-based compensation expense, which was partially offset by an increase in personnel expenses.

**Selling, general and administrative expenses** for the quarter ended September 30, 2021 were $101.6 million, compared to $88.2 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 and corporate giving, which was partially offset by a decrease in stock-based compensation expense.

**Provision for (benefit from) income taxes** for the quarter ended September 30, 2021 was $15.1 million, compared to $(6.0) million for the comparable period in 2020, primarily due to the change in pre-tax income (loss).

**GAAP net income (loss)** for the quarter ended September 30, 2021 was $38.2 million, or $0.12 per share, basic and diluted, compared to GAAP net loss of $(32.0) million, or $(0.10) per share, basic and diluted, for the comparable period in 2020.

**Non-GAAP net income** for the quarter ended September 30, 2021 was $64.5 million, or $0.20 per share, basic and diluted, compared to non-GAAP net income of $11.2 million, or $0.04 per share, basic and 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 $1.8 billion at September 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 (loss) (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 (1) | $1,300 million - $1,350 million |
| Net product revenues (1) | $1,050 million - $1,100 million |
| Cost of goods sold | Approximately 5% - 6% of net product revenues |
| Research and development expenses (1)(2) | $650 million - $675 million |
| Selling, general and administrative expenses (1)(3) | $400 million - $425 million |
| Effective tax rate | 20% - 22% |
| Cash and investments (1)(4)(5) | Approximately $1.8 billion |

(1) Guidance updated on November 2, 2021 from previously provided guidance on August 5, 2021.

(2) Includes $50 million of non-cash stock-based compensation expense.

(3) Includes $70 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 $263.1 million during the third quarter of 2021, with net product revenues of $259.8 million from CABOMETYX and $3.3 million from COMETRIQ® (cabozantinib). Exelixis earned $27.1 million in royalty revenues during the quarter ended September 30, 2021, pursuant to collaboration agreements with our partners, Ipsen and Takeda.

**Exelixis Partner Takeda and Ono Pharmaceutical Co., Ltd. (Ono) Receive Approval in Japan for CABOMETYX in Combination with OPDIVO for the Treatment of Unresectable or Metastatic Renal Cell Carcinoma (RCC).** In August, Exelixis announced that Takeda, its partner responsible for the clinical development and commercialization of CABOMETYX in Japan, and Ono, Bristol Myers Squibb's partner responsible for the clinical development and commercialization of OPDIVO in Japan, received approval from the Japanese Ministry of Health, Labour and Welfare to manufacture and market CABOMETYX in combination with OPDIVO as a treatment for unresectable or metastatic RCC. The approval was based on the results of CheckMate -9ER, a phase 3 pivotal trial evaluating CABOMETYX in combination with OPDIVO in previously untreated patients with advanced or metastatic RCC compared with sunitinib. Upon the first commercial sale of the combination in Japan, Exelixis received a milestone payment of $20.0 million from Takeda in the third quarter of 2021.

**FDA Approval of CABOMETYX for Patients with Previously Treated Radioactive Iodine (RAI)-Refractory Differentiated Thyroid Cancer (DTC).** In September, Exelixis announced that the FDA approved CABOMETYX for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic DTC that has progressed following prior vascular endothelial growth factor receptor-targeted therapy and who are RAI-refractory or ineligible. The FDA granted Breakthrough Therapy designation and Priority Review to CABOMETYX for this indication, and its approval came more than two months ahead of the Prescription Drug User Fee Act target action date of December 4, 2021.

**Cabozantinib Presentations at the 2021 European Society of Medical Oncology (ESMO) Congress.** In September, cabozantinib was the subject of multiple clinical data presentations at the 2021 ESMO Congress, including: a post-hoc exploratory analysis of the phase 3 CheckMate -9ER pivotal trial demonstrating efficacy benefits of the combination of CABOMETYX and OPDIVO compared with sunitinib as a first-line treatment in advanced RCC patients regardless of prior nephrectomy status; detailed results from the expanded cohort 6 of the phase 1b COSMIC-021 trial of cabozantinib in combination with atezolizumab in patients with metastatic castration-resistant prostate cancer; and final results from the phase 3 COSMIC-311 pivotal trial of CABOMETYX in patients with previously treated RAI-refractory DTC.

**Pipeline Highlights**

**Exelixis and Invenra, Inc. (Invenra) Expand Collaboration to Discover and Develop Novel Biologics in Oncology.** In August, Exelixis and Invenra announced an expansion to their discovery and licensing collaboration to include an additional 20 oncology targets. The augmented partnership builds on the two companies' ongoing collaboration and license agreement to discover and develop mono-specific and multi-specific antibodies for incorporation into novel biologics to treat cancer, which was initially announced in May 2018 and expanded in October 2019.

**Exelixis In-Licenses Second Anti-Cancer Compound from Aurigene Discovery Technologies Limited (Aurigene) Following FDA Acceptance of Investigational New Drug (IND) Application.** In October, Exelixis and Aurigene announced that Exelixis exercised its exclusive option to in-license XL114 (formerly AUR104) under the companies' July 2019 collaboration, option and license agreement. As a result, Exelixis assumed responsibility for all subsequent clinical development, manufacturing and commercialization of the compound, which inhibits the CARD11-BCL10-MALT1 signaling pathway that promotes lymphocyte survival and proliferation. Following the FDA's recent acceptance of Exelixis' IND, the company plans to initiate a phase 1 trial of XL114 as a monotherapy in patients with non-Hodgkin's lymphoma.

**Corporate Updates**

**Exelixis and STORM Therapeutics (STORM) Enter Exclusive Collaboration and License Agreement to Discover and Develop Inhibitors of Novel RNA Modifying Enzymes.** In October, Exelixis and STORM entered into an exclusive collaboration and license agreement under which the companies will discover and advance novel drug leads intended for the treatment of cancer. The collaboration will focus initially on ADAR1, advancing early work by STORM applying its proprietary RNA epigenetic platform, as well as explore an additional undisclosed target.

**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 periods ended October 1, 2021, January 1, 2021 and October 2, 2020 are indicated as being as of and for the periods ended September 30, 2021, December 31, 2020, and September 30, 2020, respectively.

**Conference Call and Webcast**

Exelixis management will discuss the company's financial results for the third 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, Tuesday, November 2, 2021.

To access the 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. Alternatively, please call 855-793-2457 (domestic) or 631-485-4921 (international) and provide the conference call passcode 9563879 to join by phone.

A telephone replay will be available until 8:00 p.m. EDT on November 4, 2021. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 9563879. A webcast replay will also be archived on 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. For more information about Exelixis, please visit www.exelixis.com, follow @ExelixisInc on Twitter or like Exelixis, Inc. on Facebook.

**Forward-Looking Statements**

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' updated 2021 financial guidance; Exelixis' plans to initiate a phase 1 trial of XL114 as a monotherapy in patients with non-Hodgkin's lymphoma; 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 August 5, 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 November 2, 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.

*OPDIVO is a registered trademark of Bristol-Myers Squibb Company.*

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Revenues: | | | | |
| Net product revenues | $ 263,117 | $ 168,587 | $ 774,577 | $ 541,197 |
| License revenues | 49,694 | 33,205 | 116,862 | 113,318 |
| Collaboration services revenues | 15,612 | 29,300 | 92,391 | 62,971 |
| Total revenues | 328,423 | 231,092 | 983,830 | 717,486 |
| Operating expenses: | | | | |
| Cost of goods sold | 11,874 | 8,725 | 39,956 | 27,235 |
| Research and development | 163,370 | 176,762 | 471,448 | 393,572 |
| Selling, general and administrative | 101,558 | 88,185 | 302,404 | 210,916 |
| Total operating expenses | 276,802 | 273,672 | 813,808 | 631,723 |
| Income (loss) from operations | 51,621 | (42,580) | 170,022 | 85,763 |
| Interest income | 1,658 | 3,994 | 6,231 | 16,376 |
| Other income (expense), net | (19) | 565 | (120) | 571 |
| Income (loss) before income taxes | 53,260 | (38,021) | 176,133 | 102,710 |
| Provision for (benefit from) income taxes | 15,056 | (5,981) | 40,236 | 19,317 |
| Net income (loss) | $ 38,204 | $ (32,040) | $ 135,897 | $ 83,393 |
| Net income (loss) per share: | | | | |
| Basic | $ 0.12 | $ (0.10) | $ 0.43 | $ 0.27 |
| Diluted | $ 0.12 | $ (0.10) | $ 0.42 | $ 0.26 |
| Weighted-average common shares outstanding: | | | | |
| Basic | 315,380 | 309,116 | 313,990 | 307,437 |
| Diluted | 322,022 | 309,116 | 322,084 | 317,495 |

**EXELIXIS, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEET DATA**
(in thousands)
(unaudited)

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Cash and investments [(1)] | $ 1,796,112 | $ 1,538,842 |
| Working capital | $ 1,392,520 | $ 1,240,737 |
| Total assets | $ 2,447,741 | $ 2,137,333 |
| Total stockholders' equity | $ 2,112,447 | $ 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 (LOSS) TO NON-GAAP NET INCOME**
(in thousands, except per share amounts)
(unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| GAAP net income (loss) | $ 38,204 | $ (32,040) | $ 135,897 | $ 83,393 |
| Adjustments: | | | | |
| Stock-based compensation - research and development expenses [(1)] | 11,487 | 18,936 | 37,550 | 30,134 |
| Stock-based compensation - selling, general and administrative expenses [(1)] | 22,479 | 36,719 | 59,104 | 55,657 |
| Income tax effect of the above adjustments | (7,631) | (12,406) | (21,655) | (19,195) |
| Non-GAAP net income | $ 64,539 | $ 11,209 | $ 210,896 | $ 149,989 |
| GAAP net income (loss) per share: | | | | |
| Basic | $ 0.12 | $ (0.10) | $ 0.43 | $ 0.27 |

| | | | | |
|---|---|---|---|---|
| Diluted | $ 0.12 | $ (0.10) | $ 0.42 | $ 0.26 |
| Non-GAAP net income per share: | | | | |
| Basic | $ 0.20 | $ 0.04 | $ 0.67 | $ 0.49 |
| Diluted | $ 0.20 | $ 0.04 | $ 0.65 | $ 0.47 |
| Weighted-average common shares outstanding: | | | | |
| Basic | 315,380 | 309,116 | 313,990 | 307,437 |
| Diluted [2] | 322,022 | 318,501 | 322,084 | 317,495 |

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

(2) The dilutive effect of shares related to employee stock plans are not included in the calculation of GAAP diluted loss per share in the third quarter of 2020 as the effect would be anti-dilutive.

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