# 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): January 12, 2020**

## 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 January 12, 2020, Exelixis, Inc. ("Exelixis") issued a press release outlining its key priorities and anticipated milestones for 2020-21. The press release included preliminary (unaudited) financial results for the quarter and full year ended January 3, 2020. A copy of such press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference. The preliminary (unaudited) financial results contained in the press release do not present all information for an understanding of Exelixis' financial condition as of January 3, 2020 and its results of operations for the quarter and year ended January 3, 2020. The audit of Exelixis' financial statements for the year ended January 3, 2020 is ongoing and could result in changes to the information in the press release.

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 January 12, 2020 | |
| 101.INS | XBRL Instance Document | The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document | |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document | |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document | |
| 101.LAB | Inline XBRL Taxonomy Extension Labels Linkbase Document | |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document | |
| 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.

| January 13, 2020 | /s/ JEFFREY J. HESSEKIEL |
| --- | --- |
| Date | **Jeffrey J. Hessekiel** |
| | Executive Vice President and General Counsel |

**Exelixis Outlines Key Priorities and Anticipated Milestones for 2020-21, Announces Preliminary Fourth Quarter and Full Year 2019 Financial Results, and Provides 2020 Financial Guidance**

***- Company announces anticipated timelines for data readouts from six cabozantinib potentially label-enabling clinical studies and up to three new potential IND candidates -***

***- Presentation and webcast at 2020 J.P. Morgan Healthcare Conference on Tuesday, January 14th at 4:30 PM Pacific Time -***

**ALAMEDA, Calif. - January 2, 2020** Exelixis, Inc. (Nasdaq: EXEL) today announced its key priorities and anticipated milestones for 2020-21, including generating top-line data from key clinical trials, completing enrollment of ongoing studies, initiating new pivotal trials, and progressing its mid-stage and early pipeline. The company intends to make appropriate investments to maximize the clinical development opportunities for CABOMETYX® (cabozantinib), which Exelixis believes could lead to as many as four additional approved indications by year-end 2021, while concurrently working to advance a pipeline of potential new Exelixis medicines through internal drug discovery and business development.

"Exelixis is moving decisively to pursue important new indications for our lead product, CABOMETYX, and potentially bring new medicines to cancer patients in need of better treatment options," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "Cabozantinib is now an oncology franchise with global net revenue of more than $1 billion on an annual basis. Over the course of the next two years, we intend to expand the depth and breadth of the cabozantinib development program by obtaining top-line results from as many as six ongoing trials with label-enabling potential and initiating at least three new pivotal trials. If the data from these trials are market differentiating and result in regulatory approvals, we believe we could dramatically expand the number of patients that might benefit from cabozantinib, addressing a potential patient population more than four times greater in magnitude than our current opportunities in advanced renal cell and previously treated hepatocellular cancer. This result could have a significant impact on our business as we continue to invest in a multi-product oncology portfolio with the potential to lead to annual U.S. net product revenues approaching $4 billion by 2025."

Dr. Morrissey continued: "We continue to make strong progress in building our pipeline. Between our internal discovery activities and the four business development deals we've signed over the past two years, there are approximately 20 ongoing discovery programs focused on potentially adding novel and differentiated assets to the Exelixis development portfolio. In 2020, we believe these efforts could yield as many as three Investigational New Drug filings, and we also expect to advance multiple additional programs into preclinical development. As cabozantinib advances, we believe this earlier stage work, which we intend to complement with external strategic assets by leveraging our strong balance sheet, could bring forth a new generation of Exelixis medicines with the potential to strengthen our business and help cancer patients recover stronger and live longer."

**Anticipated Cabozantinib Data Readouts in 2020**

- **CheckMate 9ER**: Bristol-Myers Squibb (BMS) and Exelixis anticipate results from CheckMate 9ER, the phase 3 pivotal trial evaluating cabozantinib in combination with nivolumab in previously untreated advanced or metastatic renal cell carcinoma (RCC), in the first half of 2020. BMS is sponsoring this trial, which completed enrollment in early 2019. If the data are positive, Exelixis, BMS and their respective partners plan to expeditiously pursue regulatory filings.

- **COSMIC-311:** In the first half of 2020, Exelixis anticipates completing enrollment of the first 100 patients in this phase 3 pivotal trial evaluating cabozantinib versus placebo in patients with radioactive iodine-refractory differentiated thyroid cancer who have progressed after up to two VEGF receptor-targeted therapies. As planned, Exelixis expects to conduct an interim analysis in these first 100 patients for the co-primary endpoints of objective response rate and progression-free survival (PFS) and reach total enrollment of 300 patients in the second half of 2020.
- **COSMIC-312:** Exelixis expects to complete enrollment in the first half of 2020 and conduct the analysis for the co-primary endpoint of PFS and an interim analysis for overall survival (OS) for this phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab (TECENTRIQ®), Genentech's anti-PD-L1 immune checkpoint inhibitor (ICI), versus sorafenib in previously untreated advanced hepatocellular carcinoma (HCC). The analyses are event-driven and may occur as early as in the second half of 2020.
- **COSMIC-021:** COSMIC-021, the phase 1b trial evaluating cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic tumors, enrolled more than 550 patients across the 24 expansion cohorts by the end of 2019. Exelixis expects to present data from the metastatic castration-resistant prostate cancer (mCRPC) cohort of the trial at the ASCO Genitourinary Cancers Symposium in February 2020, and from the non-small cell lung cancer (NSCLC) cohort when data have matured and at the appropriate time in 2020. Based on regulatory feedback from the U.S. Food & Drug Administration (FDA) and if supported by the data from the mCRPC expansion cohorts, Exelixis intends to file with the FDA for accelerated approval in an mCRPC indication as early as 2021.
- **CheckMate 040, EXAMINER, and CANTATA:** BMS and Exelixis expect that results of a cohort from the phase 1/2 CheckMate 040 trial investigating the safety and efficacy of nivolumab plus cabozantinib with or without ipilimumab in patients with advanced HCC will be presented at the ASCO Gastrointestinal Cancers Symposium in January 2020. In addition, the PFS results for the medullary thyroid cancer EXAMINER trial, which compares the 140 mg capsule formulation with the 60 mg tablet formulation of cabozantinib, are expected in 2020. Finally, Calithera expects the analysis of CANTATA, a randomized phase 2 pivotal study of cabozantinib plus glutaminase inhibitor telaglenastat (CB-839) versus cabozantinib in previously treated RCC patients, to take place in the second half of 2020. CANTATA completed enrollment in October 2019 and is sponsored by Calithera; Exelixis provides cabozantinib for the trial.

Based on the milestones for trial enrollment and data readout, and if supported by the results, the current pivotal trials could support regulatory filings for cabozantinib in various additional tumor types and settings beginning in 2020.

**Anticipated New Pivotal Trials in 2020**

In 2020, based on emerging data from the COSMIC-021 trial, Exelixis and its collaboration partner Roche expect to initiate three new pivotal trials of cabozantinib in combination with atezolizumab under the companies' expanded clinical development collaboration announced on December 19, 2019. The clinical program, which Roche and Exelixis will co-fund, is expected to include three phase 3 pivotal trials in advanced NSCLC, mCRPC and RCC. Additional details will be provided when the individual trials are initiated.

**Additional Clinical Updates**

- **COSMIC-021:** In late 2020, Exelixis anticipates completing enrollment in COSMIC-021, which currently includes a total of 24 expansion cohorts and a projected target enrollment of up to 1,700 patients, pending the initiation of additional cohorts or expansion of selected existing cohorts. Since its initiation in 2017, data from COSMIC-021 have been instrumental in guiding Exelixis' clinical development strategy

for cabozantinib plus ICIs, including supporting the initiation of COSMIC-312 and the additional future trials described above.

- **COSMIC-313:** Exelixis expects to complete enrollment for COSMIC-313, the phase 3 pivotal trial evaluating the triplet combination of cabozantinib, nivolumab and ipilimumab versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC, in early 2021 and to report top-line results of the event-driven analyses from the study in the 2022 timeframe.
- **XL092:** The dose escalation phase 1 trial for this next generation MET, AXL and VEGFR targeting tyrosine kinase inhibitor is ongoing, and Exelixis anticipates that dose expansion cohorts and potential combination cohorts with ICIs will begin to enroll in 2020.

**Anticipated Discovery Milestones in 2020**

Exelixis and its partners are currently advancing three compounds through preclinical development. If the data are supportive, Exelixis believes there is the potential for these compounds to reach Investigational New Drug (IND) filing status before the end of 2020. The programs are anticipated to include both small molecules (a CDK7 inhibitor and a TAM kinase inhibitor) and a next generation antibody-drug conjugate targeting tissue factor. In addition, multiple development candidates from internal and collaborative efforts are expected to reach preclinical development in 2020, and Exelixis believes these candidates have the potential to move into clinical trials starting in 2021.

**Preliminary Fourth Quarter and Full Year 2019 Financial Results**

Exelixis is providing the following unaudited preliminary 2019 financial results:

- Total revenues for 2019 are approximately $972 million for the full year and approximately $245 million for the fourth quarter 2019.
- Net product revenues for 2019 are approximately $765 million for the full year and approximately $200 million for the fourth quarter 2019.
- Research and development expenses for 2019 are approximately $340 million for the full year and approximately $98 million for the fourth quarter 2019.
- Selling, general and administrative expenses for 2019 are approximately $230 million for the full year and approximately $60 million for the fourth quarter 2019.
- Cash and investments at year-end 2019 were approximately $1.4 billion.

The preliminary 2019 financial information presented in this press release has not been audited and is subject to change. The complete Exelixis Fourth Quarter and Full Year 2019 Financial Results are planned for release after market on Wednesday, February 26, 2020.

**2020 Financial Guidance**

Exelixis is providing the following financial guidance for 2020:

- Total revenues are expected to be between $850 million and $900 million.
- Net product revenues from the cabozantinib franchise (COMETRIQ® and CABOMETYX) are anticipated to be between $725 million and $775 million, reflecting the continued evolution of the metastatic RCC and HCC treatment landscapes.
- Cost of goods sold are expected to be between 4 percent and 5 percent of net product revenues.
- Research and development expenses are expected to be between $460 million and $500 million corresponding with the expected initiation and completion of numerous late-stage cabozantinib trials

as outlined previously and are expected to include non-cash expenses related to stock-based compensation expense of $25 million.

- Selling, general and administrative expenses are expected to be between $230 million and $250 million with the continued commercial investment in CABOMETYX and the broader organization and are expected to include non-cash stock-based compensation expense of $30 million.
- Guidance for the effective tax rate in 2020 is between 20 percent and 22 percent.
- Cash and investments at year end 2020 are expected to be in the $1.5 billion to $1.6 billion range, reflecting our continued focus on balancing the appropriate level of investment in the business with a continued emphasis on generating free cash flow. Importantly, this cash guidance does not include any potential new business development activity, which remains a key priority for Exelixis as we continue to build toward becoming a multi-product oncology company.

**Presentation and Webcast**

Exelixis President and Chief Executive Officer Michael M. Morrissey, Ph.D., will provide a corporate overview and discuss the company's preliminary fourth quarter and full year 2019 financial results, 2020 financial guidance, and key priorities and milestones for 2020-21 during the company's presentation at the J.P. Morgan Healthcare Conference beginning at 4:30 p.m. PT on Tuesday, January 14, 2020.

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 presentation to ensure adequate time for any software download that may be required to listen to the webcast. A replay will also be available at the same location for 14 days.

**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 approved 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 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, Good Faith Revenue Estimate and Preliminary Financial Results**

This press release contains forward-looking statements, including, without limitation, statements related to: the clinical, therapeutic and commercial potential of CABOMETYX; Exelixis' key priorities and anticipated milestones, including Exelixis' priority to become a multi-product oncology company; Exelixis' intention to expand the depth and breadth of the cabozantinib development program; Exelixis' expectations for, and the related anticipated timelines for, initiating and completing enrollment in, conducting analyses of and obtaining top-line results from its ongoing potential label-enabling clinical studies and initiating new pivotal trials evaluating cabozantinib, and if supported by the data, pursuing potential regulatory approvals; the potential

for as many as four additional approved indications for CABOMETYX by year-end 2021; Exelixis' belief that if the data from ongoing and new trials evaluating cabozantinib are market differentiating and result in regulatory approvals, it could dramatically expand the number of patients that might benefit from cabozantinib and potentially lead to annual U.S. net product revenues approaching $4 billion by 2025; Exelixis' belief that its discovery efforts could yield as many as three IND filings and result in multiple additional programs advancing into preclinical development in 2020, as well as its belief that certain preclinical candidates have the potential to move into clinical trials starting in 2021; Exelixis' expectations that results from various trials evaluating cabozantinib will be presented at upcoming conferences; Exelixis' anticipation that dose expansion cohorts in the phase 1 trial of XL092, as well as potential cohorts combining XL092 with ICIs, will begin to enroll in 2020; Exelixis' 2020 financial guidance; 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; and other statements that are not historical facts. 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. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "build," "estimate," "project," "predict," "propose," "intend," "continue," "potential," "possible," and similar expressions intended to identify forward-looking statements. 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, risks and uncertainties associated with: the degree of market acceptance of CABOMETYX and other Exelixis products in the territories where they are approved, and Exelixis' 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, including the risk that Exelixis may not properly judge the requisite size and experience of its commercialization teams or the level of distribution necessary to market and sell CABOMETYX successfully in multiple indications; 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, including evolving regulatory requirements, slower than anticipated patient enrollment or inability to identify a sufficient number of clinical trial sites; 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; the regulatory review and approval processes, including the risk that regulatory authorities may not approve Exelixis' products as treatments for the indications in which approval has been sought, if at all, as well as the related risk that regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of CABOMETYX in any additional indications or of any newly-approved product; 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 manufacture and supply of its products; 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 filed with the Securities and Exchange Commission (SEC) on October 30, 2019, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' Annual Report on Form 10-K expected to be filed with the SEC on February 26, 2020. 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.

This press release includes an estimate for Exelixis' potential annual U.S. net product revenue by 2025, which is a forward-looking statement. While this revenue estimate was prepared in good faith, no assurance can be made regarding future events. This revenue estimate is a projection based on historical performance trends and management outlook that is dependent in principal part on the successful outcomes of ongoing and planned clinical trials, the related anticipated scope and nature of potential labeling updates for CABOMETYX and approvals from regulatory authorities, and management assumptions and estimates regarding pricing, coverage and reimbursement of CABOMETYX over time, estimates of the size of the eligible patient populations that may ultimately be served by CABOMETYX in the future, new patient market share, duration of therapy, and the safety and efficacy profiles of therapies competing with CABOMETYX, all of which are inherently uncertain. The estimates and assumptions underlying this revenue estimate involve significant judgments with respect to, among other things, future economic, competitive, regulatory, market and financial conditions, as well as future clinical and regulatory outcomes and future business decisions that may not be realized, and that are inherently subject to significant business, economic, competitive and regulatory risks and uncertainties, including, among other things, the inherent uncertainty of the clinical development and regulatory approval process, CABOMETYX's perceived benefit/risk profile as compared to the benefit/risk profiles of other competitive treatments now available or in development, obtaining and maintaining coverage and reimbursement for CABOMETYX, and business and economic conditions affecting the biotechnology industry generally, all of which are difficult to predict and many of which are outside the control of Exelixis. There can be no assurance that the underlying assumptions will prove to be accurate or that the projected results will be realized and actual results likely will differ, and may differ materially, from those reflected in this revenue estimate. This revenue estimate is not fact, should not be construed or relied upon as financial guidance, and should not otherwise be relied upon as being necessarily indicative of future results, and investors are cautioned not to place undue, if any, reliance on this information. Exelixis undertakes no obligation, except as required by law, to update or otherwise revise this revenue estimate to reflect circumstances existing since its preparation or to reflect the occurrence of unanticipated events, even in the event that any or all of the underlying assumptions and estimates are shown to be in error, or to reflect changes in general economic or industry conditions.

In addition, this press release includes Exelixis' preliminary financial results for the quarter and fiscal year ended January 3, 2020. Exelixis is currently in the process of finalizing its full financial results for the quarter and fiscal year ended January 3, 2020, and the preliminary financial results presented in this press release are based only upon preliminary information available to Exelixis as of January 12, 2020. Exelixis' preliminary financial results should not be viewed as a substitute for full audited financial statements prepared in accordance with U.S. GAAP, and undue reliance should not be placed on Exelixis' preliminary financial results. Exelixis' independent registered public accounting firm has not audited or reviewed the preliminary financial results included in this press release or expressed any opinion or other form of assurance on such preliminary financial results. In addition, items or events may be identified or occur after the date of this press release due to the completion of operational and financial closing procedures, final audit adjustments and other developments may arise that would require Exelixis to make material adjustments to the preliminary financial results included in this press release. Therefore, the preliminary financial results included in this press release may differ, perhaps materially, from the financial results that will be reflected in Exelixis' audited consolidated financial statements for the fiscal year ended January 3, 2020.

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