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): April 30, 2024

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 $0.001 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 April 30, 2024, Exelixis, Inc. (Exelixis) issued a press release announcing its financial results for the quarter ended March 29, 2024, and providing a corporate update. A copy of such press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

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 April 30, 2024.	
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.

April 30, 2024	/s/ Jeffrey J. Hessekiel
Date	**Jeffrey J. Hessekiel**
	Executive Vice President, General Counsel and Secretary

Exhibit 99.1

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Exelixis Announces First Quarter 2024 Financial Results and Provides Corporate Update

- Total Revenues of $425 million, Cabozantinib Franchise U.S. Net Product Revenues of $379 million -
- Restructuring Expenses of $32.8 million Recorded -
- GAAP Diluted EPS of $0.12, Non-GAAP Diluted EPS of $0.17 -
- Conference Call and Webcast Today at 5:00 PM Eastern Time -

ALAMEDA, Calif. – April 30, 2024 - Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the first quarter of 2024, provided an update on progress toward achieving key corporate objectives, and detailed its recent and anticipated commercial, clinical and pipeline development milestones.

“In the first quarter of 2024, Exelixis made important progress to advance a diverse, multi-product portfolio of small molecules and biotherapeutics with the potential to improve standards of care for patients with cancer,” said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. “The team continued to execute across our three ongoing pivotal trials for zanzalintinib, as well as the phase 1 studies of our tissue-factor targeting ADC, XB002, and our small molecule USP1 inhibitor, XL309. We expect to provide updates from these programs as clinical data mature. In addition, we are on track for up to three Investigational New Drug filings this year, pending continued supportive preclinical data.”

Dr. Morrissey continued: “We also continued to pursue our label expansion plans for cabozantinib to drive future potential revenue growth of our flagship franchise and will provide additional updates on our regulatory strategies for both neuroendocrine tumors and metastatic castration-resistant prostate cancer, when appropriate. We believe the recent restructuring of our business, announced in January, further enhances our integrated research, development and commercial capabilities to deliver an innovative pipeline of cancer therapies for patients, while continuing to return capital back to our shareholders through our 2024 share repurchase program. As we drive the commercial and pipeline components of our business forward, we remain steadfast in our defense of cabozantinib’s intellectual property and anticipate a ruling on the second bench trial for our ongoing litigation with MSN Pharmaceuticals in the spring timeframe of this year.”

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First Quarter 2024 Financial Results

Total revenues for the quarter ended March 31, 2024 were $425.2 million, as compared to $408.8 million for the comparable period in 2023.

Total revenues for the quarter ended March 31, 2024 included net product revenues of $378.5 million, as compared to $363.4 million for the comparable period in 2023. The increase in net product revenues was primarily due to an increase in sales volume, partially offset by a decrease in average net selling price.

Collaboration revenues, composed of license revenues and collaboration services revenues, were $46.7 million for the quarter ended March 31, 2024, as compared to $45.4 million for the comparable period in 2023. The increase in collaboration revenues was primarily due to higher royalty revenues for the sales of cabozantinib outside of the U.S. generated by Exelixis' collaboration partners, Ipsen Pharma SAS and Takeda Pharmaceutical Company Limited, partially offset by a decrease in development cost reimbursements earned.

Research and development expenses for the quarter ended March 31, 2024 were $227.7 million, as compared to $234.2 million for the comparable period in 2023. The decrease in research and development expenses was primarily related to a decrease in license and other collaboration costs, partially offset by an increase in clinical trial costs.

Selling, general and administrative expenses for the quarter ended March 31, 2024 were $114.0 million, as compared to $131.4 million for the comparable period in 2023. The decrease in selling, general and administrative expenses were primarily related to decreases in corporate giving and legal and advisory fees.

Restructuring expenses for the quarter ended March 31, 2024 were $32.8 million. The restructuring expenses primarily consist of severance and employee-related costs, asset impairment and contract termination costs.

Provision for income taxes for the quarter ended March 31, 2024 was $12.0 million, as compared to $8.3 million for the comparable period in 2023.

GAAP net income for the quarter ended March 31, 2024 was $37.3 million, or $0.12 per share, basic and diluted, as compared to GAAP net income of $40.0 million, or $0.12 per share, basic and diluted, for the comparable period in 2023. GAAP net income per share for the quarter ended March 31, 2024 was favorably impacted by lower weighted-average common shares outstanding for the quarter ended March 31, 2024, as compared to the comparable period in 2023, as a result of the stock repurchase programs.

Non-GAAP net income for the quarter ended March 31, 2024 was $52.0 million, or $0.17 per share, basic and diluted, as compared to non-GAAP net income of $52.8 million, or $0.16 per share, basic and diluted, for the comparable period in 2023.

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.

2024 Financial Guidance

Exelixis is maintaining the previously provided financial guidance for fiscal year 2024 [(1)]:

Total revenues	$1.825 billion - $1.925 billion
Net product revenues [(2)]	$1.650 billion - $1.750 billion
Cost of goods sold	4% - 5% of net product revenues
Research and development expenses [(3)]	$925 million - $975 million
Selling, general and administrative expenses [(4)]	$425 million - $475 million
Effective tax rate	20% - 22%

(1) 2024 financial guidance excludes expenses related to the restructuring plan announced in January 2024.
(2) Exelixis' 2024 net product revenues guidance range includes the impact of a U.S. wholesale acquisition cost increase of 2.2% for both CABOMETYX and COMETRIQ effective on January 1, 2024.
(3) Includes $40 million of non-cash stock-based compensation expense.
(4) Includes $60 million of non-cash stock-based compensation expense.

Cabozantinib and Pipeline Highlights

Cabozantinib Franchise Net Product Revenues and Royalties. Net product revenues generated by the cabozantinib franchise in the U.S. were $378.5 million during the first quarter of 2024, with net product revenues of $376.4 million from CABOMETYX® (cabozantinib) and $2.1 million from COMETRIQ® (cabozantinib). Based upon cabozantinib-related net product revenues generated by Exelixis' collaboration partners during the quarter ended March 31, 2024, Exelixis earned $39.6 million in royalty revenues.

Detailed Results from Phase 3 CONTACT-02 Pivotal Trial Evaluating Cabozantinib in Combination with Atezolizumab in Metastatic Castration-Resistant Prostate Cancer (mCRPC) Presented at the American Society of Clinical Oncology 2024 Genitourinary Cancers Symposium (ASCO GU). In January, positive results from the primary progression-free survival (PFS) analysis in the global phase 3 CONTACT-02 pivotal trial were presented during an oral abstract session at ASCO GU. The results demonstrated a statistically significant improvement in PFS, as assessed by a blinded independent radiology committee (BIRC), for cabozantinib in combination with atezolizumab in the first 400 randomized patients in the intent-to-treat (PFS ITT) population and per protocol.

A PFS benefit was observed across all subgroups of high-risk populations who have a poor prognosis and a high unmet need for additional treatment options, notably in patients with liver metastases or those who had received prior docetaxel chemotherapy. A statistically significant improvement in PFS was also observed by BIRC both in the ITT population (n=507) and according to Prostate Cancer Clinical Trials Working Group 3 (PCWG3) criteria. An interim analysis for overall survival (OS), conducted at the time of the primary PFS analysis, demonstrated a trend favoring the combination of cabozantinib and atezolizumab. The study continues toward the next analysis of OS, which is anticipated in 2024. CONTACT-02 is evaluating cabozantinib in combination with atezolizumab compared with a second novel hormonal therapy (NHT) in patients with mCRPC and measurable soft-tissue disease who have progressed on one prior NHT. The safety profile of the combination regimen was consistent with the known profiles of each single agent, and no new safety findings were identified.

Four-Year Follow-up Results from Phase 3 CheckMate -9ER Trial Evaluating CABOMETYX in Combination with Nivolumab (OPDIVO®) in Previously Untreated Renal Cell Carcinoma (RCC) Presented at ASCO GU. In January, four-year follow-up results from the CheckMate -9ER trial were featured in an oral presentation at ASCO GU. Results continued to show superior PFS and objective response rates in patients treated with the combination of CABOMETYX and nivolumab over sunitinib, the comparator studied in the trial, regardless of risk classification. Superior OS was also observed in patients treated with the combination. The presentation included data showing health-related quality-of-life benefits with the combination as compared to sunitinib. No new safety concerns were identified in the follow-up analysis.

Cabozantinib and Zanzalintinib Data Presentations at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting. Cabozantinib and zanzalintinib will be the subject of 10 presentations at this year's ASCO Annual Meeting, which is being held from May 31 through June 4 in Chicago. Notably, presentations will include a biomarker analysis from the clear cell RCC cohort of the phase 1b/2 STELLAR-001 study of zanzalintinib in advanced solid tumors.

Corporate Highlights

Announcement of Key Priorities and Anticipated Milestones for 2024. In January, Exelixis announced its key priorities and anticipated milestones for 2024, including: implementation of a corporate restructuring to prioritize the advancement of the company's deep pipeline of clinical and near-clinical programs; potential U.S. regulatory filings for cabozantinib in advanced NET and mCRPC indications; the anticipated outcome of the cabozantinib Abbreviated New Drug Application litigation with MSN Pharmaceuticals in the Spring timeframe of 2024; expansion of zanzalintinib's pivotal development program with priorities defined by emerging phase 1b/2 data and potential clinical co-funding opportunities; advancing JEWEL-101, the phase 1 study of XB002, a next-generation tissue factor-targeting antibody-drug conjugate (ADC), alone and in combination with immunotherapy in a variety of solid tumor settings with the goal of prioritizing sensitive tumor types for full development; accelerating the phase 1 development of XL309, a potentially best-in-class small molecule inhibitor of USP1, as a potential therapy for tumors that have become refractory to PARP inhibitor (PARPi) therapy, including forms of ovarian, breast and prostate cancers, and pursuing potential PARPi combinations; potentially filing three Investigational New Drug applications for XB010 (5T4-MMAE ADC), XB628 (PD-L1 + NKG2A bispecific antibody), and XL495 (small molecule PKMYT1 inhibitor) if preclinical data continue to be supportive; and advancing two new programs to development candidate status, including a small molecule PLK4 inhibitor and an additional ADC. Exelixis presented the details of its key priorities and anticipated milestones at the 42nd Annual J.P. Morgan Healthcare Conference.

Share Repurchase Program. As of March 31, 2024, Exelixis has repurchased $190.7 million of the company's common stock, at an average price of $22.08 per share. In January, Exelixis announced that the company's Board of Directors authorized the repurchase of up to an additional $450 million of the company's common stock before the end of 2024.

Upon fulfillment of the 2024 share repurchase program, the company expects to have returned $1 billion to shareholders over two years along with the 2023 program successfully completed in December 2023. Share repurchases under the 2024 program may be made from time to time through a variety of methods, which may include open market purchases, in block trades, accelerated share repurchase transactions, exchange transactions, or any combination of such methods. The timing and amount of any share repurchases under the share repurchase program will be based on a variety of factors, including ongoing assessments of the capital needs of the business, alternative investment opportunities, the market price of Exelixis' common stock and general market conditions.

Appointments of Two New Board Members with Extensive Drug Development and Corporate Governance Expertise. In January, Exelixis announced the appointments of Mary C. Beckerle, Ph.D., and S. Gail Eckhardt, M.D., to the Exelixis Board of Directors, effective January 5, 2024. Dr. Beckerle is Chief Executive Officer of the Huntsman Cancer Institute and Associate Vice President for Cancer Affairs and Distinguished Professor of Biology and Oncological Sciences at the University of Utah. Since 2006, she has had responsibility for the vision, strategic direction and management of the University's oncology programs, including research, care, education and community outreach. Dr. Eckhardt is Associate Dean of Experimental Therapeutics at Baylor College of Medicine and Associate Director of Translational Research at the College's Dan L. Duncan Comprehensive Cancer Center. A recognized leader in translational medicine relative to oncology, she has focused her career on the preclinical and early clinical development of molecularly targeted therapies and combination regimens to treat colorectal and other gastrointestinal cancers.

European Patent Office (EPO) Rules in Favor of Exelixis on Formulation Patent Covering Cabozantinib Tablets. In January, Exelixis successfully defended European Patent number EP2593090 (c-MET Modulator Pharmaceutical Compositions) against three opponents, STADA Arzneimittel AG, Teva Pharmaceutical Industries Ltd. and Generics (U.K.) Ltd., in a hearing before the Opposition Division of the EPO. The patent at issue, which expires on July 18, 2031, covers tablet formulations of cabozantinib, including the tablet formulation approved as CABOMETYX (cabozantinib) tablets by the European Medicines Agency. The decision is specific to the European patent at issue and is subject to appeal to the EPO Technical Boards of Appeal.

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 period ended March 29, 2024 is indicated as being as of and for the period ended March 31, 2024.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the first quarter of 2024 and provide a general business update during a conference call beginning at 5:00 p.m. ET / 2:00 p.m. PT today, Tuesday, April 30, 2024.

To access the conference call, please register using this link. Upon registration, a dial-in number and unique PIN will be provided to join the call. To access the live webcast link, log onto www.exelixis.com and proceed to the Event Calendar page under the Investors & News heading. A webcast replay of the conference call will also be archived on www.exelixis.com for one year.

About Exelixis

Exelixis is a globally ambitious oncology company innovating next-generation medicines and regimens at the forefront of cancer care. Powered by drug discovery and development excellence, we are rapidly evolving our product portfolio to target an expanding range of tumor types and indications with our clinically differentiated pipeline of small molecules, antibody-drug conjugates and other biotherapeutics. This comprehensive approach harnesses decades of robust investment in our science and partnerships to advance our investigational programs and extend the impact of our flagship commercial product, CABOMETYX® (cabozantinib). Exelixis is driven by a bold scientific pursuit to create transformational treatments that give more patients hope for the future. For information about the company and its mission to help cancer patients recover stronger and live longer, visit www.exelixis.com, follow @ExelixisInc on X (Twitter), like Exelixis, Inc. on Facebook and follow Exelixis on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the potential for Exelixis' portfolio of small molecules and biotherapeutics to improve standards of care for patients with cancer; Exelixis' expectation to submit Investigational New Drug filings for up to three development candidates in 2024, pending continued supportive preclinical data, and to provide updates for the zanzalintinib, XB002 and XL309 development programs as clinical data mature; Exelixis' plans to advance its regulatory strategies for cabozantinib label expansions into NET and mCRPC indications, which could drive future potential revenue growth of the franchise, and to provide additional updates when appropriate; Exelixis' belief that its restructuring will further enhance the company's integrated research, development and commercial capabilities to deliver an innovative pipeline of cancer therapies for patients; Exelixis' anticipation of a ruling in the second bench trial for its ongoing litigation with MSN Pharmaceuticals in the spring timeframe of 2024; Exelixis' 2024 financial guidance; Exelixis' anticipated timing of 2024 for the next analysis of OS from CONTACT-02; Exelixis' plans to present cabozantinib and zanzalintinib data at the 2024 ASCO Annual Meeting, including a biomarker analysis from the clear cell RCC cohort of the phase 1b/2 STELLAR-001 study of zanzalintinib in advanced solid tumors; Exelixis' key priorities and anticipated milestones for 2024; Exelixis' plans to repurchase up to an additional $450 million of its common stock before the end of 2024, and Exelixis' expectation to have returned $1 billion to shareholders over two years along with the successfully completed 2023 share repurchase program; and Exelixis' scientific pursuit to create transformational treatments that give more patients hope for the future. 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 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, zanzalintinib 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

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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 product candidates; 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 detailed from time to time under the caption "Risk Factors" in Exelixis' most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and in Exelixis' other future filings with the Securities and Exchange Commission. 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.

-see attached financial tables-

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

	Three Months Ended March 31,	
	2024	**2023**
Revenues:		
Net product revenues	$ 378,523	$ 363,400
License revenues	44,676	38,292
Collaboration services revenues	2,027	7,096
Total revenues	425,226	408,788
Operating expenses:		
Cost of goods sold	21,256	14,315
Research and development	227,689	234,246
Selling, general and administrative	113,984	131,397
Restructuring	32,835	—
Total operating expenses	395,764	379,958
Income from operations	29,462	28,830
Interest income	19,894	19,502
Other expense, net	(89)	(54)
Income before income taxes	49,267	48,278
Provision for income taxes	11,950	8,250
Net income	$ 37,317	$ 40,028
Net income per share:		
Basic	$ 0.12	$ 0.12
Diluted	$ 0.12	$ 0.12
Weighted-average common shares outstanding:		
Basic	300,757	324,420
Diluted	305,530	326,279

EXELIXIS, INC.
RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2024	**2023**
GAAP net income	$ 37,317	$ 40,028
Adjustments:		
Stock-based compensation - research and development expenses [1]	3,892	3,252
Stock-based compensation - selling, general and administrative expenses [1]	15,221	13,409
Income tax effect of the above adjustments	(4,448)	(3,861)
Non-GAAP net income	$ 51,982	$ 52,828
GAAP net income per share:		
Basic	$ 0.12	$ 0.12
Diluted	$ 0.12	$ 0.12
Non-GAAP net income per share:		
Basic	$ 0.17	$ 0.16
Diluted	$ 0.17	$ 0.16
Weighted-average common shares outstanding:		
Basic	300,757	324,420
Diluted	305,530	326,279

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