
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): February 16, 2005

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other
Jurisdiction of Incorporation)

0-30235
(Commission File Number)

04-3257395
(IRS Employer
Identification No.)

170 Harbor Way
P.O. Box 511
South San Francisco, California 94083
(Address of principal executive offices, and including 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))

Item 2.02 Results of Operations and Financial Condition.

On February 16, 2005, Exelixis, Inc. issued a press release announcing financial results for the quarter and year ended December 31, 2004. 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 herein 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.

The information furnished in this report, including the exhibit hereto, shall not be deemed to constitute an admission that such information or exhibit is required to be furnished by Regulation FD or that the information or exhibit in this report contains material information that is not otherwise publicly available.

Use of Non-GAAP Financial Information

Exelixis provides certain historical net loss and future operating expense information in the press release to illustrate the company's results from operations excluding acquired in-process research and development, restructuring charges, gain from insurance settlement and certain non-cash charges, including (a) stock-based compensation expense and (b) amortization of purchased intangibles related to business combinations. Exelixis' management believes the non-GAAP results are a useful measure of the company's results from continuing operations, excluding the non-cash charges, which, in management's view, are not necessarily reflective of or directly attributable to operations. These non-GAAP results are not in accordance with, or an alternative for, generally accepted accounting principles and may be different from non-GAAP measures used by other companies.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 16, 2005

Exelixis, Inc.

/s/ Christoph Pereira

Christoph Pereira

Vice President, Legal Affairs and Secretary

EXHIBIT LIST

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued February 16, 2005.



For Immediate Release

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EXELIXIS ANNOUNCES FOURTH QUARTER AND YEAR-END 2004 FINANCIAL RESULTS

SOUTH SAN FRANCISCO, Calif. – February 16, 2005 – Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the quarter and year-ended December 31, 2004.

Net loss for the quarter ended December 31, 2004, under generally accepted accounting principles (GAAP), was approximately \$51.9 million, or \$0.70 per share, compared to a GAAP net loss of \$23.3 million, or \$0.33 per share, for the fourth quarter of 2003. Non-GAAP net loss, excluding restructuring expense, non-cash charges for stock compensation, acquired in-process research and development and amortization of intangibles, was approximately \$25.6 million, or \$0.35 per share, compared to approximately \$22.6 million, or \$0.32 per share, for the fourth quarter of 2003. During the quarter ended December 31, 2004 we recorded a \$26.0 million in-process research and development charge related to our acquisition of X-Ceptor Therapeutics. A reconciliation of GAAP net loss to non-GAAP net loss is set forth at the end of this press release.

For the year ended December 31, 2004 net loss under GAAP was approximately \$137.2 million, or \$1.89 per share, compared to a GAAP net loss of \$94.8 million, or \$1.45 per share, for the year ended December 31, 2003. Non-GAAP net loss, excluding restructuring expense, gain from insurance settlement, non-cash charges for stock compensation, acquired in-process research and development and amortization of intangibles, was approximately \$107.8 million, or \$1.49 per share, compared to approximately \$93.0 million, or \$1.42 per share, for the year ended December 31, 2003. A reconciliation of GAAP net loss to non-GAAP net loss is set forth at the end of this press release.

Cash, cash equivalents, short-term investments and restricted cash totaled approximately \$171.2 million at December 31, 2004, compared to \$241.9 million at December 31, 2003.

Revenues for the quarter and year ended December 31, 2004 were approximately \$15.7 million and \$52.9 million, respectively, compared to \$13.8 million and \$51.5 million, respectively, for the comparable periods in 2003. The increases in 2004 compared to 2003 were driven primarily by two \$1.0 million milestone payments earned under our Bristol-Myers Squibb collaboration, \$1.0 million in R&D funding from Sankyo Co., Ltd., a collaboration agreement acquired as part of the X-Ceptor transaction, \$1.3 million increase in R&D funding under our GSK collaboration, and an increase in revenues of \$0.8 million from compound deliveries under our combinatorial chemistry collaborations. These increases were offset by decreases of \$1.7 million related to the successful conclusion of our collaboration with Protein Design Labs in May 2003 and \$2.3 million due to the upfront payments from Bristol-Myers Squibb being fully amortized in July 2004.

Research and development expenses for the quarter and year ended December 31, 2004 were \$35.0 million and \$137.7 million, respectively, compared to \$32.6 million and \$127.6 million, respectively, for the comparable periods in 2003. The increases in 2004 from the 2003 levels were driven primarily by the expansion of our development activities associated with advancing our clinical and preclinical development programs.

General and administrative expenses for the quarter and year ended December 31, 2004 were \$5.5 million and \$20.9 million, respectively, compared to \$4.2 million and \$18.6 million, respectively, for the comparable periods in 2003. The increases in 2004 from the 2003 levels were driven primarily due to increases in staffing costs to support our research and development activities, facility expenses as well as legal and accounting expenses.

2004 Business Highlights

- Three Investigational New Drug Applications (INDs): We filed INDs with the U.S. Food and Drug Administration (FDA) for XL647, XL999 and XL880, our lead Spectrum Selective Kinase Inhibitors™. Phase I trials are ongoing for XL647 and XL999 and we anticipate initiating a Phase I trial for XL880 in early 2005.
- Initiation of a Phase III multinational clinical trial for XL119 (becatecarin), a compound developed as the first potential treatment indicated for bile duct tumors.
- Three new development candidates: We advanced XL844, XL184 and XL820 to development candidate status and anticipate filing INDs in 2005.
- Ongoing development of XL784: We continued to explore the potential of XL784 for chronic administration in renal failure and our development program is progressing well and is on track.

- Refocusing of R&D organizations: We restructured and consolidated our research and discovery organizations resulting in significant costs savings and efficiencies
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- Acquisition of X-Ceptor: We expanded our metabolism program through the acquisition of X-Ceptor, which has developed biology assets and advanced lead optimization programs focused on the Liver X Receptor (LXR), Farnesoid X Receptor (FXR) and Mineralocorticoid Receptor (MR). We anticipate that some of these programs will advance to development candidate status in 2005 and become potential IND candidates in 2006.

For additional details on our compounds please visit our website at www.exelixis.com under the heading "Pipeline."

"We made tremendous strides toward our goal of developing therapies that positively impact the lives of patients. We hope to complete the Phase I trials for our lead compounds XL647, XL999 and possibly XL880 this year. If the data warrant it, we will quickly start Phase II trials in 2005. While proud of our accomplishments, we realize that there is much work to be done," said George A. Scangos, Ph.D., President and CEO of Exelixis.

"In 2005, our focus is on continued high-quality execution that will allow us to advance our compounds toward commercialization. We will also make the necessary business and partnering decisions that will allow us efficiently manage our financial resources", continued Dr. Scangos.

Outlook

With respect to financial expectations for the full year 2005 as compared to 2004, we anticipate that revenues will increase in the range of 50% to 60% primarily due to expected milestones under our amended GSK collaboration as well as additional revenue from certain business development activities. We expect operating expenses, excluding acquired in-process research and development, stock-based compensation and other non-cash charges, to increase in the range of 7% to 12%. The increase in operating expenses is primarily related to the on going advancement and expansion of our development activities and corresponding increases in our general and administrative infrastructure. The Company's cash, cash equivalents, short term investments and restricted cash balance at the end of 2005 is expected to exceed \$100 million.

The above guidance reflects the impact of expected milestones under our GSK collaboration and a moderate level of business development activity. The guidance does not include the potential impact of any security offering or business combination that may be entered into after December 31, 2004.

Conference Call and Webcast

Exelixis' management will discuss the company's fourth quarter and year-end 2004 financial results and 2005 outlook as well as other business developments during a conference call beginning at 5:00 p.m. U.S. EST today, Wednesday, February 16, 2005. To listen to the discussion, log onto www.exelixis.com and click on the webcast link

under the heading "Investor Info". A copy of Exelixis' press releases, including this release, can be found at www.exelixis.com under the heading "Press Room."

About Exelixis

Exelixis, Inc. (Nasdaq: EXEL) is a leading genomics-based drug discovery company dedicated to the discovery and development of novel therapeutics across various disease areas. The company is leveraging its fully integrated gene-to-drug platform to fuel the growth of its proprietary drug pipeline. Exelixis' development pipeline covers cancer and metabolism and is comprised of the following compounds: XL119 (becatecarin), for which a Phase III clinical trial has been initiated in patients with bile duct tumors; XL784, initially an anticancer compound, which completed a Phase I clinical trial and is being developed as a treatment for renal disease; XL647 and XL999, anticancer compounds currently in Phase I clinical trials; XL880, an anticancer compound for which an IND application has been filed; XL820, XL844 and XL184, potential IND candidates for the treatment of cancer; and multiple compounds in preclinical development for diseases including cancer, lipid disorders, hyperlipidemia and congestive heart failure. Exelixis has established broad corporate alliances with major pharmaceutical and biotechnology companies, including GlaxoSmithKline (GSK) and Bristol-Myers Squibb Company. Pursuant to a product development and commercialization agreement between Exelixis and GSK, GSK has the option, after completion of Phase IIa clinical trials, to elect to develop a certain number of compounds in Exelixis' product pipeline, which may include the cancer compounds identified in this press release (other than XL119), thus potentially triggering milestone payments and royalties from GSK and co-promotion rights by Exelixis. The company has also established agricultural research collaborations with Bayer CropScience and Dow AgroSciences. For more information, please visit the company's web site at www.exelixis.com

This press release contains forward-looking statements, including without limitation statements related to our ability to enter into new collaborations, continue existing collaborations and receive milestones and royalties derived from future products developed from research efforts under collaborative agreements; the rate of growth, if any, in license and contract revenues; the timing and level of expenses associated with the growth of proprietary programs and the GSK collaboration; our estimated future balances of cash, cash equivalents, short-term investments and restricted cash; and the matters discussed in the "Outlook" Section. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "slated," "goal" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Exelixis' current expectations. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation the potential failure of Exelixis' product candidates to demonstrate safety and efficacy in clinical testing; the ability of Exelixis to file IND applications and initiate clinical trials at the referenced times; the ability of Exelixis to conduct the Phase III clinical trial of XL119 sufficient to achieve FDA

approval; plans to initiate and conduct a Phase I/II trial of XL784 in 2005, the ability to conduct the Phase I clinical trial of XL647, XL999 or XL880 sufficient to achieve a positive completion; the ability of Exelixis to successfully advance and develop additional compounds including XL820, XL844 and XL184; the ability to develop drug candidates and/or INDs as part of the metabolism program; the ability of the company to advance additional preclinical

compounds into clinical development; the uncertainty of the FDA approval process; and the therapeutic and commercial value of the company's compounds; the matters discussed in the "Outlook" section and others. These and other risk factors are discussed under "Risk Factors" and elsewhere in our quarterly report on Form 10-Q for the quarter ended September 30, 2004 and other filings with the Securities and Exchange Commission. The company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

*Exelixis and the Exelixis logo are registered U.S. trademarks.
Spectrum Selective Kinase Inhibitor is a trademark of Exelixis, Inc.*

-see attached financials tables-

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

	Three Months Ended December 31,		Year Ended December 31,	
	2004	2003	2004	2003 (1)
Revenues:				
Contracts	\$ 13,528	\$ 10,638	\$ 42,340	\$ 39,027
License	2,216	3,128	10,517	12,513
Total revenues	<u>15,744</u>	<u>13,766</u>	<u>52,857</u>	<u>51,540</u>
Operating expenses:				
Research and development	35,030	32,568	137,724	127,622
General and administrative	5,549	4,222	20,905	18,586
Restructuring charge	—	319	2,275	925
Acquired in-process research and development	25,981	—	26,376	—
Amortization of intangibles	278	167	779	666
Total operating expenses	<u>66,838</u>	<u>37,276</u>	<u>188,059</u>	<u>147,799</u>
Loss from operations	(51,094)	(23,510)	(135,202)	(96,259)
Other income (expense):				
Interest income	806	902	3,232	4,266
Interest expense	(1,639)	(983)	(5,378)	(3,722)
Other income (expense), net	5	(145)	103	596
Total other income (expense)	<u>(828)</u>	<u>(226)</u>	<u>(2,043)</u>	<u>1,140</u>
Loss before income taxes	(51,922)	(23,736)	(137,245)	(95,119)
Benefit for income taxes	—	(457)	—	(345)
Net loss	<u>\$ (51,922)</u>	<u>\$ (23,279)</u>	<u>\$ (137,245)</u>	<u>\$ (94,774)</u>
Net loss per share, basic and diluted	<u>\$ (0.70)</u>	<u>\$ (0.33)</u>	<u>\$ (1.89)</u>	<u>\$ (1.45)</u>
Shares used in computing basic and diluted net loss per share	<u>74,322</u>	<u>71,152</u>	<u>72,504</u>	<u>65,387</u>

(1) Derived from the audited consolidated financial statements

EXELIXIS, INC.
RECONCILIATION OF GAAP NET LOSS TO NON-GAAP NET LOSS ⁽¹⁾
(in thousands, except per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2004	2003	2004	2003
GAAP net loss	\$ (51,922)	\$ (23,279)	\$ (137,245)	\$ (94,774)
Add:				
Restructuring charges	—	319	2,275	925
Acquired in-process research and development	25,981	—	26,376	—
Non-cash charges for amortization of intangibles	278	167	779	666
Non-cash charges for stock compensation expense	17	168	56	912
Less:				
Gain from insurance settlement included in other income	—	—	—	(773)

Non-GAAP net loss	\$ (25,646)	\$ (22,625)	\$ (107,759)	\$ (93,044)
Non-GAAP net loss per share, basic and diluted	\$ (0.35)	\$ (0.32)	\$ (1.49)	\$ (1.42)
Shares used in computing basic and diluted Non-GAAP net loss per share	74,322	71,152	72,504	65,387

(1) These non-GAAP amounts are intended to illustrate the company's results from operations excluding acquired in-process research and development, restructuring charges, gain from insurance settlement and certain non-cash charges, including (a) stock-based compensation expense, (b) amortization of purchased intangibles related to business combinations and (c) charges for acquired in-process research and development. Management of the company believes the non-GAAP results are a useful measure of the company's results from continuing operations, excluding the non-cash charges, which, in management's view, are not necessarily reflective of or directly attributable to operations. These non-GAAP results are not in accordance with, or an alternative for, generally accepted accounting principles and may be different from non-GAAP measures used by other companies.

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

	December 31, 2004 (unaudited)	December 31, 2003 (1)
Cash, cash equivalents and short-term investments, including restricted cash of \$16.0 million in 2004	\$ 171,223	\$ 241,930
Working capital	100,161	189,968
Total assets	291,340	357,794
Stockholders' equity	50,671	161,482

(1) Derived from the audited consolidated financial statements

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