

-----  
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 17, 2004

EXELIXIS, INC.

-----  
(Exact Name of Registrant as Specified in Charter)

Delaware

0-30235

04-3257395

-----  
(State or Other  
Jurisdiction of Incorporation)

-----  
(Commission File Number)

-----  
(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)  
-----

Item 12. Results of Operations and Financial Condition.

On February 17, 2004, Exelixis, Inc. issued a press release announcing financial results for the quarter and year ended December 31, 2003. 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 net loss information in the press release to illustrate the company's results from operations excluding discontinued operations, gain on insurance settlement, restructuring charges and certain non-cash charges, including (a) stock-based compensation expense and (b) amortization of purchased intangibles related to business combinations. Exelixis' management believes that the presentation of these non-GAAP results is a useful measure of the company's results from continuing operations, excluding the restructuring charges, non-cash charges and gain on insurance settlement, which, in management's view, are not necessarily reflective of, or directly attributable to, operations. Exelixis provides certain cash burn information in the press release, which Exelixis' management believes is useful to illustrate the company's use of cash, cash equivalents, short-term investments and restricted cash during the period for operating activities and other recurring items directly related to operations, such as capital expenditures. These non-GAAP measures 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.

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 17, 2004

Exelixis, Inc.

/s/ Frank Karbe

-----  
Frank Karbe  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

EXELIXIS ANNOUNCES FOURTH QUARTER AND  
YEAR-END 2003 FINANCIAL RESULTS

SOUTH SAN FRANCISCO, Calif. - February 17, 2004 - Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the quarter and year ended December 31, 2003.

For the quarter ended December 31, 2003, the company reported a net loss of approximately \$23.3 million, or \$0.33 per share, under generally accepted accounting principles (GAAP), compared to a net loss of \$20.9 million, or \$0.36 per share, for the quarter ended December 31, 2002. Excluding restructuring expense and non-cash charges for stock compensation and amortization of intangibles, the company reported a non-GAAP net loss of approximately \$22.6 million, or \$0.32 per share, for the quarter ended December 31, 2003. For the quarter ended December 31, 2002, the comparable non-GAAP net loss was approximately \$19.8 million, or \$0.34 per share. 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, 2003, the company reported a GAAP net loss of approximately \$94.8 million, or \$1.45 per share, compared to a net loss of \$86.1 million, or \$1.52 per share, for the year ended December 31, 2002. Excluding restructuring expense, gain from insurance settlement, loss from discontinued operations and non-cash charges for stock compensation and amortization of intangibles, the company reported a non-GAAP net loss of approximately \$93.0 million, or \$1.42 per share, for the year ended December 31, 2003. For the year ended December 31, 2002, the comparable non-GAAP net loss was approximately \$81.0 million, or \$1.43 per share. A reconciliation of GAAP net loss to non-GAAP net loss is set forth at the end of this press release.

Our cash burn for 2003 was \$86.4 million. Cash burn is the sum of the net cash used in operating activities; plus purchases of property and equipment, net of proceeds from bank obligations; plus principal payments on capital lease obligations, notes payable and bank obligations as derived from our consolidated statements of cash flows prepared in accordance with GAAP. A calculation of cash burn is set forth at the end of this press release. At December 31, 2003, cash, cash equivalents, short-term investments and restricted cash totaled approximately \$241.9 million, compared to \$222.0 million at December 31, 2002.

For the quarter and year ended December 31, 2003, total revenues were approximately \$13.8 million and \$51.5 million, respectively, compared to \$12.5 million and \$44.3 million, respectively, for the same periods of 2002. The increases in 2003 compared to 2002 were driven primarily by revenue from our corporate collaboration with SmithKlineBeecham Corporation (GlaxoSmithKline) and from compound deliveries under our chemistry collaborations with Cytokinetics, Elan Pharmaceuticals, Merck, Scios and Schering Plough Research Institute, partially offset by the successful conclusion of our collaboration with Protein Design Labs in May 2003.

Research and development expenses for the quarter and year ended December 31, 2003 were \$32.6 million and \$127.6 million, respectively, compared to \$27.7 million and \$112.0 million, respectively, for the equivalent periods of 2002. The increases in 2003 from the 2002 levels were driven primarily by the expansion of our drug discovery and development operations and activities associated with advancing our clinical and pre-clinical development programs.

General and administrative expenses for the quarter and year ended December 31, 2003 were \$4.2 million and \$18.6 million, respectively, compared to \$4.8 million and \$18.8 million, respectively, for the comparable periods in 2002.

"Exelixis delivered a strong performance in 2003 by achieving our clinical and strategic goals and maintaining a high level of fiscal responsibility and operational efficiency," said George A. Scangos, Ph.D., president and chief executive officer. "Throughout our organization, we believe that we are operating at high levels of efficiency, innovation and quality. In 2003, our research and development efforts were highly productive, resulting in the advancement of multiple compounds toward the clinic. We anticipate that we will be able to file at least two investigational new drug (IND) applications per year beginning in 2004. We are generating an expanding pipeline of what we believe are innovative and exciting compounds that have the potential to be important new therapeutics in cancer and other serious diseases. We anticipate that 2004 will be an important and highly productive year for our company as we progress toward our goals of delivering new medicines to patients in need and of building a sustainable biotechnology company."

Exelixis' 2003 accomplishments include the following:

- Phase 2 clinical trials of XL119 were concluded successfully, and the company is on track to initiate a Phase 3 clinical trial of XL119 as a potential treatment for bile duct tumors in the second quarter of 2004.
- The Phase 1 trial of XL784 was successfully conducted. The compound was administered orally to healthy volunteers and was shown to be free of side effects and to have an attractive pharmacokinetic profile. The compound showed good activity in preclinical models of renal and cardiac disease, providing a basis for the company to pursue development of XL784 as a potential treatment for renal and cardiovascular failure.
- Exelixis advanced multiple proprietary compounds towards the clinic. Exelixis is on track to file an IND application for XL647 in the first quarter of 2004 and to file an IND application for XL999 in the second quarter of 2004. The company anticipates filing an IND application for XL844 in early 2005, and has several additional preclinical programs

slated for IND applications in 2005 and beyond.

- Exelixis extended and expanded its oncology collaboration with Bristol-Myers Squibb, extended its herbicide collaboration with Dow AgroSciences and achieved its collaboration goals with Bayer, GlaxoSmithKline and all of its other strategic partners.
- Exelixis delivered a strong financial performance and exceeded its year-end cash balance goal by ending the year with approximately \$242 million in cash, cash equivalents, short-term investments and restricted cash.

#### Outlook

- - - - -

The following statements are based on current expectations. These statements are forward-looking, and actual results may differ materially. Except as expressly set forth below, these statements do not include the potential impact of any product in-licensing, equity offerings or business combinations that may be closed or entered into after December 31, 2003.

With respect to financial expectations for 2004 as compared to 2003, we anticipate that revenues will increase in the range of 15 to 25% and that operating expenses, excluding non-cash and restructuring charges, will increase in the range of 23 to 28%. The increase in operating expenses is primarily related to the on-going expansion of our development and drug discovery operations as we advance and expand our clinical and preclinical research programs. The company's cash, cash equivalents, short-term investments and restricted cash balance at the end of 2004 is expected to exceed \$175 million, including estimated proceeds of \$30 million in 2004 from our loan facility with GlaxoSmithKline.

With respect to financial expectations for the first quarter of 2004, we expect our revenues to decrease by approximately 15 to 20% due to timing of shipments under our chemistry collaborations, and our operating expenses, excluding non-cash and restructuring charges, to increase by 10 to 15% from fourth quarter 2003 levels.

Exelixis' management will discuss the company's fourth quarter and year-end 2003 financial results and outlook during a conference call beginning at 5:00 p.m. U.S. EDT today, Tuesday, February 17, 2004. To participate in the conference call, log onto [www.exelixis.com](http://www.exelixis.com) and click on the webcast link under the heading

-----  
"Investor Info" to access the live call. A copy of Exelixis' press releases, including this release, can be found on the company's website at [www.exelixis.com](http://www.exelixis.com) under the heading "Press Room."

Exelixis, Inc. (Nasdaq: EXEL) is a leading genomics-based drug discovery company dedicated to the discovery and development of novel therapeutics. The company is leveraging its fully integrated gene-to-drug platform to fuel the growth of its proprietary drug pipeline. Exelixis' development pipeline includes: XL119, which is anticipated to enter a Phase 3 clinical trial as a potential treatment for bile duct tumors; XL784, an anticancer compound that has completed a Phase 1 clinical trial; XL647, XL999 and XL844, anticancer compounds that are potential IND candidates; and multiple compounds in preclinical development. Exelixis has established broad corporate alliances with major pharmaceutical and biotechnology companies, including GlaxoSmithKline and Bristol-Myers Squibb Company. After completion of Phase 2a clinical trials, GlaxoSmithKline has the right to elect to develop a certain number of the cancer compounds identified in this release, other than XL119, thus potentially triggering milestone payments and royalties from GlaxoSmithKline and co-promotion by Exelixis. The company has also established agricultural research collaborations with Bayer CropScience, Dow AgroSciences and Renessen LLC. Other partners include Merck & Co., Inc., Schering-Plough Research Institute, Inc., Cytokinetics, Inc., Elan Pharmaceuticals, Inc. and Scios Inc. For more information, please visit the company's web site at [www.exelixis.com](http://www.exelixis.com).

-----  
This press release contains forward-looking statements, including without limitation statements related to our Phase 3 registration trial of XL119, the prospects for XL784, potential INDs for XL647, XL999 and XL844, potential additional INDs and the matters discussed in the "Outlook" section. Words such as "goal", "believes," "anticipates," "plans," "expects," "will," "slated" 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, risk related to: Exelixis' ability to enter into new collaborations, continue existing collaborations and receive milestones and royalties derived from future products developed from its 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 GlaxoSmithKline collaboration; the potential failure of clinical testing of Exelixis' product candidates to demonstrate safety and efficacy; the ability of Exelixis to file IND applications at the referenced times; the ability of Exelixis to conduct the Phase 3 clinical trial of XL119 sufficient to achieve FDA approval, or to initiate the planned Phase 3 clinical trial in the second quarter of 2004; the ability of Exelixis to successfully advance and develop additional preclinical compounds including XL647, XL999, XL844 and others. These and other risk factors are discussed under "Risk Factors" and elsewhere in Exelixis' Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and other SEC reports. Exelixis 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 its 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.

-see attached financials tables-

EXELIXIS, INC.  
CONSOLIDATED STATEMENTS OF OPERATIONS  
(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2003	2002	2003	2002
	(Unaudited)		(Unaudited)	
<b>Revenues:</b>				
Contract and government grants	\$ 10,638	\$ 9,713	\$ 39,027	\$ 34,981
License	3,128	2,741	12,513	9,341
<b>Total revenues</b>	<b>13,766</b>	<b>12,454</b>	<b>51,540</b>	<b>44,322</b>
<b>Operating expenses:</b>				
Research and development (1)	32,568	27,724	127,622	112,014
General and administrative (2)	4,222	4,796	18,586	18,758
Restructuring charge	319	708	925	708
Amortization of intangibles	167	167	666	666
<b>Total operating expenses</b>	<b>37,276</b>	<b>33,395</b>	<b>147,799</b>	<b>132,146</b>
<b>Loss from operations</b>	<b>(23,510)</b>	<b>(20,941)</b>	<b>(96,259)</b>	<b>(87,824)</b>
<b>Other income (expense):</b>				
Interest income	902	1,187	4,266	5,916
Interest expense	(983)	(795)	(3,722)	(2,885)
Other income (expense), net	(145)	32	596	259
<b>Total other income (expense)</b>	<b>(226)</b>	<b>424</b>	<b>1,140</b>	<b>3,290</b>
<b>Loss from continuing operations before income taxes</b>	<b>(23,736)</b>	<b>(20,517)</b>	<b>(95,119)</b>	<b>(84,534)</b>
Provision (benefit) for income taxes	(457)	345	(345)	345
<b>Loss from continuing operations</b>	<b>(23,279)</b>	<b>(20,862)</b>	<b>(94,774)</b>	<b>(84,879)</b>
Loss from operations of discontinued segment	-	-	-	(1,251)
<b>Net loss</b>	<b>\$ (23,279)</b>	<b>\$ (20,862)</b>	<b>\$ (94,774)</b>	<b>\$ (86,130)</b>
<b>Loss per share from continuing operations</b>	<b>\$ (0.33)</b>	<b>\$ (0.36)</b>	<b>\$ (1.45)</b>	<b>\$ (1.50)</b>
Loss per share from discontinued operations	-	-	-	(0.02)
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.33)</b>	<b>\$ (0.36)</b>	<b>\$ (1.45)</b>	<b>\$ (1.52)</b>
Shares used in computing basic and diluted net loss per share	71,152	58,170	65,387	56,615

(1) Includes stock compensation expense of \$248 and \$210 in the three-months ended December 31, 2003 and 2002, respectively, and \$712 and \$1,559 for the years ended December 31, 2003 and 2002, respectively.

(2) Includes a reversal of previously recorded stock compensation expense of \$80 and \$60 in the three-months ended December 31, 2003 and 2002, respectively, and stock compensation expense of \$200 and \$897 for the years ended December 31, 2003 and 2002, respectively.

(3) 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 amounts)  
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2003	2002	2003	2002

GAAP net loss	\$	(23,279)	\$	(20,862)	\$	(94,774)	\$	(86,130)
Add back:								
Loss from operations of discontinued segment		-		-		-		1,251
Non-cash charges for amortization of intangibles		167		167		666		666
Non-cash charges for stock compensation expense		168		150		912		2,456
Restructuring charge		319		708		925		708
Less:								
Gain from insurance settlement included in other income		-		-		(773)		-
		-----		-----		-----		-----
Non-GAAP net loss	\$	(22,625)	\$	(19,837)	\$	(93,044)	\$	(81,049)
		=====		=====		=====		=====
Non-GAAP net loss per share, basic and diluted	\$	(0.32)	\$	(0.34)	\$	(1.42)	\$	(1.43)
		=====		=====		=====		=====
Shares used in computing basic and diluted Non-GAAP net loss per share		71,152		58,170		65,387		56,615
		=====		=====		=====		=====

(1) These non-GAAP amounts are intended to illustrate the company's results from operations excluding discontinued operations, gain from insurance settlement, restructuring charges and certain non-cash charges, including (a) stock-based compensation expense and (b) amortization of purchased intangibles related to business combinations. Management of the company believes the non-GAAP results are a useful measure of the company's results from continuing operations, excluding restructuring expenses, gain from insurance settlement and 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, 2003	December 31, 2002 (2)
	-----	-----
	(unaudited)	
Cash, cash equivalents, short-term investments, including restricted cash of \$4.8 million in 2003	\$ 241,930	\$ 221,987
Working capital	189,968	173,153
Total assets	357,794	339,113
Stockholders' equity	161,482	175,920

(2) Derived from the audited consolidated financial statements

Exelixis, Inc.  
CALCULATION OF CASH BURN (1)  
Year Ended December 31, 2003  
(in thousands)  
(unaudited)

Net cash used in operating activities	\$ (79,237)
Purchases of property and equipment	(14,248)
Proceeds from bank obligations	17,038
Principal payments on capital lease obligations	(6,841)
Principal payments on notes payable and bank obligations	(3,099)
	-----
Total cash burn	\$ (86,387)
	=====

(1) Cash burn amounts are intended to illustrate the Company's use of cash, cash equivalents, short-term investments and restricted cash during the period for operating activities and other recurring items directly related to operations, such as capital expenditures. Cash burn is the sum of the net cash used in operating activities; plus purchases of property and equipment, net of proceeds from bank obligations; plus principal payments on capital lease obligations, notes payable and bank obligations, as derived from our consolidated statements of cash flows prepared in accordance with generally accepted accounting principles.

# # #