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): November 8, 2004

EXELIXIS, INC.

(Exact name of registrant as specified in its 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)

Check the appropriate box below if the Form 8K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a12 under the Exchange Act (17 CFR 240.14a12)
- o Precommencement communications pursuant to Rule 14d2(b) under the Exchange Act (17 CFR 240.14d2(b))
- o Precommencement communications pursuant to Rule 13e4(c) under the Exchange Act (17 CFR 240.13e4(c))

Item 2.02 Results of Operations and Financial Condition.

On November 8, 2004, Exelixis, Inc. issued a press release announcing financial results for the quarter ended September 30, 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 inprocess research and development, restructuring charges, gain from insurance settlement and certain noncash charges, including (a) stockbased 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 noncash 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.

Exhibit 99.1 Press release issued November 8, 2004.

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: November 8, 2004

Exelixis, Inc.

/s/ Christoph Pereira
Christoph Pereira
Vice President, Legal Affairs and Secretary

EXHIBIT LIST

Exhibit No.	Description
99.1	Press release issued November 8, 2004.

Exhibit 99.1

For Immediate Release

Contact:
Frank Karbe
Chief Financial Officer
Exelixis, Inc.
650 837 7565
fkarbe@exelixis.com

EXELIXIS ANNOUNCES THIRD QUARTER 2004 FINANCIAL RESULTS

SOUTH SAN FRANCISCO, California — November 8, 2004 — Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the quarter ended September 30, 2004.

Third Quarter 2004 Financial Results

Net loss, under generally accepted accounting principles (GAAP), was approximately $27.2 million, or $0.38 per share, compared to a GAAP net loss of $25.0 million, or $0.35 per share, for the third quarter 2003. Non-GAAP net loss, excluding restructuring expense and non-cash charges for stock compensation and amortization of intangibles, was approximately $27.1 million, or $0.37 per share, compared to approximately $24.1 million, or $0.34 per share, for the third quarter of 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 $147.2 million, compared to $170.3 million at June 30, 2004, $207.0 million at March 31, 2004 and $241.9 million at December 31, 2003.

Revenues were approximately $12.7 million, compared to $12.4 million for the same period of 2003. The increase from 2003 to 2004 was primarily a result of increased revenues from compound deliveries under our combinatorial chemistry collaborations and a $1.0 million milestone payment under our Bristol-Myers Squibb collaboration following another draft pick of novel cancer targets. The increase was partially offset by lower quarterly revenues from amortized upfront payments related to our initial Bristol-Myers Squibb collaboration being fully amortized in July 2004.

Research and development expenses were approximately $34.1 million, compared to $32.3 million for the equivalent period of 2003. The increase in 2004 from the 2003 level was driven primarily by increased expenses associated with advancing the

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company's clinical and pre-clinical development programs and was partially offset by a decrease in salaries and other personnel-related expenses as a result of our restructuring activities during the second quarter of 2004.

General and administrative expenses were approximately $5.1 million, compared to $4.5 million for the equivalent period for 2003. The increase in 2004 from the 2003 level is primarily related to increases in personnel and facility expenses.

Third Quarter 2004 Business Highlights

- Acquisition of X-Ceptor: On October 18, we completed the acquisition of X-Ceptor Therapeutics, Inc., a leader in the discovery and development of small molecules that modulate nuclear hormone receptors (NHRs). This acquisition is an important element of our strategy to diversify into new therapeutic areas and is expected to accelerate the development and commercialization of a diverse, highly differentiated pipeline of products to treat diseases including cancer, metabolic syndrome, lipid disorders, hypertension and congestive heart failure. We anticipate filing IND applications for some of the newly acquired compounds in 2006.
- Posters presented at European Organization for the Research and Treatment of Cancer (EORTC): We presented two posters on pre-clinical data for XL647 and XL999, our first two internally generated Spectrum Selective Kinase Inhibitors that have moved into clinical development, targeting proteins involved in both tumor proliferation and angiogenesis. The pre-clinical data shown for XL647 confirmed its modulation of angiogenesis and tumor cell proliferation. The data shown for XL999 exhibited a broad spectrum of activity across several tumor types and regression of large, well-established xenografts.
- XL119: The Phase III trial began dosing patients in North America and is proceeding with additional patient and investigator enrollment in North America and Europe.
- XL784: (inhibitor of Adam 10 metalloprotease) We continue to explore the potential of this compound in renal disease, with a goal of pursuing that indication in the clinic in early 2005.
- XL647: (inhibitor of EGF, VEGF receptors and Her2) The Phase I trial for this novel, orally available compound, which was initiated in June, is on track and continues to enroll additional subjects.
- XL999: (inhibitor of VEGF, PDGF, and FGF receptors) We initiated the Phase I trial for this proprietary, novel anticancer compound in October.
- XL880, XL820 and XL844: All three compounds continue to be on track for IND applications in the first half of 2005, with the IND application for XL880 expected no later than the first quarter of 2005.
- XL184: We advanced XL184 toward IND filing, with the submission anticipated in the first half of 2005.

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

"While Exelixis continued its strong fiscal management this quarter, we also demonstrated the realization of both short and long-term strategic goals," said Frank Karbe, Senior Vice President and CFO of Exelixis. "We advanced the first two proprietary anticancer compounds from the Exelixis pipeline into clinical development while expanding our therapeutic base into metabolism focusing on the areas of GPCRs and NHRs," said George Scangos, PhD, President and CEO of Exelixis. "Moving forward we feel that Exelixis is poised to advance multiple high quality compounds into clinical development, that demonstrate substantial therapeutic benefits for patients."

Outlook

With respect to financial expectations for the fourth quarter of 2004 as compared to the third quarter, we anticipate that revenues will increase in the range of 35% to 40% primarily due to increasing revenues under our combinatorial chemistry collaborations and a substantial increase of our annual research and development funding under our GSK collaboration. We expect operating expenses, excluding acquired in-process research and development and non-cash charges, will increase in the range of 12% to 17% primarily due to the further advancement of our clinical and preclinical programs.

We are revising our 2004 financial guidance for revenues. For the year ending December 31, 2004 as compared to 2003, we anticipate that revenues will increase in the range of 0% to 10%. The decrease in our revenue guidance is primarily due to timing differences in the recognition of revenue from new business development initiatives. Our guidance for both operating expenses and cash and investments balance remains unchanged. For the year ending December 31, 2004 as compared to 2003, we anticipate that operating expenses, excluding restructuring charges, acquired in-process research and development and non-cash charges, will increase in the range of 10% to 15%. The company's cash, cash equivalents, short-term investments and restricted cash balance at the end of 2004 is expected to exceed $180 million, including estimated proceeds of $30 million in 2004 from our loan facility with GlaxoSmithKline.

The above guidance does not reflect the potential impact of any product in-licensing, equity offering or business combination, excluding the X-Ceptor acquisition, that may be closed or entered into after September 30, 2004.

Conference Call and Webcast

Exelixis' management will discuss the company's third quarter 2004 financial results and outlook as well as other developments in the company's business during a conference call beginning at 4:30 p.m. U.S. EST today, Monday, November 8, 2004. To participate in the conference call, log onto 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 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 therapy areas. The company is leveraging its fully integrated gene-to-drug platform to fuel the growth of its proprietary drug pipeline. Exelixis' development pipeline currently covers cancer and metabolism and is comprised of the following compounds: XL119 (becatecarin), for which a Phase 3 clinical trial has been initiated in patients with bile duct tumors; XL784, initially an anticancer compound, which has completed a Phase 1 clinical trial and is currently being developed as a treatment for renal disease; XL647 and XL999, which are currently in Phase 1 clinical trials; XL880, XL820, XL844 and XL184, anticancer compounds that are potential IND candidates; 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 2a 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 the company's cancer compound 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. Other partners include Merck & Co., Inc., Schering-Plough Research Institute, Inc., Cytokinetics, Inc., and Scios Inc. 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; the rate of growth, if any, in license and contract revenues; our estimated future balances of cash, cash equivalents, short-term investments and restricted cash. Words such as "believes," "anticipates," "plans," "expects," "intend," "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 3 clinical trial of XL119 sufficient to achieve FDA approval; the ability to conduct the Phase I clinical trial of XL647 or XL999 sufficient to achieve a positive completion; the ability of Exelixis to successfully

advance and develop additional compounds including XL784, XL880, XL820, XL844 and XL184; the ability to develop drug candidates and/or INDs for the GPCR or NHR targets 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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenues:				
Contracts	$ 10,617	$ 9,310	$ 28,812	$ 28,389
License	2,045	3,129	8,301	9,385
Total revenues	12,662	12,439	37,113	37,774
Operating expenses:				
Research and development	34,054	32,298	102,694	95,054
General and administrative	5,078	4,495	15,356	14,364
Restructuring charge	—	606	2,275	606
Acquired in-process research and development	—	—	395	—
Amortization of intangibles	168	166	501	499
Total operating expenses	39,300	37,565	121,221	110,523
Loss from operations	(26,638)	(25,126)	(84,108)	(72,749)
Other income (expense):				
Interest income	728	1,096	2,426	3,364
Interest expense	(1,285)	(907)	(3,739)	(2,739)
Other income (expense), net	6	(133)	98	741
Total other income (expense)	(551)	56	(1,215)	1,366
Loss before income taxes	(27,189)	(25,070)	(85,323)	(71,383)
Provision (benefit) for income taxes	—	(75)	—	112
Net loss	$ (27,189)	$ (24,995)	$ (85,323)	$ (71,495)
Net loss per share, basic and diluted	$ (0.38)	$ (0.35)	$ (1.19)	$ (1.13)
Shares used in computing basic and diluted net loss per share	72,170	70,994	71,898	63,466

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
GAAP net loss	$ (27,189)	$ (24,995)	$ (85,323)	$ (71,495)
Add:				
Restructuring charges	—	606	2,275	606
Acquired in-process research and development	—	—	395	—
Non-cash charges for amortization of intangibles	168	166	501	499
Non-cash charges (reversals) for stock compensation expense	(34)	167	40	744
Gain from insurance settlement included in other income	—	—	—	(773)
Non-GAAP net loss	(27,055)	$ (24,056)	(82,112)	$ (70,419)
Non-GAAP net loss per share, basic and diluted	$ (0.37)	$ (0.34)	$ (1.14)	$ (1.11)

Shares used in computing basic and diluted Non-GAAP net loss per share	72,170	70,994	71,898	63,466

(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 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 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)

	September 30, 2004 (Unaudited)	December 31, 2003 (2)
Cash, cash equivalents and short-term investments, Including restricted cash of $16.4 million ($4.8 million in 2003)	$ 147,234	$ 241,930
Working Capital	100,298	191,736
Total assets	267,869	357,794
Stockholders' equity	80,667	161,482

(2) Derived from the audited consolidated financial statements

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