

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 3, 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 November 3, 2005, Exelixis, Inc. issued a press release announcing financial results for the quarter ended September 30, 2005. 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 information in the press release to illustrate the company's results from operations excluding acquired in-process research and development, 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 the non-GAAP results are a useful measure of the company's results from continuing operations because, in management's view, the excluded charges 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 3, 2005.

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 3, 2005

Exelixis, Inc.

/s/ Christoph Pereira

Christoph Pereira

Vice President, Legal Affairs and Secretary

EXHIBIT LIST

Exhibit No.

Description

99.1

Press release issued November 3, 2005.



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

Charles Butler
Associate Director,
Corporate Communications
Exelixis, Inc.
650 837 7277
cbutler@exelixis.com

EXELIXIS ANNOUNCES THIRD QUARTER 2005 FINANCIAL RESULTS

SOUTH SAN FRANCISCO, Calif. - November 3, 2005 - Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the quarter ended September 30, 2005.

Net loss under generally accepted accounting principles (GAAP) was \$22.8 million, or \$0.29 per share, compared to \$27.2 million, or \$0.38 per share, for the third quarter of 2004. Non-GAAP net loss, which excludes restructuring expense, acquired in-process research and development, and non-cash charges for stock compensation and amortization of intangibles, was \$22.5 million, or \$0.28 per share, compared to \$27.1 million, or \$0.37 per share for the third quarter of 2004. 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, investments held by Symphony Evolution, Inc. and restricted cash and investments totaled \$214.0 million at September 30, 2005, compared to \$202.3 million at June 30, 2005 and \$171.2 million at December 31, 2004.

Revenues were \$14.4 million, compared to \$12.7 million for the comparable period in 2004. The increase from 2004 to 2005 was primarily due to revenue related to milestones achieved in May 2005, increased research and development funding under our GlaxoSmithKline collaboration and an upfront payment received under our new license agreement with Helsinn. These increases were partially offset by a loss of revenues from the completion of our Genoptera collaboration and most of our combinatorial chemistry collaborations.

Research and development expenses were \$35.2 million compared to \$34.1 million for the comparable period in 2004. The increase from 2004 to 2005 was primarily due to increased

development expenses associated with advancing and expanding our clinical and preclinical development activities. The increase was partially offset by a significant decrease in expenses for lab supplies as a result of the termination of most of our combinatorial chemistry collaborations.

General and administrative expenses were \$6.8 million compared to \$5.1 million for the comparable period in 2004. The increase from 2004 to 2005 was primarily a result of higher personnel and facility related expenses to support our research and development activities as well as increased expenses for professional services.

Third Quarter 2005 Highlights

Development: We continued to make significant advances in our clinical programs. We initiated three phase 1 clinical trials and now have a total of eight compounds in clinical development, as well as three compounds in preclinical development. We are pleased with the progress of the trials and the enrollment rates. All of the compounds are of high quality and each is directed to a different spectrum of targets. Importantly, the third quarter marks our entry into a new phase where we will be able to begin to discuss our clinical data publicly. Abstracts from our three lead internally-developed cancer compounds were accepted for presentation at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics meeting in Philadelphia, and we are excited about the opportunity to discuss these data. Highlights for the quarter include the following:

- **Phase 1: XL820, XL844, XL184** – We initiated phase 1 clinical trials for each of these compounds. XL820 and XL184 are being studied in patients with refractory solid tumors for whom there are no available therapies known to prolong survival. XL844 is being studied in patients with chronic lymphocytic leukemia
- **XL784:** A repeat-dose phase 1 clinical trial of a capsule formulation of XL784 was initiated in healthy volunteers to assess safety, pharmacokinetics and pharmacodynamics
- **Phase 2:** We announced plans for broad phase 2 programs for our three most advanced internally generated development compounds - XL999, XL647 and XL784
- **Clinical Data:** Abstracts describing phase 1 data for XL647, XL999 and XL880 were accepted for poster presentation at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, which will be held in Philadelphia, PA November 14-18

Financing: In August, we raised net proceeds of \$49.6 million through the issuance of 6.5 million shares of common stock pursuant to a shelf registration statement to support our ongoing research and development activities.

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

“2005 is an unprecedented year for Exelixis. Our ability to advance 8 compounds through clinical development, including one compound in phase 3 testing and three compounds that will soon move to phase 2 is a strong validation of our entire process from target identification through clinical development, and reflects our continued ability to execute,” said George A. Scangos, Ph.D. president and chief executive officer of Exelixis. “The first four orally

administered compounds to enter the clinic all exhibit good oral bioavailability and appropriate half-lives. I am excited about the quality and number of compounds in the pipeline, and I believe that the reasons for our enthusiasm will become evident as we are able to share the data, as we will begin to do at the upcoming AACR-NCI-EORTC meeting. Our solid financial position is a reflection of the cash that we have brought in from a variety of sources this year, and enables us to aggressively move our pipeline forward. I believe that we are crossing an inflection point and that 2005 marks the beginning of a new, clinically-focused era for Exelixis.”

Outlook

With respect to financial expectations for the full year 2005, we maintain our revenue guidance of \$75 to \$80 million but we are reducing our operating expense guidance to a range of \$170 to \$180 million, primarily reflecting lower operating expenses in the fourth quarter 2005. We are raising our guidance for the Company’s cash, cash equivalents, short term investments, investments held by Symphony Evolution and restricted cash balance and expect to end the year with a balance of at least \$200 million. The increase reflects the impact from our financing transaction in August of this year as well as the lower operating expense forecast. The expected year-end cash balance does not include the second capital draw of up to \$40 million from Symphony Evolution, which we can draw before June 2006.

Conference Call and Webcast

Exelixis’ management will discuss the company’s third quarter 2005 financial results as well as other business developments during a conference call beginning at 2:00 p.m. PST/ 5:00 p.m. EST today, Thursday, November 3, 2005. To listen to the discussion, visit the Webcast section under Investor Information on the Exelixis website at www.exelixis.com.

About Exelixis

Exelixis, Inc. is a biotechnology company dedicated to the discovery and development of novel therapeutics that will potentially enhance the care and lives of patients with cancer and other serious diseases. 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 multinational Phase 3 clinical trial in bile duct tumor is ongoing and which has been exclusively licensed to Helsinn Healthcare S.A. with rights to reacquire commercial rights for North America; XL784, which is being advanced as a treatment for renal disease and is currently in a Phase 1 clinical trial using a newly developed capsule formulation of the compound; XL647, XL999, XL880, XL820, XL844 and XL184, anticancer compounds currently in Phase 1 clinical trials; and multiple compounds in preclinical development for diseases including cancer and various metabolic and cardiovascular disorders. 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 by Exelixis, to elect to develop a certain number of compounds in Exelixis’ product pipeline, which may include XL784 and 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. 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 estimated future revenues and expenses; our estimated future balances of cash, cash equivalents, short-term investment, investments held by Symphony Evolution, Inc. 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 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 Helsinn Healthcare S.A. to conduct the Phase 3 clinical trial of XL119 sufficient to achieve FDA approval; the ability to conduct Phase 1 clinical trials of XL784, XL647, XL999, XL880, XL820, XL844 and XL184 sufficient to achieve a positive completion; the ability to develop drug candidates and file INDs as part of the metabolism program; the ability of Exelixis 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. 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, 2005 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.

-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,	
	2005	2004	2005	2004
Revenues:				
Contract	\$ 10,279	\$ 10,617	\$ 45,323	\$ 28,812
License	4,121	2,045	16,261	8,301
Total revenues	14,400	12,662	61,584	37,113
Operating expenses:				
Research and development	35,202	34,054	105,091	102,694
General and administrative	6,819	5,078	20,173	15,356
Amortization of intangibles	271	168	815	501
Restructuring charge	—	—	—	2,275
Acquired in-process research and development	—	—	—	395
Total operating expenses	42,292	39,300	126,079	121,221
Loss from operations	(27,892)	(26,638)	(64,495)	(84,108)
Other income (expense):				
Interest income	1,581	728	3,555	2,426
Interest expense	(1,550)	(1,285)	(4,647)	(3,739)
Other income (expense), net	—	6	190	98
Total other income (expense)	31	(551)	(902)	(1,215)
Loss before noncontrolling interest in Symphony Evolution, Inc.	(27,861)	(27,189)	(65,397)	(85,323)
Loss attributable to noncontrolling interest in Symphony Evolution, Inc.	5,086	—	5,515	—
Net loss	\$ (22,775)	\$ (27,189)	\$ (59,882)	\$ (85,323)
Net loss per share, basic and diluted	\$ (0.29)	\$ (0.38)	\$ (0.77)	\$ (1.19)
Shares used in computing basic and diluted net loss per share	79,540	72,170	77,288	71,898

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,	
	2005	2004	2005	2004
GAAP net loss	\$(22,775)	\$(27,189)	\$(59,882)	\$(85,323)
Add:				
Restructuring charges	—	—	—	2,275
Acquired in-process research and development	—	—	—	395
Non-cash charges for amortization of intangibles	271	168	815	501
Non-cash charges (reversals) for stock compensation expense	29	(34)	35	40
Non-GAAP net loss	\$(22,475)	\$(27,055)	\$(59,032)	\$(82,112)
Non-GAAP net loss per share, basic and diluted	\$ (0.28)	\$ (0.37)	\$ (0.76)	\$ (1.14)
Shares used in computing basic and diluted Non-GAAP net loss per share	79,540	72,170	77,288	71,898

⁽¹⁾ These non-GAAP amounts are intended to illustrate the company's results from operations excluding restructuring charges, acquired in-process research and development 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, 2005	December 31, 2004 ⁽¹⁾
	(unaudited)	
Cash, cash equivalents and short-term investments ⁽²⁾	\$ 214,003	\$ 171,223
Working capital	125,600	100,161
Total assets	338,706	291,340
Stockholders' equity	55,905	50,671

⁽¹⁾ Derived from the audited consolidated financial statements

⁽²⁾ These amounts also include investments held by Symphony Evolution, Inc. of \$37.5 million and restricted cash of \$13.5 million as of September 30, 2005, and restricted cash of \$16.0 million as of December 31, 2004.

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