

**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): August 8, 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))
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Item 2.02 Results of Operations and Financial Condition.

On August 8, 2005, Exelixis, Inc. issued a press release announcing financial results for the quarter ended June 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 August 8, 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: August 8, 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 August 8, 2005.



For Immediate Release

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EXELIXIS ANNOUNCES SECOND QUARTER 2005 FINANCIAL RESULTS

SOUTH SAN FRANCISCO, Calif. - August 8, 2005 - Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the quarter ended June 30, 2005.

Net loss under generally accepted accounting principles (GAAP) was approximately \$9.7 million, or \$0.13 per share, compared to \$29.3 million, or \$0.41 per share, for the second 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 \$9.4 million, or \$0.12 per share, compared to approximately \$27.0 million, or \$0.37 per share for the first 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 approximately \$202.3 million at June 30, 2005, and \$171.2 million at December 31, 2004.

Revenues were approximately \$34.3 million, compared to \$12.6 million for the same period in 2004. The increase from 2004 to 2005 was primarily related to revenue recognition related to the termination of our Genoptera collaboration; revenue from milestones achieved in May 2005; and increased research and development funding under our GlaxoSmithKline (GSK) collaboration. These increases were partially offset by the expiration of one of our Bristol-Myers Squibb collaborations in July 2004.

Research and development expenses were approximately \$36.6 million compared to \$34.4 million for the comparable period in 2004. The increase from 2004 to 2005 was primarily due to royalties payable as a result of our Genentech collaboration and increased development expenses associated with advancing and expanding our clinical and preclinical development activities. The increase was partially offset by a decrease in lab supplies as a result of the termination of most of our combinatorial chemistry collaborations.

General and administrative expenses were approximately \$7.1 million compared to \$4.7 million for the comparable period in 2004. The increase from 2004 to 2005 was primarily a result of an increase in legal expenses associated with our business development activities in the second quarter of 2005, as well as increased facility and equipment rental expense.

Second Quarter 2005 Business Highlights

- **GlaxoSmithKline:** In May 2005, we received two milestones totaling \$35.0 million under our collaboration agreement with GlaxoSmithKline. The first milestone in the amount of \$30.0 million was achieved in April 2005 as a result of having submitted investigational new drug (INDs) applications for XL880, XL820 and XL844. The second milestone in the amount of \$5.0 million was achieved in May 2005 as a result of progress that we made in earlier stage programs.
- **Genentech:** In May 2005, we established a collaboration with Genentech, Inc. for the discovery and development of therapeutics to target cancer, inflammatory diseases, and tissue growth and repair. The collaboration combines the intellectual property and biological capabilities of both companies to target proteins and genes that are involved in cell proliferation and differentiation. We granted Genentech a license to certain intellectual property relating to our Notch portfolio. In return, Genentech made an upfront payment and will provide research and development funding over three years - total funding amounts to \$16.0 million.
- **Symphony Evolution:** In June 2005, we entered into a transaction with Symphony Capital Partners, L.P. and its investors to provide up to \$80.0 million of funding for the further clinical development of XL647, XL999 and XL784. We licensed the intellectual property for the three compounds to Symphony Evolution, Inc., a newly formed entity, but retain the exclusive right to reacquire the compounds. We will continue to be primarily responsible for the management of the clinical trials.
- **Helsinn Healthcare:** In June 2005, we entered into an agreement with Helsinn Healthcare S.A. for the development and commercialization of XL119 (becatecarin). We received an upfront payment of \$4.0 million, we are eligible to receive further milestones of up to \$21.0 million and Helsinn will assume the cost of the Phase 3 program going forward. In return, we granted Helsinn an exclusive worldwide, royalty bearing license to XL119. We retained rights to reacquire commercial rights to XL119 for North America and are also entitled to receive milestones and royalties on worldwide sales.
- **Pipeline Update:** In the second quarter of 2005, we filed three INDs - XL820, XL844 and XL184. The Phase 1 trial for XL820 was initiated in July 2005 and we anticipate initiating the trials for XL844 and XL184 later this year. The Phase 1 clinical trials for XL647 and XL999 continued to progress as anticipated and we are planning to initiate broad Phase 2 clinical trial programs for both compounds later this year. In addition, we completed the

additional clinical studies and the reformulation for XL784 which will re-enter clinical trials later this year.

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

"We just completed the most productive quarter in Exelixis' history. We secured significant additional funding through our various business transactions and continue to demonstrate an unprecedented level of productivity in advancing and expanding our pipeline of product candidates, filing three new INDs and advancing two additional compounds into preclinical development," said George A. Scangos, Ph.D., president and chief executive officer of Exelixis. "We are now positioned better than ever to realize the potential of our compounds, capabilities and technologies. We have a lot of exciting work ahead of us with the start of broad Phase 2 clinical programs for XL647, XL999 and XL784 and the release of our first human clinical data in the second half of 2005."

Outlook

With respect to financial expectations for the full year 2005 as compared to the original guidance provided in February 2005, we are lowering our revenue guidance by approximately 6% to a range of \$75.0 million to \$80.0 million primarily due to a change in the anticipated timing of revenue recognition for milestones received in 2005 under our amended GSK collaboration. We expect operating expenses, excluding restructuring, acquired in-process research and development, non-cash charges for stock compensation, and amortization of intangibles, to increase by approximately 10% to a range of \$185.0 million to \$195.0 million. The increase in our operating expense guidance is exclusively driven by the expansion of our development activities for XL647, XL999 and XL784, which will be fully reimbursed by Symphony Evolution and will therefore not negatively impact our net loss. We are raising our guidance for the Company's cash, cash equivalents, short term investments, investments held by Symphony Evolution, Inc. and restricted cash balance at the end of 2005 by 40% and expect to end the year with a balance of at least \$140.0 million. The cash forecast does not include the second capital draw of up to \$40.0 million from Symphony Evolution, which we can draw at any point before June 2006.

Conference Call and Webcast

Exelixis' management will discuss the company's second quarter 2005 financial results as well as other business developments during a conference call beginning at 2:00 p.m. PDT/ 5:00 p.m. EDT today, Monday, August 8, 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 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 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, initially an anticancer compound, which completed a Phase 1 clinical trial and is being advanced as a treatment for renal disease; XL647, XL999, XL880 and XL820, anticancer compounds currently in Phase 1 clinical trials; XL844 and XL184, anticancer compounds for which INDs have been filed; 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 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 ability to continue existing collaborations and receive milestones and royalties 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, including programs licensed to Symphony Evolution, and the GSK collaboration; 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; plans to initiate and conduct additional studies for XL784 in 2005, the ability to conduct Phase 1 clinical trials of XL647, XL999, XL880 and XL820 sufficient to achieve a positive completion; the ability of Exelixis to successfully advance and develop additional compounds, including XL844 and XL184; 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 June 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 June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Revenues:				
Contracts	\$ 24,954	\$ 9,431	\$ 35,044	\$ 18,195
License	9,356	3,128	12,140	6,256
Total revenues	34,310	12,559	47,184	24,451
Operating expenses:				
Research and development	36,568	34,416	69,889	68,640
General and administrative	7,112	4,702	13,354	10,278
Amortization of intangibles	272	167	544	333
Restructuring charge	—	1,738	—	2,275
Acquired in-process research and development	—	395	—	395
Total operating expenses	43,952	41,418	83,787	81,921
Loss from operations	(9,642)	(28,859)	(36,603)	(57,470)
Other income (expense):				
Interest income	1,046	782	1,974	1,698
Interest expense	(1,545)	(1,221)	(3,097)	(2,454)
Other income (expense), net	16	7	190	92
Total other income (expense)	(483)	(432)	(933)	(664)
Loss before non-controlling interest	(10,125)	(29,291)	(37,536)	(58,134)
Loss attributable to non-controlling interest	429	—	429	—
Net loss	\$ (9,696)	\$ (29,291)	\$ (37,107)	\$ (58,134)
Net loss per share, basic and diluted	\$ (0.13)	\$ (0.41)	\$ (0.49)	\$ (0.81)
Shares used in computing basic and diluted net loss per share	76,405	72,011	76,162	71,762

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
GAAP net loss	\$ (9,696)	\$ (29,291)	\$ (37,107)	\$ (58,134)
Add:				
Restructuring charges	—	1,738	—	2,275
Acquired in-process research and development	—	395	—	395
Non-cash charges for amortization of intangibles	272	167	544	333
Non-cash charges for stock compensation expense	23	41	7	74
Non-GAAP net loss	\$ (9,401)	\$ (26,950)	\$ (36,556)	\$ (55,057)
Non-GAAP net loss per share, basic and diluted	\$ (0.12)	\$ (0.37)	\$ (0.48)	\$ (0.77)
Shares used in computing basic and diluted Non-GAAP net loss per share	76,405	72,011	76,162	71,762

- (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)

	<u>June 30, 2005</u>	<u>December 31, 2004 (1)</u>
	(unaudited)	
Cash, cash equivalents and short-term investments (2)	\$ 202,261	\$ 171,223
Working capital	106,018	100,161
Total assets	325,145	291,340
Stockholders' equity	28,485	50,671

(1) Derived from the audited consolidated financial statements

(2) These amounts also include investments held by Symphony Evolution, Inc. of \$40.0 million as of June 30, 2005 and restricted cash of \$14.8 million and \$16.0 million as of June 30, 2005 and December 31, 2004, respectively.

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