

**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 2, 2006

**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 November 2, 2006, Exelixis, Inc. issued a press release announcing financial results for the quarter ended September 30, 2006. 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 both GAAP and non-GAAP financial measures in the press release to illustrate the company's results from operations. The non-GAAP measures exclude 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, it provides an additional tool to investors to evaluate the company's continuing operations, including its ability to meet future obligations. 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 7.01 Regulation FD Disclosure**

The information set forth in Item 8.01 is incorporated herein by reference.

**Item 8.01 Other Events**

The Company has suspended enrollment of new patients into the XL999 clinical trial program until further data have been collected and analyzed. The Company suspended enrollment after a preliminary review of patient data relating to adverse events for the month of October showed an apparent increase in the rate of serious cardiovascular events compared to the period prior to October. Four out of the 14 patients enrolled in the XL999 clinical program during October experienced serious cardiac adverse events. The Company was notified of the first of these on October 12. The majority of cardiac adverse events seen in the total patient population of the XL999 program to date improved following discontinuation. The events included reductions in left ventricular ejection fraction and ECG changes. Three of the four patients were in the trial for AML and one was in an ovarian cancer trial. Patients with AML often are treated with anthracyclines, which are cardiotoxic and may make patients more susceptible to subsequent cardiac events. However, at this time, the Company has not completed its review of the patient histories, and the absolute numbers are small, so no definite conclusions can be drawn. The Company is in the process of collecting and reviewing data. Patients currently enrolled in the trial continue to receive treatment. The XL999 clinical program consists of six separate trials in colon, non-small cell lung and ovarian cancers, renal cell carcinoma, multiple myeloma, and acute myelogenous leukemia.

A copy of the Company's press release relating to these events is attached hereto as Exhibit 99.2.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

- |              |  |
|--------------|--|
| Exhibit 99.1 | Financial Press release issued November 2, 2006. |
| 99.2         | Press release issued November 2, 2006.           |

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 2, 2006

Exelixis, Inc.

/s/ Christoph Pereira

Christoph Pereira

Vice President, Legal Affairs and Secretary

EXHIBIT LIST

<u>Exhibit No.</u>	<u>Description</u>
99.1	Financial results press release issued November 2, 2006.
99.2	Press release issued November 2, 2006.



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### EXELIXIS ANNOUNCES THIRD QUARTER 2006 FINANCIAL RESULTS

SOUTH SAN FRANCISCO, Calif. – November 2, 2006 - Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the quarter ended September 30, 2006.

**Net loss** under generally accepted accounting principles (GAAP) for the quarter ended September 30, 2006 was \$25.2 million, or \$0.30 per share, compared to \$22.8 million, or \$0.29 per share, for the comparable period in 2005. Non-GAAP net loss for the third quarter was \$20.9 million, or \$0.25 per share, compared to \$22.5 million, or \$0.28 per share for the comparable period in 2005. Non-GAAP net loss for the quarter ended September 30, 2006 excludes stock-based compensation expense of \$4.1 million and amortization of intangibles of \$0.2 million. A reconciliation of GAAP net loss to non-GAAP net loss for both periods is included at the end of this press release.

**Revenues** for the quarter ended September 30, 2006 were \$23.5 million, compared to \$14.4 million for the comparable period in 2005. The increase in revenues from 2005 to 2006 was primarily due to revenue recognition associated with our new collaboration agreements with Sankyo Company, Bristol-Myers Squibb Company and Wyeth Pharmaceuticals Division. This increase was partially offset by the conclusion of our development activities under the Helsinn Healthcare SA license agreement in January 2006.

**Research and development expenses** for the quarter ended September 30, 2006 were \$46.0 million, compared to \$35.2 million for the comparable period in 2005. The increase from 2005 to 2006 was primarily due to increased development expenses associated with the expansion of our clinical trial activity and the advancement of our compounds through preclinical development as well as employee stock-based compensation expense of \$2.5 million.

**General and administrative expenses** for the quarter ended September 30, 2006 were \$8.8 million, compared to \$6.8 million for the comparable period in 2005. The increase from 2005 to

2006 was primarily due to employee stock-based compensation expense of \$1.5 million and higher personnel-related expenses to support our expanding operations.

**Cash** and cash equivalents, short-term and long-term marketable securities, investments held by Symphony Evolution, Inc. (a consolidated clinical development financing vehicle) and restricted cash and investments totaled \$154.4 million at September 30, 2006, compared to \$210.5 million at December 31, 2005.

### **Business Update**

- We initiated a Phase 2 clinical trial for XL647 in patients with non-small cell lung cancer who have not previously been treated with chemotherapy in August.
- We filed an investigational new drug application (IND) for XL228, a novel anticancer compound designed to inhibit the insulin-like growth factor type-1, Src and Abl tyrosine kinases in August.
- We filed an IND for XL281, a novel anticancer compound designed to potentially inhibit the RAS/RAF/MEK/ERK signaling pathway in October.
- We closed a public equity offering of 11.5 million shares of common stock at a public offering price of \$8.40 per share in October. The aggregate net proceeds of the offering, after payment of underwriting discounts and estimated offering expenses, are approximately \$90.5 million.
- On November 2, the company announced that it suspended enrollment of new patients into the XL999 clinical trial program until further data have been collected and analyzed. Exelixis suspended enrollment after a preliminary review of patient data relating to adverse events for the month of October showed an apparent increase in the rate of serious cardiovascular events compared to the period prior to October.

“We continued to execute on all fronts this quarter - we advanced our clinical development pipeline, our proprietary pre-clinical compounds continued to move forward, and we made substantial progress on a number of business transactions,” said George A. Scangos, Ph.D., president and chief executive officer of Exelixis. “As discussed in our press release issued this morning, we noted an apparent increase in the frequency of cardiovascular events among patients treated with XL999 during October. We are still in the process of collecting and analyzing the data, but in the interim we felt that it is prudent to halt enrollment of new patients in this trial. We will continue to provide drug to patients already enrolled in the trial, and we will provide updates once we have had a chance to analyze the data.”

### **Conference Call and Webcast**

Exelixis' management will discuss the company's third quarter 2006 financial results as well as general business updates during a conference call beginning at 2:00 p.m. PT/ 5:00 p.m. ET today, Thursday, November 2, 2006. To listen to a webcast of the discussion, visit the Event Calendar page under Investors at [www.exelixis.com](http://www.exelixis.com).

### **About Exelixis**

Exelixis, Inc. is a development-stage biotechnology company dedicated to the discovery and development of novel small molecule therapeutics for the treatment of cancer and other serious diseases. The company is leveraging its fully integrated drug discovery platform to fuel the growth of its development pipeline, which is primarily focused on cancer. Currently, Exelixis' broad product pipeline includes investigational compounds in Phase 3 (XL119, exclusively out-licensed to Helsinn Healthcare S.A), Phase 2, and Phase 1 clinical development for cancer and renal disease. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including GlaxoSmithKline, Bristol-Myers Squibb Company, Genentech, Wyeth Pharmaceuticals and Sankyo. 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 Exelixis' clinical development plans. 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 Helsinn Healthcare S.A. to conduct the Phase 3 clinical trial of XL119 sufficient to achieve FDA approval; the ability to complete and initiate trials at the referenced times; the ability to conduct clinical trials sufficient to achieve a positive completion; the ability to file INDs at the referenced times; 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, 2006 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 financial tables-

**EXELIXIS, INC.**  
**CONSOLIDATED STATEMENT OF OPERATIONS DATA**  
(in thousands, except per share data)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
<b>Revenues:</b>				
Contract	\$ 13,347	\$ 10,279	\$ 42,609	\$ 45,323
License	10,193	4,121	26,290	16,261
Total revenues	<u>23,540</u>	<u>14,400</u>	<u>68,899</u>	<u>61,584</u>
<b>Operating expenses:</b>				
Research and development	46,048	35,202	133,344	105,091
General and administrative	8,843	6,819	27,834	20,173
Amortization of intangibles	210	271	722	815
Total operating expenses	<u>55,101</u>	<u>42,292</u>	<u>161,900</u>	<u>126,079</u>
Loss from operations	(31,561)	(27,892)	(93,001)	(64,495)
<b>Other income (expense):</b>				
Interest income	1,892	1,581	5,829	3,555
Interest expense	(1,071)	(1,550)	(3,943)	(4,647)
Other income (expense), net	(3)	—	(29)	190
Total other income (expense)	<u>818</u>	<u>31</u>	<u>1,857</u>	<u>(902)</u>
Loss before noncontrolling interest	(30,743)	(27,861)	(91,144)	(65,397)
Loss attributed to noncontrolling interest	5,546	5,086	14,834	5,515
Net loss	<u>\$ (25,197)</u>	<u>\$ (22,775)</u>	<u>\$ (76,310)</u>	<u>\$ (59,882)</u>
Net loss per share, basic and diluted	<u>\$ (0.30)</u>	<u>\$ (0.29)</u>	<u>\$ (0.91)</u>	<u>\$ (0.77)</u>
Shares used in computing basic and diluted net loss per share	<u>84,178</u>	<u>79,540</u>	<u>83,972</u>	<u>77,288</u>



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
GAAP net loss	\$(25,197)	\$(22,775)	\$(76,310)	\$(59,882)
Stock-based compensation expense	4,076	29	13,155	35
Non-cash charges for amortization of intangibles	210	271	722	815
Non-GAAP net loss	<u>\$(20,911)</u>	<u>\$(22,475)</u>	<u>\$(62,433)</u>	<u>\$(59,032)</u>
Non-GAAP net loss per share, basic and diluted	<u>\$ (0.25)</u>	<u>\$ (0.28)</u>	<u>\$ (0.74)</u>	<u>\$ (0.76)</u>
Shares used in computing basic and diluted Non-GAAP net loss per share	<u>84,178</u>	<u>79,540</u>	<u>83,972</u>	<u>77,288</u>

<sup>(1)</sup> These non-GAAP amounts are intended to illustrate the company's results from operations excluding certain non-cash charges, such as: (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 because, in management's view, it provides an additional tool to investors to evaluate the company's continuing operations, including its ability to meet future obligations. 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>September 30,</u> <u>2006</u>	<u>December 31,</u> <u>2005 <sup>(1)</sup></u>
Cash and cash equivalents and short-term and long-term marketable securities <sup>(2)</sup>	\$ 154,394	\$ 210,499
Working capital	\$ 60,087	\$ 86,463
Total assets	\$ 270,657	\$ 332,712
Stockholders' equity (deficit)	\$ (19,598)	\$ 33,543

<sup>(1)</sup> Derived from the audited consolidated financial statements

<sup>(2)</sup> These amounts include investments held by Symphony Evolution, Inc. of \$59.7 million and \$34.0 million and restricted cash and investments of \$11.2 million and \$12.7 million as of September 30, 2006 and December 31, 2005, respectively.

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**EXELIXIS SUSPENDS ENROLLMENT OF NEW PATIENTS IN XL999  
PHASE II CLINICAL TRIAL PROGRAM**

SOUTH SAN FRANCISCO, Calif. - November 2, 2006 - Exelixis, Inc. (Nasdaq: EXEL) today announced that it has suspended enrollment of new patients in the XL999 clinical trial program until further data have been collected and analyzed. The company currently anticipates that it will incur a delay in the clinical program for XL999 of between two weeks and three months. Exelixis suspended enrollment after a preliminary review of patient data relating to cardiovascular adverse events for the month of October. Through the end of September, 117 patients had been dosed with XL999, of whom 12 (10.3%) experienced serious adverse cardiovascular events. However, 4 of the 14 patients enrolled during October also experienced such events, which raised a concern with the company's internal safety monitoring committee. The company therefore decided to suspend enrollment of new patients pending further review of the data. Because 115 of the 131 subjects enrolled in the XL999 clinical program to date have received repeated doses of XL999 (every week or every other week) ranging from 2 doses (2 weeks) to 53 doses (approximately 2 years) with no reported cardiac toxicities, the company has elected to allow patients already enrolled to continue to receive XL999.

"The apparent increase in the frequency of cardiovascular events during October concerns us," said George A. Scangos, PhD, president and chief executive officer of Exelixis. "These are recent observations, and we are in the process of collecting and analyzing all of the relevant primary data. Our primary responsibility is the safety of the patients in the trial, and so we are suspending the enrollment of new patients until we have had a chance to analyze the data. Since all but one of the events occurred on first administration of XL999, we are continuing to treat those patients presently enrolled in the trial. We will of course keep you informed as we go forward analyzing the data."

**Conference Call and Webcast**

Exelixis' management will discuss recent developments involving the XL999 clinical trial program and the company's third quarter 2006 financial results as well as general business updates during a conference call beginning at 2:00 p.m. PT/ 5:00 p.m. ET today, Thursday, November 2, 2006. To listen to a webcast of the discussion, visit the Event Calendar page under Investors at [www.exelixis.com](http://www.exelixis.com).

## **About Exelixis**

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*This press release contains forward-looking statements, including, without limitation, statements related to the anticipated two-week to three-month delay with respect to the clinical program for XL999 and the general clinical development plans for XL999. 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 to resume enrollment in the XL999 trial in a timely manner; the potential failure of product candidates to demonstrate safety and efficacy in clinical testing, which could prevent or significantly delay regulatory approval; negative or inconclusive clinical trial results may require Exelixis to conduct further testing, to modify clinical trial protocols or to abandon trials; patient enrollment in the company's clinical trials may be lower than anticipated, resulting in the delay or cancellation of clinical testing; regulators or institutional review boards may not authorize, delay, suspend or terminate clinical trials for various reasons, including their determination that patients are being exposed to unacceptable health risk; the degree of market acceptance of any of the company's products in light of clinical trial results; the company's ability to achieve milestone payments under its collaboration agreements; the ability to conduct clinical trials sufficient to achieve a positive completion; 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, 2006 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.*