

**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, 2006**

ALEXION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

000-27756

(Commission
File Number)

13-3648318

(I.R.S. Employer
Identification No.)

352 Knotter Drive, Cheshire, Connecticut 06410

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (203) 272-2596

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 August 8, 2006, Alexion Pharmaceuticals, Inc. issued a press release relating to its results of operations and financial conditions for the quarter ended June 30, 2006. A copy of the press release is furnished as Exhibit 99.1 to this form 8-K.

The attached press release contains both GAAP and non-GAAP financial measures. The non-GAAP financial measures exclude share-based compensation expenses. Reconciliations between non-GAAP and GAAP financial measures are included in the press release set forth as Exhibit 99.1 furnished to this form 8-K. The Company's management utilizes non-GAAP financial measures to better understand the comparative operating performance of the Company. The non-GAAP financial measures are supplemental to and not a substitute for, measures of financial performance prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP").

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release issued by Alexion Pharmaceuticals, Inc. on August 8, 2006.

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALEXION PHARMACEUTICALS, INC.

Date: August 9, 2006

By: /s/ Thomas I. H. Dubin

Name: Thomas I. H. Dubin

Title: Senior Vice President and General Counsel

Index to Exhibits

Exhibit No.

Description

99.1 Press Release issued by Alexion Pharmaceuticals, Inc. on August 8, 2006.

Alexion Pharmaceuticals Reports Second Quarter 2006 Results
European Medicines Agency Grants Accelerated Assessment for Alexion's
Planned Marketing Authorization Application for Soliris™ (eculizumab) in
Paroxysmal Nocturnal Hemoglobinuria

Cheshire, Conn., August 8, 2006 – Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the second quarter ended June 30, 2006. The Company also announced that the European Medicines Agency (EMA) has accepted the Company's request for evaluation of its anticipated Marketing Authorization Application (MAA) for Soliris™ (eculizumab) in PNH under the Accelerated Assessment procedure. Accelerated Assessment is granted for medicinal products of major therapeutic interest and shortens the timeframe for review by the agency. The Company further announced that it is on track for submission of both its anticipated Biological License Application (BLA) for Soliris™ (eculizumab) in PNH in the United States and its MAA in Europe for Soliris™ (eculizumab) in PNH during the second half of this year.

For the second quarter, Alexion (the "Company") reported revenues of \$0.3 million and a net loss of \$33.2 million, resulting in a basic and diluted loss per share of \$1.06 compared to revenues of \$0.2 million net loss of \$35.1 million and basic and diluted loss per share of \$1.25 for the same period last year.

Total reported operating expenses for the second quarter were \$34.9 million compared to \$34.9 million for the same period last year. Due to changes in GAAP for share-based compensation, operating expenses for the three months reported include \$3.7 million of share-based compensation expense compared to \$287,000 in the same period last year. Research and development expenses for the second quarter ended June 30, 2006 were \$23.5 million compared to \$29.2 million for the same period last year. General and administrative expenses were \$11.4 million for the second quarter ended June 30, 2006, compared to \$5.6 million for the same period last year.

The Company posted investment income for the second quarter ended June 30, 2006 of \$2.0 million compared to \$1.4 million for the same period last year, reflecting higher market interest rates. Interest expense was \$0.7 million compared to \$1.9 million for the same period last year. The decrease in interest expense is attributable to the write off of deferred financing costs from the convertible subordinated notes, which were repaid in March 2005.

Adjusted to exclude share-based compensation expenses, total operating expenses for the second quarter ended June 30, 2006 were \$31.2 million (non-GAAP, due to the adjustment) compared to \$34.6 million in the same period last year. Adjusted to exclude share-based compensation expenses, the Company's research and development expenses for the second quarter ended June 30, 2006 was \$21.3 million, (non-GAAP, due to the adjustment) compared to \$29.2 million for the same period last year. The decrease in research and development expenses resulted primarily from lower spending related to the pexelizumab programs, partially offset by higher payroll and benefits costs to support our research and development activities as well as the SHEPHERD and E05-001 PNH extension clinical study costs. Adjusted to exclude share-based compensation expenses, the Company's general and administrative expenses were \$9.9 million, (non-GAAP, due to the adjustment) for the second quarter ended June 30, 2006 compared to \$5.3 million for the same period last year. The increase resulted principally from increased staff dedicated to commercial development activities and higher professional fees principally for commercial, patent, and technology activities.

The Company incurred a non-GAAP net loss for the second quarter ended June 30, 2006 of \$29.5 million, or \$0.94 per common share, versus a net loss of \$34.8 million, or \$1.26 per common share, respectively, for the same period last year.

As of June 30, 2006, Alexion had approximately \$165.0 million in cash, cash equivalents, and marketable securities as compared to \$212.5 million at December 31, 2005. Non-GAAP Financial Information—Non-GAAP financial information is utilized by Alexion's management to better understand the comparative operating performance of the Company. A reconciliation between non-GAAP financial measures and GAAP financial measures is included in the table accompanying this press release after the unaudited Selected Financial Data. Regulatory Update – Soliris™ (eculizumab)

The Company announced that its plans remain on target to submit marketing applications for Soliris™ (eculizumab) in both the US and Europe in the second half of this year. The Company currently anticipates that both the U.S. and

European marketing applications will be primarily based upon the currently available Soliris™ (eculizumab) PNH clinical study data, including the Phase 3 TRIUMPH pivotal efficacy study and the six month interim analysis of the Phase 3 SHEPHERD study. The Company has received notification from the EMEA that the EMEA has granted the Company's request for evaluation of its anticipated MAA for Soliris™ (eculizumab) in PNH under the Accelerated Assessment procedure. According to published guidelines from the EMEA on the Accelerated Assessment procedure, request for evaluation of the procedure may be accepted if the medicinal product is of major public health interest particularly from the point of view of therapeutic innovation. The Accelerated Assessment procedure provides that the review part of the overall MAA procedure timeline is shortened (150 days versus 210 days). To the Company's knowledge, this is the first non-HIV or non-oncology drug to be accepted for the Accelerated Assessment review process in Europe.

"We continue to focus our attention on Soliris for the orphan blood disorder Paroxysmal Nocturnal Hemoglobinuria (PNH)," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "On the clinical front, the quarter was marked by positive six-month interim safety and efficacy data from SHEPHERD, our Phase 3 safety trial of Soliris in a broader population of PNH patients. On the regulatory front, we are very pleased to announce that our European marketing application will be reviewed under the European accelerated assessment procedure, potentially accelerating our timing to market in Europe. As we have previously described, Alexion anticipates filing for marketing approval of Soliris for PNH in both the United States and in Europe by the end of this year."

Financial Guidance

For Alexion's 2006 calendar year, the net loss for the year ending December 31, 2006, is now expected to be in a range of \$115 to \$125 million. This projected net loss excludes the expense of employee stock options and other stock based compensation expense.

This increased net loss results from stepped up pre-marketing development activities driven by accelerated projected commercial timelines in the United States and Europe, costs related to expensing of pre-commercial launch manufacturing, increased BLA (U.S.) and MAA (Europe) preparation related expenses, initiation of the multi-center EXPLORE clinical diagnostic study to examine the frequency of PNH in patients with aplastic anemia (AA), myelodysplastic syndrome (MDS), and other bone marrow failure disorders, and acquisition and development of the Company's Rhode Island biopharmaceutical manufacturing facility. Due to these variables, net losses might result that are above or below the Company's guidance. In addition, this guidance excludes any impact of potential business development activities that may occur during the year. The financial results and the amount of loss may vary depending upon many factors, including the timing of regulatory filings for Soliris™ (eculizumab), pre-commercial development and roll out in Europe and elsewhere.

Within this revised projected net loss, R&D costs in 2006 are expected to be approximately \$70 to \$75 million, including \$15-\$17 million in costs related to pexelizumab. The Company does not currently expect these pexelizumab expenses to recur after fiscal 2006. The increase in R&D costs compared to our previous guidance of \$65 to \$70 million is mainly driven by pre-marketing development costs. General and administrative costs, including U.S. commercial and European organizations, are projected to increase substantially in 2006 compared to previous reporting years due to the earlier than planned ramp up of pre-launch commercialization activities in the U.S. and Europe.

"Our commercial planning is well on its way for Soliris™," said David Keiser, President and Chief Operating Officer of Alexion. "In particular, as recently announced, we have enhanced our management ranks with the hiring of David Hallal as Vice President, U.S. Commercial Operations, and we have secured a manufacturing plant in Rhode Island for the long-term production of Soliris™. All of these events reflect that Alexion is actively engaged in the preparation for a successful launch of Soliris™ in the United States and Europe at the soonest date possible."

• Conference Call/Web cast Information

Alexion will host a conference call/webcast to discuss matters mentioned in this release. The call is scheduled for today, August 8th at 9:00 a.m., Eastern Time. To participate in this call, dial 913-981-5558, confirmation code 5486962, shortly before 9:00 a.m., Eastern Time. A replay of the call will be available for a limited period following the call, beginning at 12:00 p.m. today. The replay number is 719-457-0820, confirmation code 5486962. The audio webcast can be accessed at: www.alexionpharm.com.

About Alexion

Alexion Pharmaceuticals is a biotechnology company working to develop and deliver life-changing drug therapies for patients with serious and life-threatening medical conditions. Alexion is engaged in the discovery and

development of therapeutic products aimed at treating patients with a wide array of severe disease states, including hematologic diseases, cancer, and autoimmune disorders. Alexion's lead product candidate, Soliris™ (eculizumab), is currently undergoing evaluation in several clinical development programs, including for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). Under the Special Protocol Assessment (SPA) process, the FDA has agreed to the design of protocols for the two phase III trials of Soliris™ (eculizumab) in PNH patients that could, if successful, serve as the primary basis of review for approval of a licensing application for eculizumab in the PNH indication. In January, 2006, Alexion announced that the first of those two PNH trials, the TRIUMPH study, achieved its co-primary endpoints with statistical significance. In June 2006, Alexion announced that interim results from the second of those two PNH trials, the SHEPHERD study, showed that eculizumab appeared to be safe and well tolerated and that all primary and secondary efficacy endpoints were achieved with statistical significance. Alexion is engaged in discovering and developing a pipeline of additional antibody therapeutics targeting severe unmet medical needs. This press release and further information about Alexion Pharmaceuticals, Inc. can be found at: <http://www.alexionpharm.com>.

This news release contains forward-looking statements, including statements related to clinical trial results, timing of announcement of clinical trial results, commercial potential of Alexion's drug candidates, the progression of Alexion's drug candidates towards commercial sales and timing for submission of, and decisions with respect to, marketing applications for Soliris™ (eculizumab). Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including delays in completion of ongoing clinical trials, delays in completion of analysis of clinical trial results, timing and evaluation by regulatory agencies of the results of these and other clinical trials, the results of pre-clinical or clinical studies (including termination or delay in clinical programs), the need for additional research and testing, decision of the FDA or other regulatory authorities not to approve (or to materially limit) marketing of Alexion's drug candidates, delays in arranging satisfactory manufacturing capability, inability to acquire funding on timely and satisfactory terms, delays in developing or adverse changes in commercial relationships, the possibility that results of earlier clinical trials are not predictive of safety and efficacy results in later clinical trials, the risk that third parties won't agree to license any necessary intellectual property to us on reasonable terms, and a variety of other risks set forth from time to time in Alexion's filings with the Securities and Exchange Commission, including but not limited to the risks discussed in Alexion's Transition Report on Form 10-K/T for the five-month transition period ended December 31, 2005 and in our other filings with the Securities and Exchange Commission. Alexion does not intend to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when a duty arises under law.

(Tables Follow)

ALEXION PHARMACEUTICALS, INC.**Selected Financial Data**

(Unaudited)

(Amounts in thousands, except per share amounts)

Consolidated Statements of Operations Data:

	Three Months Ended June 30		Six Months Ended June 30	
	2006	2005	2006	2005
Revenues	\$ 339	\$ 167	\$ 1,107	\$ 732
Operating expenses:				
Research and development	23,462	29,239	44,676	49,516
General and administrative	11,421	5,632	19,567	10,401
Total operating expenses	34,883	34,871	64,243	59,917
Operating loss	(34,544)	(34,704)	(63,136)	(59,185)
Other income (expense):				
Investment income	1,976	1,392	3,939	3,078
Interest expense	(687)	(1,910)	(1,375)	(2,741)
Loss on early extinguishment of debt	—	—	—	(3,184)
Total other income (expense)	1,289	(518)	2,564	(2,847)
State tax benefit	90	112	180	341
Net Loss	\$ (33,165)	\$ (35,110)	\$ (60,392)	\$ (61,691)
Basic and diluted net loss per common share	\$ (1.06)	\$ (1.25)	\$ (1.94)	\$ (2.21)
Shares used in computing net loss per common share	31,203	27,988	31,098	27,957

Consolidated Balance Sheet Data:

	As of	
	June 30, 2006	December 31, 2005
Cash, cash equivalents, and marketable securities	\$ 165,033	\$ 212,456
Total assets	214,581	262,711
Total stockholders' equity	34,336	81,890

The following table represents a reconciliation of GAAP to non-GAAP financial information related to share-based compensation for the six month periods ended June 30, 2006 and 2005:

	<u>Reported Amounts</u>	<u>Share-Based Compensation Adjustment</u>	<u>Excluding Share-Based Compensation</u>
<u>Six Months Ended June 30, 2006</u>			
Research and development	\$ 44,676	\$ (4,080)	\$ 40,596
General and administrative	19,567	(2,761)	16,806
Operating expenses	64,243	(6,841)	57,402
Operating loss	(63,136)	6,841	(56,295)
Net loss	(60,392)	6,841	(53,551)
Basic and diluted net loss per share	\$ (1.94)	\$ 0.22	\$ (1.72)
<u>Six Months Ended June 30, 2005</u>			
Research and development	\$ 49,516	\$ —	\$ 49,516
General and administrative	\$ 10,401	(287)	10,114
Operating expenses	\$ 59,917	(287)	59,630
Operating loss	(59,185)	287	(58,898)
Net loss	(61,691)	287	(61,404)
Basic and diluted net loss per share	\$ (2.21)	—	\$ (2.21)
<u>Three Months Ended June 30, 2006</u>			
Research and development	\$ 23,462	\$ (2,200)	\$ 21,262
General and administrative	\$ 11,421	\$ (1,475)	9,946
Operating expenses	\$ 34,883	\$ (3,675)	31,208
Operating loss	\$(34,544)	\$ 3,675	(30,869)
Net loss	\$(33,165)	\$ 3,675	(29,490)
Basic and diluted net loss per share	\$ (1.06)	\$ 0.12	\$ (0.94)
<u>Three Months Ended June 30, 2005</u>			
Research and development	\$ 29,239	\$ —	\$ 29,239
General and administrative	\$ 5,632	(287)	5,345
Operating expenses	\$ 34,871	(287)	34,584
Operating loss	(34,704)	287	(34,417)
Net loss	(35,110)	287	(34,823)
Basic and diluted net loss per share	\$ (1.26)	—	\$ (1.26)

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