ALEXION PHARMACEUTICALS INC
Form 10-Q
May 10, 2007
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FORM 10-Q

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

x Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended March 31, 2007

OR

¨ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____ to _____

Commission file number: 0-27756

Alexion Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**13-3648318**
(State or other jurisdiction of Incorporation or organization)	**(I.R.S. Employer Identification No.)**

352 Knotter Drive, Cheshire, Connecticut 06410

(Address of principal executive offices) (Zip Code)

203-272-2596

(Registrant s telephone number, including area code)

N/A

(Former name, former address, and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨

Indicate by check mark whether the registrant is a shell company (as defined in rule 12b-2 of the Act)

Yes ¨ No x

Common Stock, $0.0001 par value	**36,417,203**
Class	**Outstanding at May 4, 2007**

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ALEXION PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In Thousands, except per share amounts)

(Unaudited)

	March 31, 2007	December 31, 2006
Assets		
Current Assets		
Cash and cash equivalents	$ 136,992	$ 166,826
Marketable securities	46,695	49,728
Trade accounts receivable, net of allowance of $0 at March 31, 2007	1,173	
Inventories	3,113	2,314
Prepaid expenses and other current assets	5,067	3,973
Prepaid manufacturing costs	13,935	
Total Current Assets	206,975	222,841
Property, plant and equipment, net	54,592	39,135
Goodwill, net	19,954	19,954
Prepaid manufacturing costs		13,935
Restricted cash	22,248	33,594
Other assets	3,968	4,078
Total Assets	$ 307,737	$ 333,537
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 8,761	$ 10,939
Accrued expenses	13,705	16,228
Deferred revenue		588
Current portion of obligations under capital lease	68	67
Total Current Liabilities	22,534	27,822
Obligations under capital lease	264	283
Deferred revenue, less current portion		4,755
Mortgage loan	26,000	26,000
Convertible notes	150,000	150,000
Total Liabilities	198,798	208,860
Stockholders' Equity		
Preferred stock, $.0001 par value; 5,000 shares authorized, no shares issued or outstanding		
Common Stock, $.0001 par value; 145,000 shares authorized; 36,302 and 35,568 shares issued at March 31, 2007 and December 31, 2006, respectively	4	4
Additional paid-in capital	780,083	763,691
Treasury Stock, at cost, 57 shares at March 31, 2007 and December 31, 2006, respectively	(1,260)	(1,260)
Accumulated other comprehensive loss	(205)	(177)
Accumulated deficit	(669,683)	(637,581)

Total Stockholders' Equity	108,939	124,677
Total Liabilities and Stockholders' Equity	$ 307,737	$ 333,537

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ALEXION PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

and Comprehensive Loss

(In Thousands, except per share amounts)

(Unaudited)

	Three months ended March 31,	
	2007	**2006**
Revenues		
Product revenues, net	$ 974	$
Contract research revenues	5,343	768
Total revenues, net	6,317	768
Costs and Expenses		
Cost of product revenues	85	
Research and development	21,219	21,214
General and administrative	19,838	8,146
Total costs and expenses	41,142	29,360
Operating loss	(34,825)	(28,592)
Other Income and Expense		
Investment income	2,769	1,963
Interest expense	(700)	(688)
Other expense	(27)	
Loss before state tax benefit	(32,783)	(27,317)
State Tax Benefit	90	90
Net Loss	$ (32,693)	$ (27,227)
Other Comprehensive Income/Loss		
Foreign currency translation	(52)	(27)
Unrealized gains on marketable securities	24	8
Comprehensive Loss	$ (32,721)	$ (27,246)
Net loss per share basic and diluted	$ (0.92)	$ (0.88)
Shares used in computing basic and diluted net loss per common share	35,361	30,991

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ALEXION PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(In Thousands)

(Unaudited)

	Three months ended March 31,	
	2007	**2006**
Cash flows from operating activities:		
Net loss	$ (32,693)	$ (27,227)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	873	881
Share-based compensation expense	4,980	3,166
Changes in operating assets and liabilities		
Accounts receivable	(1,173)	
Inventories	(799)	
Prepaid expenses and other assets	(1,094)	1,167
Accounts payable	(2,178)	(2,545)
Accrued expenses	(1,933)	(3,211)
Deferred revenue	(5,343)	(326)
Net cash used by operating activities	(39,360)	(28,095)
Cash flows from investing activities:		
Purchase of marketable securities	(43,157)	(231,085)
Proceeds from maturity or sale of marketable securities	46,214	222,597
Purchase of property, plant and equipment	(16,219)	(477)
Release of restricted cash	11,346	
Net cash used by investing activities	(1,816)	(8,965)
Cash flows from financing activities:		
Payment on capital leases	(18)	
Net proceeds from issuance of common stock	11,412	5,405
Net cash provided by financing activities	11,394	5,405
Effect of exchange rate changes	(52)	(27)
Net change in cash and cash equivalents	(29,834)	(31,682)
Cash and cash equivalents at beginning of period	166,826	43,629
Cash and cash equivalents at end of period	$ 136,992	$ 11,947

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ALEXION PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

(in thousands, except share and per share amounts)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. These accounting principles were applied on a basis consistent with those of the consolidated financial statements contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2006. In our opinion, the accompanying unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to state fairly our financial position as of March 31, 2007, the results of our operations for the three months ended March 31, 2007 and 2006, and our cash flows for the three months ended March 31, 2007 and 2006. The December 31, 2006 condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2006 included in our Annual Report on Form 10-K.

The financial position and results of operations of our foreign subsidiaries are measured using the local currency as the functional currency. Assets and liabilities of each subsidiary have been translated at end of period exchange rates, and related revenues and expenses have been translated at weighted average exchange rates with the resulting translation gain or loss recorded in accumulated other comprehensive income. Transaction gains and losses are included in other expense.

The results of operations for the three months ended March 31, 2007 are not necessarily indicative of the results to be expected for the full year.

During the three month period ended March 31, 2007, we established three new entities to support our planned growth and preparation for commercialization. Alexion Pharma Italy Srl, a simplified joint stock company, is registered under the laws of Italy and is wholly owned by Alexion Holding B.V. Alexion Pharma Germany GmbH, a simplified joint stock company, is registered under the laws of Germany and is wholly owned by Alexion Holding B.V. Alexion Pharma Spain S.L., a simplified joint stock company, is registered under the laws of Spain and is wholly owned by Alexion Holding B.V. There were no material transactions that occurred in the newly formed entities during the three month period ending March 31, 2007.

2. Revenue

Principal sources of revenue are product sales and contract research revenues from research and development support payments. We have applied the following principles in recognizing revenue:

Product Revenues, net

We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured and we have no further performance obligations. All revenues from product sales are recorded net of applicable provisions for distribution fees. The distribution fee represents handling fees and third-party carrier costs.

In Europe, we have entered into an agreement with a distributor to distribute Soliris (eculizumab) under pre-approval programs existing in certain European countries. As commercial approval, or marketing authorization, for Soliris had not been granted by the European Medicines Agency, or EMEA, in the three months ending March 31, 2007, all sales in Europe to date have been made on a named-patient or pre-approval basis. For revenue recognition purposes, our distributor is considered the final customer. For the three months ended March 31, 2007, we realized net sales of Soliris totaling $974.

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(in thousands, except share and per share amounts)

Distributor Fees

We have adopted the provisions set forth in EITF Issue No. 01-09, Accounting for Consideration given by a Vendor to a Customer (including a Reseller of a Vendor s Products) , which specifies that cash consideration (including a sales incentive) given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor s products or services and, therefore, should be characterized as a reduction of revenue. That presumption is overcome and the consideration should be characterized as a cost incurred if, and to the extent that, both of the following conditions are met: (1) the vendor receives, or will receive, an identifiable benefit (goods or services) in exchange for the consideration; and (2) the vendor can reasonably estimate the fair value of the benefit received.

We record fees paid to our distributors for their logistical, distribution and similar services as a reduction of product revenue.

Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in our income statement, in that taxes billed to customers are not included as a component of net product sales, as per Emerging Issues Task Force (EITF) Issue No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement* .

Contract Research Revenue

Procter & Gamble Pharmaceuticals Collaboration

In January 1999, we and Procter & Gamble Pharmaceuticals, or P&G, entered into an exclusive collaboration to develop and commercialize pexelizumab. We granted P&G an exclusive license to our intellectual property related to pexelizumab, with the right to sublicense.

In December 2001, we and P&G entered into a binding memorandum of understanding, or MOU, pursuant to which the January 1999 collaboration was revised. We and P&G agreed, as per the MOU, to share concurrently 50% of the ongoing U.S. pre-production and development manufacturing costs for pexelizumab as well as any acute myocardial infarction or coronary artery bypass graft Phase III clinical trial costs.

We had recognized a non-refundable up-front license fee of $10,000 related to the P&G collaboration as revenue over 17 years, representing the average of the remaining patent lives of the underlying technologies at the time the payment was received in fiscal 1999. We recorded this payment as deferred revenue.

During 2006, we completed a final Phase III trial of pexelizumab. After reviewing results from that trial, we along with P&G, determined not to pursue further development of pexelizumab. Effective March 30, 2007, we and P&G mutually agreed to terminate the collaboration agreement. As we have no further obligations under the agreement, the remaining portion of the $10,000 non-refundable up-front license fee, or $5,343, was recognized as revenue.

3. Inventories

Inventories are stated at the lower of cost or estimated realizable value. Cost is computed using standard cost, which approximates actual cost, on a first-in, first-out, or FIFO, basis. We periodically analyze our inventory levels, and write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory in excess of expected sales requirements to cost of product revenues. Expired inventory is disposed of and the related costs are written off to cost of product revenues. Additionally, we may be required to expense previously capitalized inventory that fails to meet commercial sale specifications.

At March 31, 2007, our inventory consists entirely of finished goods. We submitted a Marketing Authorization Application, or MAA, in the European Union and a Biologics License Application, or BLA, in the United States in September 2006. In March 2007, we received approval of

Soliris from the U.S. Food and Drug Administration, or FDA. We have launched Soliris in the U.S., and anticipate European Union approval in 2007. As of March 31, 2007 the carrying value of our inventory did not include any costs associated with products that have not yet received regulatory approval.

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Notes to Condensed Consolidated Financial Statements

(in thousands, except share and per share amounts)

Soliris currently has an estimated shelf life of up to 42 months and, based on our sales forecasts, we expect the carrying value of the Soliris inventory, and prepaid manufacturing costs to be fully realized.

Our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. Periodically, certain batches or units of product may no longer meet quality specifications or may expire. In certain instances, we may write-down, to net realizable value, commercial inventory that did not meet quality specifications or that became obsolete due to dating expiration. Based on this review, there are no write-downs against the value of our inventory, as of March 31, 2007.

4. Cost of Product Revenues

Our policy is to capitalize inventory costs associated with our products subsequent to the filing of a BLA, but prior to regulatory approval, when, based on management s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized, which is customary in our industry. At the point of sale, we recognize costs of product revenues which include the cost of inventory sold and estimated royalties payable to third parties. Product sold during the three months ended March 31, 2007 under the named-patient program was previously expensed prior to submission of our BLA, and therefore is not included in the cost of product revenues during this period. For the three months ended March 31, 2007, our cost of product revenues consists entirely of estimated royalties owed to third parties related to the sale and commercial manufacture of Soliris.

5. Exit Activities

In December 2006, we initiated an integration plan at our subsidiary, Alexion Antibody Technologies, Inc., to consolidate certain functions and operations, including the termination of all Alexion Antibody personnel, closure of Alexion Antibody facilities, and impairment of equipment in that facility. These costs have been recognized as liabilities and were included in general and administrative expenses for the year ended December 31, 2006. The following table summarizes the liabilities established for exit activities as of December 31, 2006 and subsequent cash payments and revision of estimates made during the three month period ended March 31, 2007:

	Employee Related Benefits	Facility Lease Costs	Other Exit Activities	Total Exit Activities
Balance at December 31, 2006	$ 5,358	$ 1,147	$ 539	7,044
Revision of estimate	93			93
Payments in 2007	(5,379)	(175)		(5,554)
Balance at March 31, 2007	$ 73	$ 972	$ 539	$ 1,584

6. Accounting for Share-Based Compensation

A summary of the status of our stock option plans at March 31, 2007 and changes during the three months then ended is presented in the table and narrative below:

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	Options	Weighted-Average Exercise Price
Options outstanding at December 31, 2006	5,372,463	$ 26.67
Options granted	612,000	40.30
Options cancelled	(80,040)	37.77
Options exercised	(521,600)	21.88
Options outstanding at March 31, 2007	5,382,823	28.52
Options exercisable at March 31, 2007	3,037,038	$ 26.72

During the three month period ended March 31, 2007, we recognized compensation expense of $3,981 for stock options and $999 for restricted stock. The expenses were charged to our condensed consolidated statement of operations. Due to our net operating loss position, a windfall tax benefit was not recognized during the period.

A summary of the status of our non-vested restricted stock as of March 31, 2007, and changes during the three months then ended are as follows:

	Restricted Stock
Nonvested at December 31, 2006	324,289
Issued	223,475
Vested	(54,000)
Cancelled	(11,625)
Nonvested at March 31, 2007	482,139

7. Net Loss Per Common Share

Basic net loss per common share is computed by dividing the net loss by the weighted average shares of common stock outstanding during the respective period. Diluted net loss per common share assumes, in addition to the above, the dilutive effect of other potential common shares outstanding during the period. Other potential common shares represent dilutive stock options, unvested restricted stock, and convertible debt. These outstanding stock options, convertible debt, and unvested restricted stock entitled holders to acquire 10,633,672 and 10,211,818 shares of common stock at March 31, 2007 and 2006, respectively. There is no difference in basic and diluted net loss per common share for the three months ended March 31, 2007 and 2006, respectively, as the effect of other potential common shares is anti-dilutive.

8. Capital Stock

During the three month periods ended March 31, 2007 and 2006, we issued 521,600 and 388,425 shares of common stock, respectively, with proceeds of $11,412 and $5,405, respectively, upon the exercise of outstanding stock options.

9. Commitments and Contingencies

We enter into agreements that contain indemnification provisions under our agreements with other companies in our ordinary course of business, typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, we generally indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to our products, or otherwise in connection with the use or testing of our product candidates. The term of these indemnification agreements is generally perpetual. The potential amount of future payments we could be required to make under these indemnification agreements is unlimited. We have not incurred material costs to defend lawsuits or settle claims related to these

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(in thousands, except share and per share amounts)

indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements as of March 31, 2007.

On March 15, 2007, Oklahoma Medical Research Foundation, or OMRF, filed a civil action against Alexion in the U.S. District Court for the Northern District of Oklahoma. OMRF claims, among other things, (i) breach of contract by Alexion under a license agreement entered into by Alexion and OMRF in 1992, relating to intellectual property owned or controlled by OMRF and (ii) willful infringement by Alexion of an OMRF patent. OMRF seeks, among other things, declaratory judgment, judicial accounting, and actual, compensatory, consequential and punitive damages, plus attorney s fees. Alexion does not believe that it infringes any valid patent owned by OMRF in connection with the commercialization of Soliris. Alexion believes it has good and valid defenses and intends to vigorously defend the case.

On March 16, 2007, PDL BioPharma, Inc., or PDL, filed a civil action against Alexion in the U.S. District Court for the District of Delaware. PDL claims willful infringement by Alexion of PDL patents due to sales of Soliris. PDL seeks unspecified damages, but no less than a reasonable royalty, plus attorney s fees. Alexion does not believe that it infringes any valid patent owned by PDL in connection with the commercialization of Soliris. Alexion believes it has good and valid defenses and intends to vigorously defend the case.

We are unable to reasonably estimate any possible range of loss related to these civil actions due to their uncertain resolution.

10. Income Taxes

We adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), on January 1, 2007. Under FIN 48, a company can recognize the benefit of an income tax position only if it is more likely than not (greater than 50%) that the position is expected to be sustained upon tax examination. As a result of the implementation of FIN 48, we recognized a benefit of $591 to the January 1, 2007 retained earnings balance. In addition, we also decreased our fully valued deferred tax assets by $6,671 as a consequence of implementing FIN 48. The total amount of unrecognized tax benefits as of January 1, 2007, including the cumulative effect of the adoption of FIN 48, is $6,671. None of the amount, if recognized, would affect the effective tax rate due to our full valuation allowance against deferred tax assets. While we believe we have adequately provided for all tax positions, amounts asserted by tax authorities could differ from our estimate.

We and our affiliates file U.S. federal income tax returns, as well as income tax returns in various states and foreign jurisdictions. With limited exceptions, and due to the impact of net operating loss and other credit carry forwards, we may be effectively subject to U.S. federal income tax examinations for periods after 1992. We are subject to examination by state and local tax authorities generally for the period mandated by statute. These states, and the earliest open period include Connecticut (1999), New York (2003), Rhode Island (2006) and California (2003). Our foreign affiliates are not subject to examination by tax authorities for periods before 2005. Subsequent periods may be examined by the relevant tax authorities.

We recognize accrued interest and penalties related to unrecognized taxes as additional tax expense. During the year ended December 31, 2006, and the quarter ended March 31, 2007, we did not recognize any interest and penalties.

In April 2007, the State of New York finalized its review for tax years 2003, 2004, and 2005. The review has resulted in additional tax of approximately $28 which is included in accrued expenses as of March 31, 2007. There are no other ongoing tax reviews as of March 31, 2007.

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(in thousands, except share and per share amounts)

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management s beliefs and certain assumptions made by our management and may include, but are not limited to, statements regarding the potential benefits and commercial potential of Soliris, clinical trial results, the safety and efficacy of Soliris and our product candidates, status of our ongoing clinical trials and prospects for regulatory approval outside of the United States, timing for completion of our ongoing clinical trials, evaluation of our clinical trial results by regulatory agencies outside the United States, the need for additional research and testing, the uncertainties involved in the drug development process, the safety and efficacy of Soliris and our product candidates, our future research and development activities, estimates of the potential markets for Soliris and our product candidates, assessment of competitors and potential competitors, estimates of the capacity of manufacturing and other facilities to support Soliris and our product candidates, the sufficiency of our existing capital resources and projected cash needs, sales and marketing plans, results of pending litigation, assessment of impact of recent accounting pronouncements as well as assumptions relating to the foregoing. Words such as anticipates, expects, intends, plans, believes, s estimates, variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled Risk Factors. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in other reports or documents we file from time to time with the Securities and Exchange Commission.

Business

We are a biotechnology company working to develop and deliver life-changing drug therapies for patients with serious and life-threatening medical conditions. We are engaged in the discovery, development and commercialization of therapeutic products aimed at treating patients with a wide array of severe disease states, including hematologic diseases, cancer, and autoimmune disorders.

In March 2007, the FDA granted marketing approval for our first product, Soliris. Soliris is the first therapy approved for paroxysmal nocturnal hemoglobinuria, or PNH, a rare, disabling and life-threatening blood disorder defined by chronic red blood cell destruction, or hemolysis. In the U.S., Soliris is indicated for the treatment of patients with PNH to reduce hemolysis. We began commercial sale of Soliris in the United States during April 2007. During January 2007, we initiated sales through a named-patient program in Europe, which allows for the sale and distribution of Soliris prior to marketing approval for the treatment of an individual patient based upon physician request.

In September 2006, we filed an MAA with the EMEA, for Soliris for the treatment of PNH; and in August 2006 we announced that the MAA was granted accelerated assessment by the EMEA. Review under the Accelerated Assessment Procedure is provided by the EMEA for medicinal products of major therapeutic interest and shortens the timeframe for review by that agency. The granting of accelerated assessment for our MAA does not ensure or increase the likelihood that our MAA will be approved. In November 2006, we announced that the EMEA had validated the Soliris MAA allowing for commencement of the review process. In April 2007, the Committee for Human Medicinal Products, or CHMP, of the EMEA adopted a positive opinion recommending marketing authorization for Soliris for the treatment of patients with PNH. The CHMP s positive recommendation will be reviewed by the European Commission, which has authority to approve medicines for the European Union.

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(in thousands, except share and per share amounts)

The Company has submitted an application for marketing authorization in Australia for Soliris for the treatment of patients with PNH. Orphan Drug Designation has also been granted to Soliris in Australia, which provides certain regulatory and filing fee advantages.

In addition to our Phase III PNH clinical program with our long term extension study, we are conducting the following activities: (1) the EXPLORE diagnostics trial, (2) a global Patient Registry for PNH patients, and (3) the EMBRACE Expanded Access Trial. We initiated the EXPLORE diagnostics trial in August 2006 to investigate the frequency and clinical characteristics of undiagnosed PNH patients who have been diagnosed with other bone marrow failure diseases such as aplastic anemia and myelodysplasia. The global PNH Patient Registry involves the study of the natural history of PNH. The EMBRACE trial (The Paroxysmal Nocturnal Hemoglobinuria Early Access Treatment Protocol) was initiated in December 2006, to provide eculizumab in the United States to PNH patients prior to obtaining marketing approval. Due to the marketing approval of Soliris in the United States, the EMBRACE trial is being terminated and patients are being transitioned to other sources of supply. Our treatment support services and case managers will help patients enrolled in EMBRACE continue access to Soliris following termination of EMBRACE.

In addition to PNH, we are evaluating other potential indications for Soliris as well as other formulations of eculizumab for additional clinical indications, and we are actively pursuing development of other antibody product candidates in early stages of development. During 2006, we completed a final Phase III trial of another product candidate known as pexelizumab under a license and collaboration agreement with P&G. After reviewing results from that trial, we along with P&G, determined not to pursue further development of pexelizumab for the cardiovascular indications being studied, and in March 2007 we and P&G terminated our license and collaboration agreement. Alexion retains ownership of pexelizumab without further obligations to P&G.

Since September 2005, we have formed a number of wholly-owned subsidiaries to support commercial and regulatory operations throughout the world, including Alexion Europe SAS, our European headquarters in Paris, France. In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the future commercial production of Soliris.

We have incurred operating losses since our inception. As of March 31, 2007, we had an accumulated deficit of approximately $670 million. We expect to incur substantial operating losses for at least the next several quarters due to expenses associated with the launch and commercialization of Soliris in the United States, pre-commercialization activities and anticipated commercialization activities outside of the United States, development of our manufacturing plant in Rhode Island, product research and development, pre-clinical studies and clinical testing, regulatory activities, commercial-scale manufacturing at our third party contractor and at our own manufacturing plant when that site is qualified to manufacture Soliris, and other infrastructure support costs. We may need to obtain additional financing to cover these costs.

In November 2006, we sold 3.45 million shares of our common stock in a registered offering at a price to the public of $43 per share resulting in proceeds of approximately $140,000, net of underwriting discount, fees and other expenses. We intend to use the net proceeds from this offering for general corporate purposes.

Results of Operations

Comparison of the Three Months ended March 31, 2007 to the Three Months ended March 31, 2006

Revenues

Product Revenues, net

We generated net sales of Soliris for the three months ended March 31, 2007 of $974, as a result of our named-patient sales in Europe. There were no sales of Soliris for the three month period ended March 31, 2006.

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(in thousands, except share and per share amounts)

Distributor Fees

We have adopted the provisions set forth in EITF Issue No. 01-09, Accounting for Consideration given by a Vendor to a Customer (including a Reseller of a Vendor s Products) , which specifies that cash consideration (including a sales incentive) given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor s products or services and, therefore, should be characterized as a reduction of revenue. That presumption is overcome and the consideration should be characterized as a cost incurred if, and to the extent that, both of the following conditions are met: (1) the vendor receives, or will receive, an identifiable benefit (goods or services) in exchange for the consideration; and (2) the vendor can reasonably estimate the fair value of the benefit received.

We record fees paid to our distributors for their logistical, distribution and similar services as a reduction of product revenue.

Contract research revenue

	Three months ended March 31,	
	2007	2006
	(amounts in thousands)	
P&G	$ 5,343	$ 147
U.S. government grants		521
Other revenue		100
Total revenues	$ 5,343	$ 768

We recorded contract research revenues of approximately $5,343 and $768 for the three months ended March 31, 2007 and 2006, respectively. Contract research revenues reflect the amortization of deferred revenue resulting from cash received from P&G under our collaboration for the development and commercialization of pexelizumab, U.S. government funded research grant revenue related to our research programs, and a nonrefundable fee for exclusive access to our xenotransplantation technologies, a program that was terminated in October 2003. During 2006, we completed a final Phase III trial of pexelizumab. After reviewing results from that trial, we along with P&G, determined not to pursue further development of pexelizumab. Effective March 30, 2007, we mutually agreed to terminate the collaboration agreement. As we have no further obligations under the agreement, the remaining portion of the $10,000 non-refundable up-front license fee, or $5,343, was recognized as revenue.

Cost of Product Revenues

Our policy is to capitalize inventory costs associated with our products, subsequent to the filing of a BLA, but prior to regulatory approval, when, based on management s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized, which is customary in our industry. At the point of sale, we recognize costs of product revenues which include the cost of inventory sold and estimated royalties payable to third parties. Product sold during the three months ended March 31, 2007 under the named-patient program was previously expensed prior to submission of our BLA, and therefore is not included in the cost of product revenues during this period. For the three months ended March 31, 2007, our cost of product revenues consists entirely of estimated royalties owed to third parties related to the sale and commercial manufacture of Soliris. Accordingly, our current product margins are higher until our current inventory of previously expensed product is used. We expect our margins to decrease as we begin sales of product that has been capitalized to inventory.

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Research and Development

The following table provides information regarding the change in research and development expenses during the periods presented:

	Three months ended March 31,		Increase/ (Decrease)
	2007	2006	% Change
	(amounts in thousands, except percentage data)		
Clinical development	$ 7,206	$ 10,210	-29%
Manufacturing and development	779	843	-8%
Product development	7,985	11,053	
Payroll and benefits	8,746	7,316	20%
Operating and occupancy	1,085	1,278	-15%
Discovery research	2,878	956	201%
Depreciation and amortization	526	611	-14%
Total research and development expense	$ 21,219	$ 21,214	0%

Research and development expenses increased approximately $5 for the three months ended March 31, 2007, as compared to the same period in 2006, respectively, primarily due to:

decrease in clinical development expenses of $3,004 for the three month periods ended March 31, 2007, due to the significant decrease in spending for the pexelizumab programs partially offset by Soliris trials and other activities;

increase of $1,922 for the three month periods ended March 31, 2007, in discovery research costs primarily due to milestone payments and increased external consulting fees, and

increase of $1,430 for the three month periods ended March 31, 2007, in research and development payroll and benefit costs resulted from the salary and wage growth versus comparable period in 2006.

General and Administrative Expenses

The following table provides information regarding the change in general and administrative expenses during the periods presented:

	Three months ended March 31,		Increase/ (Decrease)
	2007	2006	% Change
	(amounts in thousands, except percentage data)		

Total general and administrative expense	$ 19,838	$ 8,146	144%

General and administrative expenses increased approximately $11,692 for the three months ended March 31, 2007, as compared to the same period of 2006, primarily due to:

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higher payroll and benefits costs of $6,962 for the three month period ended March 31, 2007 primarily resulting from growth of our headcount dedicated to commercial development activities and the growth of existing headcounts, salary and wage base, and

an increase of $3,500 for the three month period ended March 31, 2007, for market research, travel and entertainment, advertising and promotion and other items related to commercial development.

Total Operating Expenses

Total operating expenses for the three month period ended March 31, 2007 were approximately $41,142 compared to approximately $29,360 for the same period of 2006.

Other Income and Expense

Investment income was approximately $2,769 for the three months ended March 31, 2007 as compared to $1,963 for the same period in 2006. The increase was due primarily to higher market interest rates.

Interest expense was approximately $700 for the three months ended March 31, 2007, as compared to approximately $688 for the same period in 2006.

Income Taxes

We recorded a state tax benefit of approximately $90 for the three months ended March 31, 2007 and 2006. The benefit is the result of the exchange for cash of our estimated 2007 and 2006 incremental research and development tax credits with the State of Connecticut.

We have adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes (FIN 48),* on January 1, 2007. As a result of the implementation of FIN 48, we recognized a benefit of $591 to the January 1, 2007 retained earnings balance. We also recognized a $6,671 decrease in the deferred tax assets for unrecognized tax benefits and decreased the valuation allowance by the same amount. The total amount of unrecognized tax benefits as of January 1, 2007, including the cumulative effect of the adoption of FIN 48, is $6,671. None of the amount, if recognized, would affect the effective tax rate due our full valuation allowance against deferred tax assets.

We and our affiliates file U.S. federal income tax returns, as well as income tax returns in various states and foreign jurisdictions. With limited exceptions, and due to the impact of net operating loss and other credit carry forwards, we may be effectively subject to U.S. federal income tax examinations for periods after 1992. We are subject to examination by state and local tax authorities generally for the period mandated by statute. These states, and the earliest open period include Connecticut (1999), New York (2003), Rhode Island (2006) and California (2003). Our foreign affiliates are not subject to examination by tax authorities for periods before 2005. Subsequent periods may be examined by the relevant tax authorities.

We recognize accrued interest and penalties related to unrecognized taxes as additional tax expense. During the years ended December 31, 2006, and the quarter ended March 31, 2007, we did not recognize any interest and penalties.

Net Loss

We incurred a net loss for the three month period ended March 31, 2007 of approximately $32,693 or $0.92 per common share, versus a net loss of approximately $27,227 or $0.88 per common share, for the same period in 2006.

Liquidity and Capital Resources

Our primary source of cash is through public offerings of our common stock and the sale of convertible notes. Also, in July 2006, we entered into a mortgage loan agreement to fund the purchase and construction of a manufacturing plant. Other sources include debt financing, payments received under corporate collaborations and grants, and equipment and leasehold improvements financing. Our primary use of cash includes business development activities and research and development.

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As of March 31, 2007, cash, cash equivalents, and marketable securities were approximately $205,935 compared with $250,148 at December 31, 2006. The decrease was primarily due to cash used to fund operating activities. As of March 31, 2007, $22,248 of cash was restricted.

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2007 was approximately $39,360, compared with $28,095 for the three months ended March 31, 2006. The increase in cash used compared to the same period in the previous year is primarily due to increased commercialization activities as compared to the same period in 2006.

Investing Activities

Net cash utilized for investing activities for the three months ended March 31, 2007 was approximately $1,816. This included proceeds of approximately $46,190 from marketable securities, net of purchases of marketable securities, approximately $43,157, $16,219 of property, plant and equipment additions mainly attributable to the construction of our Smithfield, Rhode Island manufacturing plant, and use of $11,346 in restricted cash pursuant to the terms of our mortgage loan.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2007 was approximately $11,394, consisting mainly of proceeds from the issuance of common stock related to the exercise of stock options of approximately $11,412.

Sufficiency of Cash Resources

We anticipate that our existing capital resources as well as interest and investment income earned on available cash and marketable securities should provide us adequate resources to fund our operating expenses and capital requirements as currently planned for at least the next twelve months.

Financial Instruments

As of March 31, 2007, the market value of our $150,000 1.375% convertible senior notes due February 1, 2012, based on quoted market prices, was estimated at $227,250. The $10,125 increase from December 31, 2006 is attributable to the increase in the price of our common stock during the period.

Critical Accounting Policies

The preparation of our financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgments. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We recognize revenue from product sales when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured and we have no further performance obligations. All revenues from product sales are recorded net of applicable provisions for distribution fees in the same period the related sales are recorded. Management assesses the specific terms and conditions of distribution agreements and circumstances of product sales in its determination of timing and extent of revenue recognition.

Our additional critical accounting policies are summarized in Form 10-K for the twelve-month period ended December 31, 2006, in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations under the caption Critical Accounting Policies and the Use of Estimates. We have reviewed those policies and determined that they remain our critical accounting policies for the three month period ended March 31, 2007.

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Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in our income statement, in that taxes billed to customers are not included as a component of net product sales, as per Emerging Issues Task Force (EITF) Issue No. 06-3, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement* .

Item 3. Quantitative and Qualitative Disclosure about Market Risks

As of March 31, 2007, we held approximately 78% of our cash and investments in financial instruments with original maturity dates of three months or less which includes restricted cash, 6% in financial instruments with original maturity dates of greater than three months and less than one year, and the remaining 16% in financial instruments with original maturity dates of equal to or greater than one year and less than two years. These financial instruments are subject to interest rate risk and will decline in value if interest rates increase. We estimate that a change of 100 basis points in interest rates would result in an increase or decrease of approximately $176 in the fair value of our cash and investments, which had a weighted average duration of approximately 1 month at March 31, 2007.

Our outstanding long-term liabilities as of March 31, 2007 included our $150,000, 1.375% Convertible Senior Notes due February 1, 2012. As the notes bear interest at a fixed rate, our results of operations would not be affected by interest rate changes. As of March 31, 2007, the market value of our $150,000 1.375% convertible senior notes due February 1, 2012, based on quoted market prices, was estimated at $227,250.

In July 2006, Alexion Manufacturing borrowed $26,000 to purchase and finance construction of the Smithfield, Rhode Island manufacturing facility. The loan bears interest at a fixed rate. Accordingly, any changes in the interest rate will not affect our future payments on the loan.

Item 4. Controls and Procedures.

We have carried out an evaluation, as of the end of the period covered by this report, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level in ensuring that material information relating to us and required to be included in the reports we file under the Securities Exchange Act of 1934, as amended, (the Exchange Act) is accumulated and communicated to the Chief Executive Officer and Chief Financial Officer or other persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

There have been no changes in our internal controls over financial reporting in connection with the evaluation required under paragraph (d) of Rule 13a-15 under the Exchange Act that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On March 15, 2007, Oklahoma Medical Research Foundation, or OMRF, filed a civil action against Alexion in the U.S. District Court for the Northern District of Oklahoma (Case No. 07CV 163 GKF SAJ). OMRF claims, among other things, (i) breach of contract by Alexion under a license agreement entered into by Alexion and OMRF in 1992, relating to intellectual property owned or controlled by OMRF and (ii) willful infringement by Alexion of an OMRF patent. OMRF seeks, among other things, declaratory judgment, judicial accounting, and actual, compensatory, consequential and punitive damages, plus attorney s fees. Alexion does not believe that it infringes any valid patent owned by OMRF in connection with the commercialization of Soliris. Alexion believes it has good and valid defenses and intends to vigorously defend the case.

On March 16, 2007, PDL BioPharma, Inc., or PDL, filed a civil action against Alexion in the U.S. District Court for the District of Delaware (Case No. 07-156). PDL claims willful infringement by Alexion of PDL patents due to sales of Soliris. PDL seeks unspecified damages, but no less than a reasonable royalty, plus attorney s fees. Alexion does not believe that it infringes any valid patent owned by PDL in connection with the commercialization of Soliris. Alexion believes it has good and valid defenses and intends to vigorously defend the case.

Item 1A. Risk factors

You should carefully consider the following risk factors before you decide to invest in our Company and our business because these risk factors may have a significant impact on our business, operating results, financial condition, and cash flows. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected.

Risks Related to Our Business

We depend heavily on the success of our lead product candidate, Soliris, which was approved in the United States in March 2007. If we are unable to successfully commercialize Soliris, are significantly delayed or limited in doing so, or if we do not obtain approval of Soliris in Europe, our business will be materially harmed.

Our ability to generate revenues will depend on successful commercialization of Soliris in the United States and obtaining approval and successfully commercializing Soliris in Europe.

The commercial success of Soliris will depend on several factors, including the following:

- the number of patients with PNH that may be treated with the product;
- successfully launching commercial sales of the product in the United States and in Europe;
- acceptance of the product in the medical community;
- ability to effectively market and distribute the product in the United States and Europe;

ability to obtain sufficient coverage or reimbursement by third-party payers;

receipt of marketing approvals from foreign regulatory authorities, including the EMEA; and

establishing commercial manufacturing capabilities ourselves or through third-party manufacturers.

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We have filed for approval of Soliris in Europe and have been granted accelerated assessment of our application. However, we may not receive required regulatory approval from the EMEA on a timely basis or at all. The approval process can involve additional lengthy clinical testing and other costly and time-consuming procedures. Even if the EMEA does grant marketing approval for Soliris, it may narrow the indications for which we are permitted to market the product, may pose other restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. A narrowed indication or other restrictions may limit the market potential for the product and obligation to conduct additional clinical trials would likely result in increased expenditures and lower revenues. Even where the EMEA indicates it is prepared to grant marketing approval for Soliris for a narrower indication or with certain restrictions, we may choose to continue negotiating and/or appeal any decision for broader indications with fewer restrictions, and such negotiations could cause a delay in marketing approval or could jeopardize the receipt of any marketing approval.

If we are not successful in commercializing Soliris in the United States, or are significantly delayed or limited in doing so, or if we do not obtain approval of and successfully commercialize Soliris in Europe, our business will be materially harmed and we may need to curtail or cease operations.

Because the target patient population for Soliris is small and has not been definitively determined, we must be able to successfully identify PNH patients and achieve a significant market share in order to achieve profitability.

The prevalence of PNH patients has not been definitively determined but can be estimated at approximately 8,000 10,000 total patients in North America and Western Europe. There can be no guarantee that any of our programs will be effective at identifying PNH patients and the number of PNH patients in the United States and Europe may turn out to be lower than expected or may not be amenable to treatment with Soliris.

If we are unable to establish and maintain effective sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully commercialize Soliris.

We expect to be able to market and sell Soliris ourselves in the United States and through our subsidiaries in Europe, but have no experience with marketing, sales or distribution of drug products. We have hired sales representatives for the commercialization of Soliris in the United States and have only recently established pre-commercial capability in Europe. If we are unable to establish capabilities to sell, market and distribute our product, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully sell Soliris. In that event, we will not be able to generate significant revenues. We cannot guarantee that we will be able to develop and maintain our own capabilities or enter into and maintain any marketing or distribution agreements with third-party providers on acceptable terms, if at all. In Europe, regulatory and commercial requirements vary on a country by country basis and we cannot guarantee that we will have the capabilities or resources to obtain regulatory approval and commercialize Soliris in every country in Europe. Even if we hire the qualified sales and marketing personnel we need in the United States and in Europe, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell our product. Establishing and maintaining sales, marketing and distribution capabilities is expensive and time-consuming. Our expenses associated with building up and maintaining the sales force and distribution capabilities may be disproportional compared to the revenues we may be able to generate on sales of our product. We cannot guarantee that we will be successful in commercializing Soliris.

We are completely dependent on a single third party to manufacture commercial quantities of Soliris and our commercialization of Soliris may be stopped, delayed or made less profitable if such third party fails to provide us with sufficient quantities of Soliris.

Only Lonza Sales AG, or Lonza, is currently capable of manufacturing commercial quantities of Soliris. We will not be capable of manufacturing Soliris for commercial sale until such time as we have requested and received the required regulatory approvals. Therefore, we anticipate that we will depend entirely on one company, Lonza, to manufacture Soliris for commercial sale until that time. We cannot be certain that our arrangement with Lonza will be extended, if necessary, or extended upon commercially reasonable terms, or that Lonza will be able to perform uninterrupted supply chain services. If Lonza were unable to perform its services for any period, we may incur substantial loss of sales. If we are forced to find an alternative supply chain service provider for Soliris, in addition to loss of sales, we may also incur costs in establishing a new arrangement.

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We may not be able to gain market acceptance among the medical community or patients which would prevent us from becoming profitable.

We cannot be certain that Soliris will gain market acceptance among physicians, patients, healthcare payers, and others. Although we have received regulatory approval for Soliris in the United States, it does not guarantee future revenue. Sales of Soliris also depend on physicians willingness to prescribe the treatment, which is likely to be primarily based on a determination by these physicians that the products are safe and therapeutically effective relative to cost. We cannot predict whether physicians, other healthcare providers, government agencies or private insurers will determine that our products are safe and therapeutically effective relative to cost. Medical doctors willingness to prescribe, and patients willingness to accept, our products depend on many factors, including prevalence and severity of adverse side effects in both clinical trials and commercial use, effectiveness of our marketing strategy and the pricing of our products, publicity concerning our products or competing products, our ability to obtain third-party coverage or reimbursement, and availability of alternative treatments. If Soliris fails to achieve market acceptance, we may not be able to market and sell it successfully, which would limit our ability to generate revenue and could harm our business.

If we are unable to obtain reimbursement for Soliris from government health administration authorities, private health insurers and other organizations, Soliris may be too costly for regular use and our ability to generate revenues would be harmed.

Our future revenues and profitability will be adversely affected if we cannot depend on governmental, private third-party payers and other third-party payers, including Medicare and Medicaid, to defray the cost of Soliris to the consumer. If these entities refuse to provide coverage and reimbursement with respect to Soliris or determine to provide an insufficient level of coverage and reimbursement, Soliris may be too costly for general use, and physicians may not prescribe it. Soliris is significantly more expensive than traditional drug treatments. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Third-party payers may be especially likely to impose these obstacles to coverage for higher-priced drugs such as Soliris.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability and worsen our financial condition. In the United States and elsewhere, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs.

Since Soliris is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers is not available, our ability to successfully commercialize Soliris may be adversely impacted. Any limitation on the use of Soliris or any decrease in the price of Soliris will have a material adverse effect on our ability to achieve profitability.

Even where patients have access to insurance, their insurance co-payment amounts may be too expensive for them to afford. Alexion will financially support the PNH Foundation of the National Organization for Rare Disorders, or NORD, which, among other things, assists patients in acquiring drugs such as Soliris. Organizations such as NORD assist patients who have no insurance coverage for drugs or whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations. NORD s ability to provide financial assistance to PNH patients will be substantially dependent on funding from Alexion and we cannot guarantee that such funding will be provided by Alexion at adequate levels, if at all. In addition to assistance from organizations such as NORD, we anticipate that Alexion will provide Soliris without charge for related charitable purposes. We are not able to predict the financial impact of the support we may provide for these and other charitable purposes; however, substantial support could have a material adverse effect on our ability to achieve profitability.

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In furtherance of our efforts to facilitate access to Soliris, we have created the Soliris OneSource Program, a treatment support service for patients with PNH and their healthcare providers. OneSource case managers will provide education about PNH and Soliris and help facilitate solutions for reimbursement, coverage and access. Although case managers will assist patients and healthcare providers in locating and accessing Soliris, we cannot guarantee a sufficient level of coverage, reimbursement or financial assistance.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operation may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

If the use of our products harms people, or is perceived to harm patients even when such harm is unrelated to our products, our regulatory approval in the United States could be revoked or otherwise negatively impacted, our regulatory approval process in Europe could be delayed, negatively impacted or abandoned, and we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing and sale of drugs for use in humans exposes us to product liability risks. Side effects and other problems from using our products could cause serious adverse events and give rise to product liability claims against us. We might have to withdraw or recall our products from the marketplace. Some of these risks are unknown at this time.

We have tested Soliris in only a small number of patients. As more patients begin to use our product, new risks and side effects associated with Soliris may be discovered, and risks previously viewed as inconsequential could be determined to be significant. As a result, regulatory authorities may delay or revoke their approvals; we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers manufacturing facilities. We may also experience a significant drop in the potential sales of Soliris, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of Soliris or substantially increase the costs and expenses of commercializing and marketing Soliris.

We may be sued by people who use Soliris. Many patients who use Soliris are already very ill. Any informed consents or waivers obtained from people who enroll in our trials or use Soliris may not protect us from liability or litigation. Our product liability insurance may not cover all potential types of liabilities or may not cover covered types of liabilities completely. Moreover, we may not be able to maintain our insurance on acceptable terms. In addition, negative publicity relating to the use of our product or to a product liability claim may make it more difficult, or impossible, for us to market and sell Soliris. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Patients who use Soliris already often have severe and advanced stages of disease and known as well as unknown significant pre-existing health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to Soliris. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to Soliris, the investigation into the circumstance may be time consuming or may be inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in Europe, impact and limit the type of regulatory approvals Soliris receives, or end our opportunity to receive regulatory approval in Europe. PNH patients sometimes have additional, pre-existing, potentially life-threatening disease, including for example bone marrow failure.

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Some patients who have participated in our PNH trials have died or suffered potentially life-threatening diseases either during or after ending study-specified treatments. In particular, use of C5 Inhibitors, such as eculizumab, is associated with an increased risk for infection with Neisseria bacteria. Serious cases of Neisseria infection can result in severe illness, including but not limited to brain damage, loss of limbs or parts of limbs, kidney failure, or death. PNH patients in our TRIUMPH and SHEPHERD trials all received vaccination against the Neisseria bacteria prior to first administration of eculizumab and all patients who are prescribed Soliris in the United States must be vaccinated prior to receiving the first dose; however, vaccination does not eliminate all risk of becoming infected with Neisseria bacteria. Some patients in our trials of eculizumab for the treatment of PNH and other diseases have become infected with Neisseria bacteria, including PNH patients in the open-label extension trial E05-001 who had been vaccinated against Neisseria bacteria. Each such incident has been reported to appropriate regulatory agencies in accordance with relevant regulations.

We are also aware of a potential risk for PNH patients who delay a dose of Soliris or discontinue their treatment of Soliris. Treatment with Soliris blocks complement and allows complement-sensitive PNH red blood cells to increase in number. If treatment with Soliris is thereafter delayed or discontinued, a greater number of red blood cells therefore would become susceptible to destruction when the patient s complement system is no longer blocked. The rapid destruction of a larger number of a patient s red blood cells may lead to numerous complications, including death. Several PNH patients in our studies of Soliris have received delayed doses or discontinued their treatment. In none of those circumstances were complications from rapid destruction of a larger number of PNH red blood cells observed to be significant; however, we have not studied the delay or termination of treatment in enough patients to determine that complications in the future are unlikely to occur. Determination of significant complications associated with the delay or discontinuation of Soliris could have a material adverse effect on our ability to sell eculizumab for PNH.

Inability to contract with third-party manufacturers on commercially reasonable terms, or failure or delay by us or our third-party manufacturers, in manufacturing our drug products in the volumes and quality required, would have a material adverse effect on our business.

We currently have no experience or capacity for manufacturing drug products in volumes that would be necessary to support commercial sales and we can provide no assurance that we will be able to do so successfully. We depend on a few outside suppliers for manufacturing and a single manufacturer for commercial supply. Our small, clinical-scale manufacturing plant cannot manufacture enough of our product candidates for later stage clinical development or commercial supply. We do not have the capacity to produce more than one product candidate at a time in that plant. We acquired a commercial-scale manufacturing plant in Smithfield, Rhode Island in July 2006. However, that plant is not currently equipped or approved by the FDA or other regulatory agencies to manufacture Soliris or our other drug candidates. We expect that it will be approximately two years before product from the plant is approved for commercial sale. We have no experience in developing commercial-scale manufacturing of the sort anticipated in Smithfield, Rhode Island. We can provide no assurance that we will be able to develop the Smithfield, Rhode Island site into a plant capable of manufacturing our drug products under conditions required by the FDA or foreign regulatory agencies on a timely basis, if at all. Our plant in Smithfield, Rhode Island will be subject to FDA inspection and approval before we can begin sales of Soliris manufactured in this facilty and we will continue to be subject to ongoing FDA inspections thereafter. Our Smithfield, Rhode Island plant will also be subject to European regulatory inspection and approval before we can sell Soliris in Europe that is manufactured in this facility and we will continue to be subject to ongoing European regulatory inspection thereafter.

One of our subsidiaries has executed a commercial-scale product supply agreement with Lonza for the long-term manufacture of eculizumab on which we will be relying for manufacturing commercial sale quantities of Soliris in the near future. The failure of Lonza to manufacture appropriate supplies of eculizumab, on a timely basis, or at all, may prevent or impede the commercialization of Soliris. Lonza or we will be required to manufacture substantially more material than we have required for clinical and preclinical trials. We and our outside manufacturers may experience higher manufacturing failure rates than in the past if and when we attempt to substantially increase production volume. If we experience interruptions in the manufacture of our products, our drug development and commercialization efforts will be delayed. If any of our outside manufacturers stops manufacturing our products or reduces the amount manufactured, or is otherwise unable to manufacture our required amounts at our required

quality, we will need to find other alternatives, which is likely to be expensive and time consuming, and even if we are able to find alternatives they may ultimately be insufficient for our needs. As a result, our ability to conduct testing and drug trials and our plans for commercialization would be materially adversely affected. Submission of products and new development programs for regulatory approval, as well as our plans for commercialization, would be delayed or suspended. Our competitive position and our prospects for achieving profitability would be materially and adversely affected.

Manufacture of drug products, including the need to develop and utilize manufacturing processes that consistently produce our drug products to their required quality specifications, is highly regulated by the FDA and other domestic and foreign authorities. Regulatory authorities must approve the facilities in which our products are manufactured prior to granting market approval for any product candidate. Manufacturing facilities are also subject to ongoing inspections, and minor changes in manufacturing processes may require additional regulatory approvals. We cannot assure you that we or our third-party collaborators will successfully comply with all of those requirements and regulations, which failure would have a materially adverse effect on our business.

Manufacture of our drug products is highly technical and only a few third-parties have the ability and capacity to manufacture our drug products for our development and commercialization needs. We cannot assure you that these potential third-party collaborators will agree to manufacture our products on our behalf on commercially reasonable terms, if at all. If we do achieve agreement from one or more third parties to manufacture our drug products, we cannot assure you that they will be able or willing to honor the terms of the agreements, including any obligations to manufacture the drug products in accordance with regulatory requirements and to our quality specifications and volume requirements. Due to the highly technical requirements of manufacturing our drug products, our third-party collaborators and we may be unable to manufacture our drug products despite their and our efforts.

Due to the nature of the current market for third-party commercial manufacturing, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity for which it contracted. We could owe substantial penalty payments to Lonza if we were not to use the manufacturing capacity for which we contracted. Penalty payments under these agreements typically decrease over the life of the agreement, and may be substantial initially and de minims or non-existent in the final period. The payment of a substantial penalty would harm our financial condition.

If we continue to incur operating losses, we may be unable to continue our operations.

We have incurred losses since we started our company in January 1992. As of March 31, 2007, we had an accumulated deficit of approximately $670 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. Since we began our business, we have focused on research and development of product candidates. We launched Soliris for sale in the United States during April 2007 and we have submitted for filing an MAA in Europe. We cannot guarantee that we will be successful in commercializing Soliris in the United States and we do not know when we will have products available for sale outside the United States, if ever. We expect to continue to operate at a net loss for at least the next several years as we transition from a research and development company to a sales and marketing company, continue our research and development efforts, continue to conduct clinical trials, and continue to develop manufacturing, sales, marketing and distribution capabilities in the United States and abroad. Our future profitability depends on our ability to successfully market Soliris, on receiving regulatory approval of Soliris outside the United States, and our ability to successfully manufacture approved drugs. The extent and the timing of our future losses and our profitability, if we are ever profitable, are highly uncertain.

If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development.

We believe that revenues and collections from sales of Soliris along with our existing cash, cash equivalents and marketable securities will provide sufficient capital to fund our operations and product development for at least twelve months. We may need to raise additional capital before or after that time to complete the development and continue the commercialization of our product candidates. We are currently preparing for the commercialization of Soliris in Europe and conducting or evaluating several clinical trials. Funding needs may shift between projects and potentially accelerate and increase, as we get closer to commercialization of Soliris in Europe, or if we initiate new clinical trials for our product candidates.

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Additional financing could take the form of public or private debt or equity offerings, equity line facilities, bank loans, collaborative research and development arrangements with corporate partners and/or the sale or licensing of some of our property. The amount of capital we may need depends on many factors, including:

- the cost necessary to sell, market and distribute Soliris;
- the time and cost necessary to obtain regulatory approvals for Soliris outside the United States and for eculizumab for other indications;
- the time and cost necessary to develop sales, marketing and distribution capabilities outside the United States;
- the time and cost necessary to purchase or to further develop manufacturing processes, arrange for contract manufacturing or build manufacturing facilities and obtain the necessary regulatory approvals for those facilities;
- changes in applicable governmental regulatory policies or requests by regulatory agencies for additional information or data;
- the progress, timing and scope of our research and development programs;
- the progress, timing and scope of our preclinical studies and clinical trials;
- any new collaborative, licensing or other commercial relationships that we may establish.

We may not get funding when we need it or funding may only be available on unfavorable terms. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back or eliminate our research and development activities or future operations. We might have to license our technology to others or relinquish commercialization rights. This could result in sharing revenues that we might otherwise retain for ourselves. Any of these actions would harm our business.

If we are unable to engage and retain third-party collaborators, our research and development efforts may be delayed.

In March 2007 we terminated our collaboration with P&G relating to the joint development of pexelizumab in cardiovascular indications. Currently, none of our product candidates are being jointly developed with third party collaborators. We may experience significant delays in the development of our product candidates if we cannot engage additional collaborators when required. We would be required to devote additional funds or other resources to these activities or to terminate them. Either of these events would divert funds or other resources from other parts of our business.

We cannot assure you that:

- we will be able to negotiate acceptable collaborative agreements to develop or commercialize our product candidates;

any arrangements with third parties will be successful; or

potential collaborators will not pursue treatments for other diseases or seek other ways of developing treatments for our disease targets.

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If our competitors get to the marketplace before we do, or with better or cheaper drugs, our product candidates may not be profitable to continue to develop.

Both the FDA and EMEA have granted orphan drug designation for Soliris in the treatment of PNH which entitles us to exclusivity for seven years in the United States, and, if our drug is approved, for ten years in Europe. However, if a competitive product that is the same as Soliris, as defined under the applicable regulations, is shown to be clinically superior to our product in the treatment of PNH, or if a competitive product is different from Soliris, as defined under the applicable regulations, the orphan drug exclusivity we have obtained may not block the approval of such competitive product. Each of Adprotech Ltd., Avant Immunotherapeutics, Inc., XOMA, Ltd., Novo Nordisk A/S, Archemix Corporation, Evolutec Ltd., Amgen Inc., Genentech, Inc., Pharming Group N.V., CSL-Behring, Peptech Ltd., Lev Pharma, Inc., Optherion, Inc., Jerini AG, and ChemoCentryx, Inc. have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. We are also aware that Abbott Laboratories, Inc., Baxter International, Inc., Millennium Pharmaceuticals, Inc. and Neurogen Corporation, have had programs develop complement inhibitor therapies. Each of AstraZeneca, MorphoSys AG and Dyax Corporation has publicly announced intentions to develop therapeutic human antibodies from libraries of human antibody genes. Additionally, each of Amgen, Inc. and Medarex, Inc. has publicly announced intentions to develop therapeutic human antibodies from mice that have been bred to include some human antibody genes. These and other pharmaceutical companies, many of which have significantly greater resources than we, may develop, manufacture, and market better or cheaper drugs than our product candidates. They may establish themselves in the marketplace even before we are able to finish our clinical trials. Other pharmaceutical companies also compete with us to attract academic research institutions as drug development partners, including for licensing these institutions proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

If we fail to recruit and retain personnel, our research and product development programs may be delayed.

We are highly dependent upon the efforts of our senior management and scientific personnel, particularly Dr. Leonard Bell, M.D., our Chief Executive Officer and a member of our Board of Directors, David W. Keiser, our President, Chief Operating Officer and a member of our Board of Directors, and Stephen P. Squinto, Ph.D., our Executive Vice President and Head of Research. There is intense competition in the biotechnology industry for qualified scientific and technical personnel. Since our business is very science-oriented and specialized, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. We have employment agreements with Dr. Bell, Mr. Keiser, and Dr. Squinto. None of our key personnel is nearing retirement age or to our knowledge, planning to retire. To our knowledge, there is no tension between any of our key personnel and the Board of Directors. If we lose the services of our management and scientific personnel and fail to recruit other scientific and technical personnel, our research and product development programs will be materially and adversely affected.

In particular, we highly value the services of Dr. Bell, our Chief Executive Officer. The loss of his services could materially and adversely affect our ability to achieve our objectives.

We are significantly leveraged.

On March 31, 2007, we had outstanding $150 million principal amount of 1.375% convertible senior notes. On July 11, 2006, our subsidiary Alexion Manufacturing borrowed $26 million to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility which may not be prepaid in whole or in part prior to July 11, 2009. The loan is guaranteed by us and bears a fixed annual rate of 9.17%. Our 1.375% convertible senior notes and the mortgage loan remain outstanding, and the degree to which we are leveraged could, among other things:

- make it difficult for us to make payments on our notes and our loan;
- make it difficult for us to obtain financing for working capital, acquisitions or other purposes on favorable terms, if at all;

make us more vulnerable to industry downturns and competitive pressures; and

limit our flexibility in planning for, or reacting to changes in, our business.

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Our ability to meet our debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

We are subject to environmental laws and potential exposure to environmental liabilities.

We are subject to various federal, state and local environmental laws and regulations that govern our operations, including the handling and disposal of non-hazardous and hazardous wastes, including medical and biological wastes, and emissions and discharges into the environment, including air, soils and water sources. Failure to comply with such laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs of remediating its property or locations to which wastes were sent from its facilities, without regard to whether the owner or operator knew of, or necessarily caused, the contamination. Such obligations and liabilities, which to date have not been material, could have a material impact on our business and financial condition.

We may expand our business through acquisitions that could disrupt our business and harm our financial condition.

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions to do so. Acquisitions involve numerous risks, including:

- substantial cash expenditures;
- potentially dilutive issuance of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- diverting our management s attention away from other business concerns;
- risks of entering markets in which we have limited or no direct experience; and
- the potential loss of our key employees or key employees of the acquired companies.

We cannot assure you that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure you that we will be able to make the combination of our business with that of acquired businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired business or companies may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, which could dilute current stockholders ownership interest in our company, or securities convertible into our capital stock, which could dilute current stockholders ownership interest in our company upon

conversion.

Our ability to use net operating loss carry forwards to reduce future tax payments may be limited if there is a change in ownership of Alexion.

As of December 31, 2006, we had approximately $618 million of net operating loss carry forwards, or NOLs, available to reduce taxable income in future years. We believe that some of these NOLs are currently subject to an annual limitation under section 382 of the Internal Revenue Code of 1986, as amended.

Our ability to utilize our NOLs may be further limited if we undergo an ownership change, as defined in section 382, as a result of subsequent changes in the ownership of our outstanding stock. We would undergo an ownership change

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if, among other things, the stockholders, or group of stockholders, who own or have owned, directly or indirectly, 5% or more of the value of our stock, or are otherwise treated as 5% stockholders under section 382 and the regulations promulgated there under, increase their aggregate percentage ownership of our stock by more than 50 percentage points over the lowest percentage of our stock owned by these stockholders at any time during the testing period, which is generally the three-year period preceding the potential ownership change. In the event of an ownership change, section 382 imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change NOLs. The limitation imposed by section 382 for any post-change year would be determined by multiplying the value of our stock immediately before the ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Any unused limitation may be carried over to later years, and the limitation may under certain circumstances be increased by built-in gains which may be present with respect to assets held by us at the time of the ownership change that are recognized in the five-year period after the ownership change. Our use of NOLs arising after the date of an ownership change would not be affected.

Risks Related to Our Industry

We are subject to extensive government regulation, and, if we do not maintain our regulatory approval in the United States or obtain and maintain regulatory approval in Europe, we will not be able to sell our drug products.

We and our partners cannot sell or market our products without regulatory approval. We obtained marketing approval of Soliris in the United States for PNH and submitted an MAA for approval in Europe. If we do not obtain regulatory approval in Europe and maintain our regulatory approvals for Soliris, the value of our company and our results of operations will be harmed. In the United States, we or our partners must obtain and maintain approval from the FDA for each indication for each drug that we intend to sell and for each facility where such drug is manufactured. Obtaining FDA approval is typically a lengthy and expensive process, and although we obtained approval for Soliris in PNH, approval is highly uncertain for our other drug candidates. Foreign governments also regulate drugs distributed outside the United States and facilities outside the United States where such drugs are manufactured, and obtaining their approvals can also be lengthy, expensive and highly uncertain. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. In certain foreign jurisdictions we would be required to obtain pricing approvals prior to marketing our products. None of our products have received regulatory approval to be marketed and sold outside the United States. We may never receive regulatory approval for Soliris outside the United States or for any of our product candidates for at least the next several years, if ever.

We may be unable to obtain regulatory approval of Soliris outside the United States or maintain our regulatory approval for Soliris in the United States. In addition, we may be unable to obtain necessary regulatory approvals in the United States and foreign countries on a timely basis, if at all, for any of our product candidates or maintain such approvals if obtained. Any delays in obtaining necessary regulatory approvals or failure to maintain them could prevent us from marketing our products.

If we fail to comply with continuing United States and foreign regulations, we could lose our approvals to market Soliris, and our business would be seriously harmed.

We and our future partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA, other federal and state agencies, and governmental authorities in other countries. These regulations continue to apply after product approval, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, adverse event reporting requirements, and export of biologics. As a condition of approval for marketing our product, FDA, or governmental authorities in other countries may require us to conduct additional clinical trials. For example, in connection with the approval of Soliris, we have agreed to perform clinical studies assessing long term safety outcomes in the Soliris Safety Registry, monitoring immunogenicity, monitoring compliance with vaccination requirements, and determining the effects of anticoagulant withdrawal among PNH patients receiving eculizumab. The FDA can propose to withdraw approval if new clinical data or information shows that a product is not safe for use in approved indication. We are required to report any serious and unexpected adverse experiences and certain quality problems with Soliris to the FDA. The FDA or we may have to

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notify healthcare providers of any such developments. The discovery of any previously unknown problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Certain changes to an approved product, including the way it is manufactured or promoted, often require prior FDA approval before the product as modified may be marketed. Our manufacturing and other facilities and those of any third parties manufacturing our products will be subject to inspection prior to grant of marketing approval and subject to continued review and periodic inspections by the regulatory authorities. Any third party we would use to manufacture our products for sale must also be licensed by applicable regulatory authorities.

Failure to comply with the laws, including statutes and regulations, administered by the FDA or other agencies could result in:

- administrative and judicial sanctions, including, warning letters;
- fines and other civil penalties;
- delays in approving or refusal to approve a product candidate;
- withdrawal of a previously granted approval;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

The discovery of previously unknown problems with a product or the facility used to produce the product could result in a regulatory authority imposing restrictions on us, or could cause us to voluntarily adopt such restrictions, including withdrawal of one or more of our products or services from the market.

Although we obtained regulatory approval of Soliris for PNH in the United States, we may be unable to obtain regulatory approval for Soliris in Europe or any other territory .

The EMEA and other regulatory agencies may require additional information or data with respect to our MAA for Soliris for PNH. Although the Soliris MAA was granted accelerated assessment by the EMEA in Europe, it does not ensure or increase the likelihood that our application for regulatory approval of Soliris in Europe will be approved. We may have to conduct additional lengthy clinical testing and other costly and time-consuming procedures to satisfy foreign regulatory agencies. Even with approval of Soliris by the FDA, the EMEA may not agree with our

interpretations of our clinical trial data for Soliris and may decide that our results are not adequate to support approval for marketing of Soliris in Europe. In those circumstances, we would not be able to obtain regulatory approval in Europe on a timely basis, if ever. Even if approval is granted in Europe, the approval may require limitations on the indicated uses for which the drug may be marketed. In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. We must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries.

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None of our product candidates except for Soliris has received regulatory approvals. If we are unable to obtain regulatory approvals to market one or more of our product candidates, our business may be adversely affected.

All of our product candidates except Soliris are in early stages of development, and we do not expect our other product candidates to be commercially available for several years, if at all. Our product candidates are subject to strict regulation by regulatory authorities in the United States and in other countries. We cannot market any product candidate until we have completed all necessary preclinical studies and clinical trials and have obtained the necessary regulatory approvals. We do not know whether regulatory agencies will grant approval for any of our product candidates. Even if we complete preclinical studies and clinical trials successfully, we may not be able to obtain regulatory approvals or we may not receive approvals to make claims about our products that we believe to be necessary to effectively market our products. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval, and failure to comply with regulatory requirements or inadequate manufacturing processes are examples of other problems that could prevent approval. In addition, we may encounter delays or rejections due to additional government regulation from future legislation, administrative action or changes in the FDA policy. Even if the FDA approves a product, the approval will be limited to those indications covered in the approval.

Outside the United States, our ability to market any of our potential products is dependent upon receiving marketing approvals from the appropriate regulatory authorities. These foreign regulatory approval processes include all of the risks associated with the FDA approval process described above. If we are unable to receive regulatory approvals, we will be unable to commercialize our product candidates, and our business may fail.

Completion of preclinical studies or clinical trials does not guarantee advancement to the next phase of development.

Completion of preclinical studies or clinical trials does not guarantee that we will initiate additional studies or trials for our product candidates, that if the studies or trials are initiated what the scope and phase of the trial will be or that they will be completed, or that if the studies or trials are completed, that the results will provide a sufficient basis to proceed with further studies or trials or to apply for or receive regulatory approvals or to commercialize products. Results of clinical trials could be inconclusive, requiring additional or repeat trials. If the results achieved in our clinical trials are insufficient to proceed to further trials or to regulatory approval of our product candidates, our company could be materially adversely affected. Failure of a preclinical study or a clinical trial to achieve its pre-specified primary endpoint generally increases the likelihood that additional studies or trials will be required if we determine to continue development of the product candidate, reduces the likelihood of timely development of and regulatory approval to market the product candidate, and may decrease the chances for successfully achieving the primary endpoint in scientifically similar indications.

There are many reasons why drug testing could be delayed or terminated.

For human trials, patients must be recruited and each product candidate must be tested at various doses and formulations for each clinical indication. In addition, to ensure safety and effectiveness, the effect of drugs often must be studied over a long period of time, especially for the chronic diseases that we are studying. Unfavorable results or insufficient patient enrollment in our clinical trials could delay or cause us to abandon a product development program. We may decide to abandon development of a product candidate at any time, or we may have to spend considerable resources repeating clinical trials or conducting additional trials, either of which would increase costs and delay any revenue from those product candidates, if any.

Additional factors that can cause delay, impairment or termination of our clinical trials or our product development efforts include:

- slow patient enrollment, including for example due to the rarity of the disease being studied;
- long treatment time required to demonstrate effectiveness;

lack of sufficient supplies of the product candidate;

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- disruption of operations at the clinical trial sites;
- adverse medical events or side effects in treated patients;
- the failure of patients taking the placebo to continue to participate in our clinical trials;
- insufficient clinical trial data to support effectiveness of the product candidates;
- lack of effectiveness of the product candidate being tested;
- lack of sufficient funds;
- inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; or
- failure to obtain the necessary regulatory approvals for the product candidate or the approvals for the facilities in which such product candidate is manufactured.

If we market Soliris in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care fraud and abuse laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, patients, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines, and imprisonment. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to

challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Maine, Minnesota, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish

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marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. We are not aware of any companies against which fines or penalties have been assessed under these special state reporting and disclosure laws to date. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Risks Related to Intellectual Property

If we cannot protect the confidentiality and proprietary nature of our trade secrets, our business and competitive position will be harmed.

Our business requires using sensitive technology, techniques and proprietary compounds that we protect as trade secrets. However, since we are a small company, we also rely heavily on collaboration with suppliers, outside scientists and other drug companies. Collaboration presents a strong risk of exposing our trade secrets. If our trade secrets were exposed, it would help our competitors and adversely affect our business prospects.

In order to protect our drugs and technology more effectively, we need to obtain and maintain patents covering the drugs and technologies we develop. We may obtain patents through ownership or license. Our drugs are expensive and time-consuming to test and develop. Without patent protection, competitors may copy our methods, or the chemical structure or other aspects of our drugs. Even if we obtain and maintain patents, the patents may not be broad enough to protect our drugs from copycat products.

If we are found to be infringing on patents owned by others, we may be forced to pay damages to the patent owner and obtain a license to continue the manufacture, sale or development of our drugs and/or pay damages. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our drugs.

Parts of our technology, techniques and proprietary compounds and potential drug candidates, including those which are in-licensed, may be found to infringe patents owned by or granted to others. In March 2007, we reported that two civil actions were filed against us relating to the commercialization of Soliris and the intellectual property rights of third parties. Oklahoma Medical Research Foundation, or OMRF, filed a civil action against us in Oklahoma alleging, among other things, breach of contract of an existing license agreement between OMRF and Alexion and Alexion s willful infringement of OMRF patents. If it is finally determined that we are in breach of the license agreement, OMRF might be entitled to terminate such agreement, including the licenses granted to Alexion, or we might be required to pay royalties to OMRF. Although we do not believe that any valid patent of OMRF covered under such license agreement is necessary for the commercialization of Soliris for PNH, we cannot guarantee that we will be successful in defending against such action. In addition, PDL BioPharma, Inc., or PDL, filed a civil action against us in Delaware, alleging willful infringement of PDL patents. If it is finally determined that we infringe the PDL patents, we might be required to pay royalties to PDL on the sales of Soliris in the United States. If we cannot resolve these or any other future conflicts, we may be liable for damages, be required to obtain costly licenses or have to stop manufacturing, using or selling our products or conducting other activities.

Additional third parties may claim that Alexion intellectual property infringes patents owned or granted to such third parties. We are aware of broad patents owned by others relating to the manufacture, use and sale of recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, and recombinant human single chain antibodies. Soliris and many of our product candidates are either genetically engineered antibodies, including recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, or recombinant human single chain antibodies. In addition to the actions filed by OMRF and PDL, we have received notices from the owners of some of these patents claiming that their patents may be infringed by the development, manufacture or sale of Soliris or some of our drug candidates. We are also aware of other patents owned by third parties that might be claimed to be infringed by the development and commercialization of Soliris and some of our drug candidates. In respect to some of these patents, we have obtained licenses, or expect to obtain licenses. However, with regard to such other patents, we have determined in our judgment that:

our products do not infringe the patents;

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the patents are not valid; or

we have identified and are testing various modifications that we believe should not infringe the patents and which should permit commercialization of our product candidates.

In addition to OMRF and PDL, any holder of these patents or other patents covering similar technology could sue us for damages and seek to prevent us from manufacturing, selling or developing our drugs. Legal disputes can be costly and time consuming to defend. If any patent holder successfully challenges our judgment that our products do not infringe their patents or that their patents are invalid, we could be required to pay costly damages or to obtain a license to sell or develop our drugs. A required license may be costly or may not be available on acceptable terms, if at all. A costly license, or inability to obtain a necessary license, could have a material adverse effect on our business.

There can be no assurance that we would prevail in a patent infringement action, including the OMRF and PDL actions; will be able to obtain a license to any third-party patent on commercially reasonable terms; successfully develop non-infringing alternatives on a timely basis; or license alternative non-infringing technology, if any exists, on commercially reasonable terms. Any impediment to our ability to manufacture or sell approved forms of our product candidates could have a material adverse effect on our business and prospects.

Risks Related to Our Common Stock

If the trading price of our common stock continues to fluctuate in a wide range, our stockholders will suffer considerable uncertainty with respect to an investment in our common stock.

The trading price of our common stock has been volatile and may continue to be volatile in the future. Factors such as announcements of fluctuations in our or our competitors operating results or clinical or scientific results, fluctuations in the trading prices or business prospects of our competitors and collaborators, changes in our prospects, particularly with respect to sales of Soliris, regulatory approval of Soliris in Europe, and market conditions for biotechnology stocks in general could have a significant impact on the future trading prices of our common stock and our convertible senior notes. In particular, the trading price of the common stock of many biotechnology companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. This is due to several factors, including general market conditions, the announcement of the results of our clinical trials or product development and the results of our efforts to obtain regulatory approval for our products. In particular, since August 1, 1999, the sales price of our common stock has ranged from a low of $9.05 per share to a high of $119.88 per share. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our common stock may result in considerable uncertainty for an investor.

Anti-takeover provisions of Delaware law, provisions in our charter and bylaws and our stockholders rights plan, or poison pill, could make a third-party acquisition of us difficult and may frustrate any attempt to remove or replace our current management.

Because we are a Delaware corporation, the anti-takeover provisions of Delaware law could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to stockholders. We are subject to the provisions of Section 203 of the Delaware General Laws, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our corporate charter and by-law provisions and stockholder rights plan may discourage certain types of transactions involving an actual or potential change of control that might be beneficial to Alexion or its stockholders. Our bylaws provide that special meetings of our stockholders may be called only by the Chairman of the Board, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own

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ALEXION PHARMACEUTICALS, INC.

of record 50% of the outstanding stock of all classes entitled to vote at such meeting. Our bylaws also specify that the authorized number of directors may be changed only by resolution of the board of directors. Our certificate does not include a provision for cumulative voting for directors, which may have enabled a minority stockholder holding a sufficient percentage of a class of shares to elect one or more directors. Under our certificate of incorporation, our board of directors has the authority, without further action by stockholders, to designate up to 5,000,000 shares of preferred stock in one or more series. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future.

Pursuant to our stockholder rights plan, each share of common stock has an associated preferred stock purchase right. The rights will not trade separately from the common stock until, and are exercisable only upon, the acquisition or the potential acquisition through tender offer by a person or group of 20% or more of the outstanding common stock. The rights are designed to make it more likely that all of our stockholders receive fair and equal treatment in the event of any proposed takeover of us and to guard against the use of partial tender offers or other coercive tactics to gain control of us.

These provisions could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices. These provisions could also limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and could adversely affect the price of our common stock.

Item 4. Submission of Matters to a Vote of Security Holders

1. At our 2007 Annual Meeting of Stockholders held on May 3, 2007, the stockholders voted to elect the following directors by the votes indicated:

	For	Against or Withheld	Abstaining
Leonard Bell, M.D.	20,543,753	10,908,672	
David W. Keiser	20,471,734	10,980,691	
Max Link, Ph.D.	20,523,746	10,928,679	
Joseph A. Madri, Ph. D., M.D.	19,725,250	11,727,175	
Larry L. Mathis	20,534,113	10,918,312	
R. Douglas Norby	20,533,748	10,918,677	
Alvin S. Parven	19,716,415	11,736,010	
Ruedi E. Waeger, Ph.D.	19,723,015	11,729,410	

2. The stockholders voted to approve the amendment to the Company s 2004 Incentive Plan to increase the number of shares of common stock available for issuance by 1.2 million shares (subject to adjustment in the event of stock splits and other similar events) by the following votes:

For	Against	Abstain	Not Voted
23,651,924	3,140,408	26,132	4,633,961

3. The stockholders voted to ratify the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm, by the following votes:

For	Against	Abstain
31,426,024	13,605	12,796

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ALEXION PHARMACEUTICALS, INC.

Item 6. EXHIBITS

(a) Exhibits

31.1 Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.

31.2 Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.

32.1 Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.

32.2 Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.

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SIGNATURES

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 thereunto duly authorized.

ALEXION PHARMACEUTICALS, INC.

Date: May 9, 2007

By: /s/ LEONARD BELL, M.D.
Leonard Bell, M.D.

Chief Executive Officer, Secretary and Treasurer
(principal executive officer)

Date: May 9, 2007

By: /s/ VIKAS SINHA
Vikas Sincha

Senior Vice President and Chief Financial Officer

(principal financial and accounting officer)