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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended September 30, 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 ☒ 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 ☒ 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 ☒

Common Stock, $0.0001 par value	**37,592,344**
Class	**Outstanding at November 2, 2007**

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ALEXION PHARMACEUTICALS, INC.

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ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

(in thousands, except per share amounts)	September 30, 2007	December 31, 2006
Assets		
Current Assets:		
Cash and cash equivalents	$ 91,500	$ 166,826
Marketable securities	20,413	49,728
Trade accounts receivable	31,625	—
Inventories	32,212	2,314
Prepaid manufacturing costs	6,755	—
Prepaid expenses and other current assets	8,197	3,973
Total current assets	190,702	222,841
Property, plant and equipment, net	92,964	39,135
Goodwill	19,954	19,954
Prepaid manufacturing costs	—	13,935
Restricted cash	13,825	33,594
Other assets	3,660	4,078
Total assets	$ 321,105	$ 333,537
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 10,547	$ 10,939
Accrued expenses	22,454	16,228
Deferred revenue	18	588
Current portion of capital lease obligations	267	67
Total current liabilities	33,286	27,822
Capital lease obligations, less current portion	570	283
Deferred revenue, less current portion	—	4,755
Mortgage loan	44,000	26,000
Convertible notes	150,000	150,000
Other liabilities	624	—
Total liabilities	228,480	208,860
Commitments and contingencies (Note 11)		
Stockholders' Equity:		
Preferred stock, $0.0001 par value; 5,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $0.0001 par value; 145,000 shares authorized; 37,405 and 35,568 shares issued at September 30, 2007 and December 31, 2006, respectively	4	4
Additional paid-in capital	811,769	763,691
Treasury stock, at cost, 57 shares at September 30, 2007 and December 31, 2006, respectively	(1,260)	(1,260)
Accumulated other comprehensive loss	(941)	(177)
Accumulated deficit	(716,947)	(637,581)
Total stockholders' equity	92,625	124,677
Total liabilities and stockholders' equity	$ 321,105	$ 333,537

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

ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

(in thousands, except per share amounts)	Three months ended September 30, 2007	Three months ended September 30, 2006	Nine months ended September 30, 2007	Nine months ended September 30, 2006
Revenues:				
Net product sales	$ 21,793	$ —	$ 32,524	$ —
Contract research revenues	317	263	5,660	1,370
Total revenues	22,110	263	38,184	1,370
Cost of sales	2,154	—	3,305	—
Operating expenses:				
Research and development	16,906	21,205	53,318	65,881
Selling, general and administrative	24,944	12,121	67,571	31,688
Total operating expenses	41,850	33,326	120,889	97,569
Operating loss	(21,894)	(33,063)	(86,010)	(96,199)
Other income and expense				
Investment income	1,796	1,801	6,724	5,740
Interest expense	(643)	(687)	(1,854)	(2,062)
Foreign currency gain (loss)	578	(13)	924	(13)
Loss before income tax benefit	(20,163)	(31,962)	(80,216)	(92,534)
Income tax benefit	78	90	258	270
Net loss	$(20,085)	$(31,872)	$ (79,958)	$(92,264)
Net loss per share—basic and diluted	$ (0.55)	$ (1.02)	$ (2.22)	$ (2.96)
Shares used in computing basic and diluted net loss per common share	36,664	31,264	36,023	31,154

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

ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

(in thousands)	Nine months ended September 30, 2007	2006
Cash flows from operating activities:		
Net loss	$ (79,958)	$ (92,264)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,206	2,651
Share-based compensation expense	16,386	11,402
Changes in operating assets and liabilities:		
Accounts receivable	(31,625)	—
Inventories	(29,898)	—
Prepaid expenses and other assets	1,695	595
Accounts payable and accrued expenses	7,318	(3,700)
Deferred revenue	(5,325)	(620)
Net cash used in operating activities	(118,201)	(81,936)
Cash flows from investing activities:		
Purchases of marketable securities	(96,556)	(516,974)
Proceeds from maturity or sale of marketable securities	125,878	615,353
Purchases of property, plant and equipment	(56,002)	(20,238)
Release of (increase in) restricted cash	19,768	(33,184)
Net cash (used in) provided by investing activities	(6,912)	44,957
Cash flows from financing activities:		
Payments under capital lease obligations	(97)	—
Proceeds from mortgage loan	18,000	26,000
Net proceeds from issuance of common stock	31,700	7,396
Net cash provided by financing activities	49,603	33,396
Effect of exchange rate changes on cash	184	(65)
Net change in cash and cash equivalents	(75,326)	(3,648)
Cash and cash equivalents at beginning of period	166,826	43,629
Cash and cash equivalents at end of period	$ 91,500	$ 39,981

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

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share amounts)

1. Business

Alexion Pharmaceuticals, Inc. ("Alexion" or the "Company") is engaged in the discovery, development and commercialization of biologic therapeutic products aimed at treating patients with a wide array of severe disease states, including hematologic and neurologic diseases, cancer and autoimmune disorders. From our inception in January 1992 through early 2007, we devoted substantially all of our resources to drug discovery, research, and product and clinical development.

In March 2007, the U.S. Food and Drug Administration, or FDA, granted approval for our lead product Soliris® (eculizumab) for the treatment of a rare, life-threatening blood disorder known as Paroxysmal Nocturnal Hemoglobinuria, or PNH. In June 2007, the European Commission, or E.C., also approved Soliris for the treatment of PNH.

Through September 30, 2007, our product sales have been solely attributable to sales of Soliris and have been generated from two sources: commercial sales in the United States (beginning in April 2007) and "named-patient" sales in certain European countries (beginning in the first quarter of 2007).

We have incurred operating losses since our inception. As of September 30, 2007, we had an accumulated deficit of $716,947. We expect to incur operating losses and negative cash flow for additional periods due to costs associated with the commercialization of Soliris in the United States, the launch and commercialization of Soliris in the European Union, pre-commercialization activities and anticipated commercialization activities in other territories, 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 approved to manufacture Soliris, and other infrastructure support costs.

Until we can generate sufficient levels of cash from our operations, we expect to continue to finance future cash needs primarily through the use of cash, cash equivalents and short-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements.

2. 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 of America 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 September 30, 2007, the results of our operations for the three and nine months ended September 30, 2007 and 2006, and our cash flows for the nine months ended September 30, 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 results of operations for the three and nine months ended September 30, 2007 are not necessarily indicative of the results to be expected for the full year.

The financial statements of our subsidiaries with functional currencies other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders' equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income in stockholders' equity. Foreign currency transaction gains and losses are included in the results of operations in other income (expense).

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share amounts)

Our consolidated financial statements include the accounts of the Company and our wholly-owned subsidiaries. All significant accounts, transactions and profits between the consolidated companies have been eliminated.

3. 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:

Net Product Sales

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. 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 the Company's statements of operations, in that taxes billed to customers are not included as a component of net product sales.

In the United States, our customers are primarily specialty pharmacies, distributors, physician buying groups and governmental organizations. The product is generally shipped directly from our third party warehouse to the patients' health-care provider, who is not typically our direct customer. Revenue is recorded upon receipt of the product by the patients' health-care provider, which is typically a hospital or physician's office.

In Europe, we have entered into transitional agreements with a distributor to distribute Soliris in specified European countries. Marketing authorization for Soliris was granted by the E.C. in June 2007. Through September 30, 2007, we have continued pre-commercial sales for individual patients through named-patient programs in European countries, while engaging with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required by each European country. Sales within Europe have been recorded upon receipt of product by the health-care provider, which is typically a hospital, after shipment by the distributor.

To date, actual refunds and returns have been negligible. Because of the pricing of Soliris, the limited number of patients, the short period from sale of product to patient infusion and the limited return rights, Soliris customers generally carry limited inventory. We monitor inventory within our distribution channel to determine whether reserves are required based on inventory in our sales channel.

We record rebates payable under governmental programs, including Medicaid, as a reduction of revenue at the time product sales are recorded. Our calculations related to Medicaid rebate accruals require estimates, including estimates of customer mix, to determine which sales will be subject to Medicaid rebates and the amount of such rebates. We update our estimates and assumptions each period and record any necessary adjustments to our reserves. We also record distribution and other fees paid to our customers as a reduction of revenue.

Financial instruments that potentially expose the Company to concentrations of credit risk are limited to accounts receivable. For the three months ended September 30, 2007, three individual customers each accounted for 33.7%, 19.1% and 16.3% of the accounts receivable balance. For the three months ended September 30, 2007, three individual customers each accounted for 19.8%, 16.1% and 9.2% of net product sales. For the nine months ended September 30, 2007, three individual customers each accounted for 31.7%, 24.8% and 15.0% of net product sales.

Contract Research Revenue

Effective March 30, 2007, we and Procter & Gamble Pharmaceuticals, or P&G agreed to terminate our 1999 collaboration agreement for the development and commercialization of pexelizumab. As the agreement has been terminated, the remaining portion of the $10,000 non-refundable up-front license fee, or $5,343, was recognized as revenue during the three months ended March 31, 2007.

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share amounts)

4. Inventories

Inventories are stated at the lower of cost or estimated realizable value. Cost is computed using standard cost, which approximates actual cost.

We capitalized inventory costs associated with Soliris subsequent to the filing of the Biologics License Application, or BLA. Product sold during the three and nine months ended September 30, 2007 was previously expensed prior to submission of our BLA, and therefore is not included in the cost of product revenues during this period. We continue to hold Soliris inventory that has been previously expensed. After the expensed inventory has been fully depleted, our cost of sales will then reflect the full manufacturing cost of the inventory.

We analyze our inventory levels to identify inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our product is subject to strict quality control, certain batches or units of product may, after a period of time, no longer meet quality specifications or may expire, at which point we would adjust our inventory values. Soliris currently has a maximum estimated life of 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.

To date, our work-in-process and finished goods inventory has been purchased under a third party contract arrangement with Lonza Sales AG. We will continue to sell all of our finished goods inventory which was purchased under this arrangement until our manufacturing facility in Smithfield, Rhode Island obtains regulatory approval, at which time we expect that inventory amounts purchased under our contract arrangement with Lonza will be significantly reduced.

The following table summarizes the components of our inventories:

	September 30, 2007	December 31, 2006
Raw materials	$ 3,959	$ —
Work-in-process	16,604	—
Finished goods	11,649	2,314
	$ 32,212	$ 2,314

5. Royalties

Our cost of sales for the three and nine months ended September 30, 2007 consists of actual and estimated royalties to third parties related to the sale and commercial manufacture of Soliris, as well as other manufacturing costs. We estimate royalties potentially owed to third parties based on contractual arrangements with certain parties, as well as our assessment of possible royalty amounts owed to other third parties. These estimates may be influenced by the outcome of current litigation, the results of which are uncertain (see Note 11). On a periodic basis and based on events such as the outcome of litigation, we may reassess these estimates, resulting in adjustments to cost of sales.

In July 2007, we amended our existing license agreement with the University of Iowa Research Foundation, or UIRF, to buy out the royalty payable to UIRF with respect to sales of Soliris for the treatment of PNH. Under the terms of the amended license agreement, we agreed to pay UIRF $1,000 in exchange for elimination of the royalty payable on net sales of Soliris for the treatment of PNH. Such payment was made in July 2007 and has been recorded within the long-term portion of Other Assets. The amount will be amortized to cost of sales over the estimated useful life. The payment does not affect any other product marketed by Alexion under the license, and net sales of any other product covered by the UIRF license agreement shall be subject to royalties.

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share amounts)

6. Debt

In July 2007, we amended our existing mortgage loan agreement with iStar Financial Inc. to increase the loan amount by $18,000, resulting in an aggregate principal balance of $44,000. From the effective date of the amendment, the mortgage loan bears interest at a new fixed annual rate of 9.12%. The loan principal is required to be repaid in equal monthly installments of $489, starting March 2010 and until August 2017, at which time all outstanding balances are due. The proceeds of the loan shall be used to finance the construction of our Smithfield, Rhode Island manufacturing facility and to satisfy other general corporate purposes. The other material terms and conditions of the original loan remain in force and effect.

7. Comprehensive Loss

The following table summarizes components of our comprehensive loss:

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Net loss	$(20,085)	$(31,872)	$(79,958)	$(92,264)
Net unrealized gains on available for sale securities	28	249	52	235
Foreign currency translation adjustment	(143)	(24)	(818)	(65)
Comprehensive loss	$(20,200)	$(31,647)	$(80,724)	$(92,094)

8. Exit Activities

In December 2006, we initiated an integration plan at our subsidiary, Alexion Antibody Technologies, Inc., or AAT, in San Diego, California, to consolidate certain functions and discovery research operations, including the termination of all AAT personnel, closure of AAT 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 and nine month periods ended September 30, 2007:

	Employee Related Benefits	Facility Lease Costs	Other Exit Activities	Total Exit Activities
Balance at December 31, 2006	$ 5,358	$1,379	$ 539	7,276
Revision of estimate	21	—	(144)	(123)
Payments and other settlements	(5,379)	(429)	(395)	(6,203)
Balance at September 30, 2007	$ —	$ 950	$ —	$ 950

The Company remains obligated for lease payments through 2012. In September 2007, the Company signed a sub-lease for the AAT facility, which provides for sub-lease payments through the term of the lease, or 2012. The accrual for restructuring activities reflects the present value of lease obligations, reduced by estimated sub-lease income. As of September 30, 2007, all remaining costs associated with employee related benefits and other exit activities have been paid or settled.

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share amounts)

9. Net Loss Per Common Share

Net loss per common share is computed by dividing the net loss by the weighted average shares of common stock outstanding during the 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.

Potentially dilutive securities include:

	September 30,	
	2007	2006
Options to purchase common stock	4,717,328	5,700,688
Unvested restricted stock	480,739	353,559
Common stock issuable under convertible debt	4,768,710	4,768,710
	9,966,777	10,822,957

There is no difference in basic and diluted net loss per common share for the nine months ended September 30, 2007 and 2006, respectively, as the effect of other potential common shares would be anti-dilutive.

10. Stock Options

During the three and nine month periods ended September 30, 2007, we issued 550,552 and 1,606,699 shares of common stock, respectively, with proceeds of $10,158 and $31,700, respectively, upon the exercise of outstanding stock options.

During the three and nine month periods ended September 30, 2006, we issued 92,726 and 523,488 shares of common stock, respectively, with proceeds of $1,417 and $7,344, respectively, upon the exercise of outstanding stock options.

During the three and nine month periods ended September 30, 2007, we recognized compensation expense of $4,878 and $13,090, respectively, for stock options and $1,188 and $3,296, respectively, for restricted stock. Deductions resulting from the exercise of stock options were not used to reduce current taxes payable, and therefore a windfall tax benefit was not recognized during the period.

11. Commitments and Contingencies

Litigation

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 subsequently amended its complaint to, among other things, allege (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, (ii) willful infringement by Alexion of an OMRF patent, and (iii) fraud and constructive fraud under Oklahoma law. We have denied OMRF’s claims. In addition, we filed counterclaims seeking declarations of non-infringement and invalidity of the OMRF patent. Alexion believes it has good and valid defenses to OMRF’s claims and intends to vigorously defend the case and pursue its counterclaims.

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 has denied PDL’s claims. In addition, we filed counterclaims seeking declarations of non-infringement and invalidity of certain U.S. patents held by PDL. Alexion believes it has good and valid defenses to PDL’s claims and intends to vigorously defend the case and pursue its counterclaims.

ALEXION PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share amounts)

The results of such civil actions cannot be predicted with certainty due to their early stages. However, depending on the outcome of these legal matters, the operating results of the Company could be materially impacted through adjustments to cost of sales (see Note 5).

Supply Agreement

In June 2007, we amended our supply agreement with Lonza Sales AG to provide for additional purchase commitments of Soliris through 2013 of $30,000 to $35,000. Such commitments may only be cancelled in limited circumstances.

12. Income Taxes

We currently record a full valuation allowance against our state and federal deferred tax assets and, accordingly, we do not record a tax benefit related to our significant net operating losses and other deferred tax assets. We record the benefit of certain research and development tax credits which are subject to a cash exchange with the State of Connecticut. In addition, we record current tax expense related to certain state 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 reserved 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 are not aware of any events that could occur within the next 12 months that could cause a significant change in our unrecognized tax benefits.

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 carryforwards, we may be effectively subject to U.S. federal income tax examinations for periods beginning in 1992. We are subject to examination by state and local tax authorities generally for the period mandated by statute.

13. Manufacturing Facility

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the future commercial production of Soliris, for manufacturing development and for manufacturing of future products. Since this date, we have incurred costs related to the construction of the plant to support full-scale commercial manufacturing. We have also capitalized costs related to activities necessary to obtain approval of the facility from government regulators, including engineering runs. We will begin depreciating the fixed assets related to the facility when the assets are substantially complete and ready for their intended use, which will occur upon regulatory approval of the facility.

Through September 30, 2007, we have capitalized $79,243 related to the facility, which includes all costs associated with construction, renovation and upgrades, engineering runs and capitalized interest. Through September 30, 2007, validation costs incurred in seeking regulatory approval, including engineering runs, has totaled $10,604, and capitalized interest has totaled $3,245.

ALEXION PHARMACEUTICALS, INC.
(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, the safety and efficacy of Soliris and our product candidates, estimates of the potential markets and estimated commercialization dates for Soliris, sales and marketing plans, any changes in the current or anticipated market demand or medical need for Soliris, utility of the FLAER diagnostic, status of our ongoing clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies in other countries, prospects for regulatory approval in other countries, the need for additional research and testing, the uncertainties involved in the drug development process and manufacturing, our future research and development activities, assessment of competitors and potential competitors, estimates of the capacity of manufacturing and other facilities to support Soliris and our product candidates, potential costs resulting from product liability or other third party claims, including pending litigation, the sufficiency of our existing capital resources and projected cash needs, 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," "seeks," "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 biopharmaceutical company that develops and delivers 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 and neurologic diseases, cancer, and autoimmune disorders.

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, Alexion International S.a.r.l., our European distribution and shared service center in Lausanne, Switzerland, and additional sales and marketing subsidiaries in France, United Kingdom, Italy, Spain, Germany and Switzerland.

Soliris

Soliris® (eculizumab) is designed to inhibit a specific aspect of the complement component of the immune system, and thereby treat inflammation related to chronic hematologic disorders and autoimmune disorders. Soliris is a humanized antibody that blocks complement activity for one to two weeks after a single dose at the doses currently prescribed. The initial indication for which we received FDA and E.C. approval for Soliris was PNH. PNH is a rare, debilitating and life-threatening, acquired genetic deficiency blood disorder defined by the destruction of red blood cells, or hemolysis. The chronic hemolysis in patients with PNH may be associated with life-threatening thromboses, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria).

ALEXION PHARMACEUTICALS, INC.
(in thousands, except share and per share amounts)

In March 2007, the FDA granted marketing approval for Soliris. Soliris is the first therapy approved for PNH. In the United States, 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.

In June 2007, the E.C. approved the use of Soliris for patients with PNH in the European Union, which also serves as the basis for approval in Iceland and Norway. Through September 30, 2007, we have continued pre-commercial sales for individual patients through named-patient programs in European countries, while engaging with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required by each European country. We expect to obtain commercial status in Germany and the United Kingdom in the fourth quarter 2007.

The Company has submitted an application for marketing authorization in Australia for Soliris for the treatment of patients with PNH. The application was accepted for priority review. Soliris has received Orphan Drug Designation in Australia, which provides certain regulatory and filing fee advantages, including market exclusivity for several years after approval. We have recently been authorized by the Pharmaceutical and Medical Devices Agency in Japan to begin our clinical trial of Soliris for PNH and expect to commence dosing in early 2008.

Recent Clinical Developments

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 myelodysplastic syndromes. We are also conducting the global PNH Patient Registry to study the natural history of PNH. Patients in some European countries, Australia and Canada continue to participate in the Phase IIIb E05-001 trial.

In July 2007, the Company acquired exclusive world-wide rights to FLAER, a highly sensitive diagnostic test for PNH. The FLAER test reagent has been shown to permit a more accurate determination of the size of the PNH clone as compared to standard flow cytometry reagents. The Company is currently reviewing optimal methods for making the FLAER test reagents more widely available.

We are also focusing our research efforts on the use of eculizumab in other rare and severe complement-mediated conditions, particularly chronic and debilitating neurological disorders. Separate studies on the effectiveness of eculizumab in treating myasthenia gravis or multifocal motor neuropathy are expected to begin in early 2008. In Canada, we have received regulatory approval from Health Canada to begin testing intravenous eculizumab in severe asthma patients and have begun the patient screening process for this trial.

In addition, we anticipate beginning a clinical study of Anti-CD200 antibody in chronic lymphocytic leukemia in early 2008.

Manufacturing

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island for the future commercial production of Soliris, for manufacturing development and for manufacturing of future products. Since this date, we have incurred costs related to the construction of the plant to support full-scale commercial manufacturing. We have also capitalized costs related to activities necessary to obtain approval of the facility from government regulators, including engineering runs. We will begin depreciating the fixed assets related to the facility when the facility is substantially complete and ready for its intended use, which will occur upon regulatory approval of the facility. We estimate that regulatory approval will occur in 2009.

Through September 30, 2007, we have capitalized $79,243 related to the facility, which includes all costs associated with construction, renovation and upgrades, engineering runs and capitalized interest. Through September 30, 2007, validation costs incurred in seeking regulatory approval, including engineering runs, has totaled $10,604, and capitalized interest has totaled $3,245.

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In July 2007, we amended our existing mortgage loan agreement with iStar Financial Inc. to increase the loan amount by $18,000, resulting in an aggregate principal balance of $44,000. The proceeds of the loan are to be used to finance the construction of the Smithfield, Rhode Island manufacturing facility and to satisfy other general corporate purposes. From the effective date of the amendment, the mortgage loan bears interest at a new fixed annual rate of 9.12%. The loan principal is required to be repaid in equal monthly installments of $489, starting March 2010 and until August 2017, at which time all outstanding balances are due. The other material terms and conditions of the original loan remain in force and effect.

A single third party contractor provides finished vials of Soliris. The contractor notified us that the FDA conducted an inspection of its facility and identified several deficiencies. We are currently assessing the contractor's ability to address and remedy the deficiencies with the FDA. The reported deficiencies do not affect the use of our current inventory of Soliris, and we do not believe that such deficiencies will have any material affect on the future production or supply of Soliris. We are currently evaluating other third parties to supplement the vialing services provided by this contractor.

License Agreements

In July 2007, we amended our existing license agreement with the University of Iowa Research Foundation, or UIRF, to buy out the royalty payable to UIRF with respect to sales of Soliris for the treatment of PNH. Under the terms of the amended license agreement, we agreed to pay UIRF $1,000 in exchange for elimination of the royalty payable on net sales of Soliris for the treatment of PNH. Such payment was made in July 2007. The payment does not affect any other product marketed by Alexion and net sales of any other product covered by the UIRF license agreement shall be subject to royalties.

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.

Our 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." Changes and/or additions to our critical accounting policies during 2007 are outlined below.

Revenue

To date, our product sales have consisted solely of Soliris for the treatment of PNH. 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. 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 the Company's statements of operations, in that taxes billed to customers are not included as a component of net product sales.

In the United States, our customers are primarily specialty pharmacies, distributors, physician buying groups and governmental organizations. The product is generally shipped directly from our third party warehouse to the patients' health-care provider, who is not our direct customer. Revenue is recorded on this transaction upon receipt of the product by the patients' health-care provider, which is typically a hospital or physician's office.

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In Europe, we have entered into transitional agreements with a distributor to distribute Soliris in specified European countries. Through September 30, 2007, we have continued pre-commercial sales for individual patients through named-patient programs in European countries, while engaging with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required by each European country. Sales within Europe have been recorded upon receipt of product by the health-care provider, which is typically a hospital, after shipment by the distributor.

To date, actual refunds and returns have been negligible. Because of the pricing of Soliris, the limited number of patients, the short period from sale of product to patient infusion and limited return rights, Soliris customers generally carry limited inventory. Accordingly, we expect that sales related to Soliris will be closely tied to patient demand. We monitor inventory within our distribution channel to determine whether reserves are required related to inventory in our sales channels. To the extent that our actual experience differs from our estimates, we will revise these estimates resulting in an impact in the period in which the adjustment was made.

We record rebates payable under governmental programs, including Medicaid, as a reduction of revenue at the time product sales are recorded. Our calculations related to Medicaid rebate accruals require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any necessary adjustments to our reserves. Generally, the length of time between product sale and the processing and reporting of the rebate is three to nine months. Upon reconciliation of government reporting to our sales records, we will revise our estimates of rebates payable, which will have an impact on revenue in the period in which the adjustment was made.

We also record distribution and other fees paid to our customers as a reduction of revenue. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

Inventories

Inventories are stated at the lower of cost or estimated realizable value. Cost is computed using standard cost, which approximates actual cost.

We capitalized inventory costs associated with Soliris subsequent to the filing of the Biologics License Application, or BLA. Product sold during the three and nine months ended September 30, 2007 was previously expensed prior to submission of our BLA, and therefore is not included in the cost of product revenues during this period. We continue to hold Soliris inventory that has been previously expensed, and we estimate that we will exhaust this supply of inventory during the fourth quarter of 2007. After the expensed inventory has been fully depleted, our cost of sales will then reflect the full manufacturing cost of the inventory.

We analyze our inventory levels to identify inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our product is subject to strict quality control, certain batches or units of product may, after a period of time, no longer meet quality specifications or may expire, at which point we would adjust our inventory values. Soliris currently has a maximum estimated life of 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.

The determination of whether or not inventory costs will be realizable requires estimates by our management. A critical input in this determination is future expected inventory requirements, based on internal sales forecasts. We then compare these requirements to the expiry dates of inventory on hand. To the extent that inventory is expected to expire prior to being sold, we will writedown the value of inventory. If actual results differ from those estimates, additional inventory write-offs may be required.

To date, we have not recorded any material adjustments to our inventory related to excess, expired or obsolete inventory. In the future, reduced demand, quality issues or excess supply may result in writedowns, which would be recorded as adjustments to cost of sales.

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Results of Operations

Comparison of the Three and Nine Months ended September 30, 2007 to the Three and Nine Months ended September 30, 2006

Revenues

Net product sales

During the three and nine months ended September 30, 2007, we have recorded sales of Soliris related to commercial sales in the United States and named-patient sales in the European Union. We generated net product sales of Soliris for the three and nine months ended September 30, 2007 of $21,793 and $32,524, respectively.

Because our pre-approval sales programs did not begin until 2007, there were no sales of Soliris for the three and nine months ended September 30, 2006. As additional PNH patients request Soliris and obtain reimbursement, we expect that the number of patients receiving Soliris will increase, resulting in increased commercial sales in the United States and Europe.

We have continued pre-commercial sales for individual patients through named-patient programs in European countries, while engaging with appropriate authorities on the operational, reimbursement, price approval and funding processes that are separately required by each European country. We expect European sales to increase as we finalize procedures in each country, expand the number of patient programs in Europe and transition to sales of commercial product.

Contract research revenue

	Three months ended September 30,		Increase/ (Decrease)	Nine months ended September 30,		Increase/ (Decrease)
	2007	2006	% Change	2007	2006	% Change
P&G	$ —	$ 147	-100%	$ 5,343	$ 441	1112%
U.S. government grants	317	116	173%	317	829	-62%
Other revenue	—	—	0%	—	100	100%
Total revenues	$ 317	$ 263	21%	$ 5,660	$ 1,370	313%

We recorded contract research revenues of $317 and $116 for the three months ended September 30, 2007 and 2006, respectively, and $317 and $829 for the nine months ended September 30, 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 and U.S. government funded research grant revenue for our asthma program.

For the nine months ended, September 30, 2007, the decrease in U.S. government grants, as compared to the same period in the prior year, was primarily due to the conclusion of the anthrax program in 2006.

Effective March 30, 2007, we and P&G agreed to terminate our 1999 collaboration agreement for the development and commercialization of pexelizumab. As the agreement has been terminated, the remaining portion of the $10,000 non-refundable up-front license fee, or $5,343, was recognized as revenue during the three months ended March 31, 2007. Due to the termination of the P&G agreement, we expect that future contract research revenue will be dependent upon future awards or grants.

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Financial instruments that potentially expose the Company to concentrations of credit risk are limited to accounts receivable. For the quarter ended September 30, 2007, three individual customers accounted for 33.7%, 19.1% and 16.3% of the accounts receivable balance. For the quarter ended September 30, 2007, three individual customers accounted for 19.8%, 16.1% and 9.2% of the net product sales. For the nine months ended September 30, 2007, three individual customers accounted for 31.7%, 24.8% and 15.0% of the net product sales.

Cost of sales

Cost of sales was $2,154 and $3,305 for the three and nine months ended September 30, 2007. Cost of sales during both periods includes actual and estimated royalty expenses associated with sales of Soliris, as well as other manufacturing costs. Changes in the estimates of royalties owed to certain third parties could have a material impact on our cost of sales in future periods.

Product sold during the three and nine months ended September 30, 2007 was previously expensed prior to submission of our BLA, and therefore is not included in the cost of sales during this period. We continue to hold Soliris inventory that has been previously expensed and, based on current sales forecasts, we estimate that we will exhaust this supply of inventory during the fourth quarter of 2007. After the expensed inventory has been fully depleted, our cost of sales will increase, reflecting the full manufacturing cost of the inventory.

Research and Development

Our research and development expense includes personnel, facility and external costs associated with the research and development of our product candidates, as well as product development costs related to Soliris, including regulatory filings, post-marketing expenses and patient registries. These research and development costs primarily include preclinical and clinical studies, discovery research, quality control and assurance, pharmacovigilance costs, and other product development expenses, such as regulatory costs.

The following table provides information regarding the changes in research and development expenses. The clinical development, product development and discovery research groupings exclude the costs of payroll and benefits, operating and occupancy and depreciation and amortization, which are listed separately for the periods presented:

	Three months ended September 30,		Increase/ (Decrease)	Nine months ended September 30,		Increase/ (Decrease)
	2007	2006	$ Change	2007	2006	$ Change
Clinical development	$ 2,735	$ 7,942	$ (5,207)	$13,022	$27,713	$(14,691)
Product development	2,576	2,357	219	8,013	7,395	618
Discovery research	1,091	1,166	(75)	2,310	3,159	(849)
Payroll and benefits	8,231	7,963	268	24,277	21,865	2,412
Operating and occupancy	1,714	1,207	507	4,075	3,966	109
Depreciation and amortization	559	571	(12)	1,621	1,783	(162)
Research and development expense	$16,906	$21,206	(4,300)	$53,318	$65,881	(12,563)

Research and development expenses decreased $4,300 for the three months and $12,563 for the nine months ended September 30, 2007, as compared to the same periods in 2006 respectively.

For the three months ended September 30, 2007, the decrease in research and development expense, as compared to the same period in the prior year, was primarily related to the following:

- Decrease of $5,207 in clinical development expense due largely to decreases in spending for pexelizumab programs of $2,505, the reduction or completion of eculizumab programs, including TRIUMPH, SHEPHERD and EXTENSION and incurrence of costs in association with the filing of the BLA of $4,541. These decreases were offset by increases of $1,566 related to new programs in 2007, including EXPLORE, EMBRACE and the PNH registry.

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- Increase of $507 in operating and occupancy due largely to the build-out of our Cheshire, Connecticut headquarters location and the closing of our pilot plant and office space located in New Haven, Connecticut.

For the nine months ended September 30, 2007, the decrease in research and development expense as compared to the same period in the prior year was primarily related to the following:

- Decrease of $14,691 in clinical development expense due largely to decreases in spending for pexelizumab program of $8,962, the reduction or completion of eculizumab programs, including TRIUMPH, SHEPHERD and EXTENSION and incurrence of costs in association with filing the BLA of $8,675. These decreases were offset by increases of $6,253 related to new programs in 2007, including EXPLORE, EMBRACE and the PNH registry.
- Increase of $618 in product development expense due to an increase of $4,034 related to expenditures for drug development, quality assurance, scientific communications and regulatory affairs due to the regulatory approvals in both the United States (March 2007) and the European Union (June 2007). The increase was offset by a decrease in manufacturing costs of $3,416 related to the capitalization of inventory costs beginning with filing of the BLA in September 2006. Prior to September 2006, we expensed all manufacturing costs, resulting in lower 2007 expenses compared to 2006.
- Increase of $2,412 in research and development payroll and benefit expense resulting from an increase in share-based compensation, salary and wage growth compared to 2006, primarily related to increased headcount in the Company's regulatory affairs, quality assurance and pharmacovigilance departments. The Company increased headcount in anticipation of enhanced regulatory obligations following approvals of Soliris in both the United States and the European Union.
- Decrease of $849 in non-labor discovery research expense, due to the closure of AAT operations of $2,188, offset by an increase of $1,341 in expenditures for pre-clinical programs.

Selling, General and Administrative Expenses

Our selling, general and administrative expense includes commercial and administrative personnel, corporate facility and external costs required to support the marketing and sales of our commercialized products. These selling, general and administrative costs include: corporate facility operating expenses and depreciation; marketing and sales operations in support of Soliris; human resources; finance, legal, information technology and support personnel expenses; and other corporate costs such as telecommunications, insurance, audit and legal expenses.

The following table provides information regarding the change in selling, general and administrative expenses during the periods presented (amounts in thousands):

	Three months ended September 30,		Increase/ (Decrease)	Nine months ended September 30,		Increase/ (Decrease)
	2007	2006	$ Change	2007	2006	$ Change
Selling, general and administrative expense	$24,944	$12,121	$ 12,823	$67,571	$31,688	$ 35,883

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Selling, general and administrative expenses increased $12,823 for the three months ended September 30, 2007 and $35,883 for the nine months ended September 30, 2007, as compared to the same periods of 2006, primarily due to the following:

- Increase in salary, benefits and other labor expenses of $8,038 and $21,859 for the three and nine months ended September 30, 2007, respectively, which included increased share-based compensation cost of $1,131 and $4,007. The increases in these costs were a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of $4,721 and $13,046 related to our global commercial operations teams. Other increases related to payroll and benefits within our executive, finance, information technology, human resources and legal groups to support our growth as a commercial entity.
- Increase in non-labor commercial operations of $1,092 and $11,278 for the three and nine months ended September 30, 2007, respectively. For the three and nine months ended September 30, 2007, this increase was comprised primarily of increases in advertising and promotion of Soliris related to the April 2007 commercial launch in the United States and market research related to approval of Soliris in the European Union.
- Increase in non-labor general and administration of $3,022 for the three months ended September 30, 2007 related to increases in infrastructure costs to support our growth as a commercial entity. Non-labor general and administration costs for the nine months ended September 30, 2007 were consistent with those for the comparable prior year period.

Other Income and Expense

We recognize investment income primarily from our portfolio of short-term marketable securities. Investment income was $1,796 and $6,724 for the three and nine months ended September 30, 2007, respectively, as compared to $1,801 and $5,740 for the same period in 2006. The increase for the nine-month period ended September 30, 2007 was due primarily to a higher cash position and higher market interest rates.

We incur interest expense on convertible note, mortgage debt and capital lease obligations. Our interest expense is net of interest capitalized related to the construction of our Rhode Island manufacturing facility, which was $919 and $2,317 for the three and nine months ended September 30, 2007, respectively. Interest expense was $643 and $1,854 for the three and nine months ended September 30, 2007, as compared to $687 and $2,062 for the same period in 2006. The decrease reflects the additional capitalization of interest in connection with the acquisition and construction of the Smithfield, Rhode Island manufacturing facility.

Foreign currency transaction gains relate to our operations in Europe, which increased significantly beginning in 2007. The foreign currency transaction gains totaled $578 and $924 for the three and nine months ended September 30, 2007 and were primarily a result of the weaker U.S. Dollar compared to the Euro.

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Income Taxes

We currently record a full valuation allowance against our state and federal deferred tax assets and, accordingly, we do not record a tax benefit related to our significant net operating losses and other deferred tax assets. We record current tax expense related to certain state income taxes. In addition, we record the benefit of certain research and development tax credits which are subject to a cash exchange with the State of Connecticut. We recorded a state tax benefit of $78 and $258 for the three and nine months ended September 30, 2007 and 2006.

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, impacts the effective tax rate due to our full valuation allowance against deferred tax assets.

Net Loss

The Company incurred a net loss for the three and nine month periods ended September 30, 2007 of $20,085 and $79,958 or $0.55 and $2.22 per common share, respectively, versus a net loss of $31,872 and $92,264 or $1.02 and $2.96 per common share, respectively, for the same periods in 2006.

Liquidity and Capital Resources

As of September 30, 2007, our consolidated cash, cash equivalents, marketable securities and restricted cash totaled $125,738, a decrease of $124,410, from $250,148 at December 31, 2006. The reduction in cash held was primarily due to our ongoing expenditures for commercialization efforts related to Soliris in the United States and the European Union, expenditures on our Rhode Island manufacturing facility, inventory purchases, and our continuing product research and development efforts. Until required for use in the business, we invest our cash reserves in money market funds and high quality commercial, corporate and U.S. Government notes in accordance with our investment policy.

As of September 30, 2007, $13,825 of cash was restricted to be used for the construction and other costs related to our Rhode Island manufacturing facility.

At September 30, 2007, our working capital was $157,416, compared to $195,019 at December 31, 2006.

We have incurred operating losses since our inception. As of September 30, 2007, we had an accumulated deficit of $716,947. We expect to incur operating losses and negative cash flows for additional periods due to costs 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.

Until we can generate sufficient levels of cash from our operations, we expect to continue to finance future cash needs primarily through cash, cash equivalents and short-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements. The requirement to obtain additional cash from debt or equity financing will be highly dependent on our sales, and related cash collections, of Soliris in the United States and European Union.

We anticipate that cash generated from operations and 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.

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Operating Activities

Net cash used in operating activities was $118,201 and $81,936 for the nine months ended September 30, 2007 and 2006, respectively, an increase of $36,265, or 44.3%. 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. The components of cash used in operating activities for the nine months ended September 30, 2007 are as follows:

- Net loss of $60,366, net of non-cash changes
- Changes in operating assets of $59,828, primarily attributable to increases in inventories and accounts receivable, as well as the recognition of revenue related to the termination of our P&G collaboration. Due to the payment terms granted to our U.S. and European Union customers, a significant portion of our product sales to date have not yet been collected. These increases were offset by an increase in our accrued expenses for compensation expenses and estimated royalties.

Investing Activities

Net cash used in investing activities was $6,912 for the nine months ended September 30, 2007 versus $44,957 provided by investing activities for the nine months ended September 30, 2006. For the nine months ended September 30, 2007, the net cash used for investing activities consisted of the following:

- $29,322 from the net purchase and sale of marketable securities, which was used to fund our operations
- $56,002 of additions to property, plant and equipment, of which $50,162 was attributable to the construction of our Rhode Island manufacturing facility, with the remaining attributable to Information Technology and facility capital costs
- $19,768 of restricted cash used for construction of our Rhode Island manufacturing facility pursuant to the terms of our mortgage loan.

Financing Activities

Net cash provided by financing activities was $49,603 and $33,396 for the nine months ended September 30, 2007 and 2006, respectively, consisting primarily of proceeds from the issuance of common stock related to the exercise of stock options and proceeds from the amendment of our mortgage loan agreement with iStar.

Borrowings and Contractual Obligations

The disclosure of payments we have committed to make under our contractual obligations 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 “Contractual Obligations.” There have been no material changes in our contractual obligations since December 31, 2006 except as disclosed below under the heading Mortgage Debt with respect to the amendment of our mortgage loan agreement with iStar Financial Inc. and under the heading Lonza Agreement with respect to the amendment of our supply agreement with Lonza Sales AG.

Significant borrowings and contractual obligations include the following:

Convertible Notes

We hold $150,000 principal amount of 1.375% Convertible Senior Notes due February 1, 2012, or the 1.375% Notes. We pay interest on these notes on a semi-annual basis on February 1 and August 1 of each year, beginning August 1, 2005. However, no principal payments are due until February 2012, except under certain circumstances such as liquidation, merger or business combination. We do not have financial covenants related to the convertible debt.

The 1.375% Notes are convertible into our common stock at an initial conversion rate of 31.7914 shares of common stock (equivalent to a conversion price of approximately $31.46 per share) per $1 principal amount of the 1.375% Notes, subject to adjustment, at any time prior to the close of business on the final maturity date of the notes. We do not have the right to redeem any of the 1.375% Notes prior to maturity.

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As of September 30, 2007, the market value of our $150,000, 1.375% Convertible Notes due February 1, 2012, based on quoted market prices, was estimated at $321,000. The $103,875 increase from December 31, 2006 is largely attributable to the increase in the price of our common stock during the period.

Mortgage Debt

In July 2007, we amended our existing mortgage loan agreement with iStar Financial Inc. to increase the loan amount by $18,000, resulting in an aggregate principal balance of $44,000. From the effective date of the amendment, the mortgage loan bears interest at a new fixed annual rate of 9.12%. The loan principal is required to be repaid in equal monthly installments of $489, starting March 2010 and until August 2017, at which time all outstanding balances are due. The proceeds of the loan shall be used to finance the construction of our Smithfield, Rhode Island manufacturing facility and to satisfy other general corporate purposes. The other material terms and conditions of the original loan remain in force and effect.

The loan may not be prepaid in whole or in part prior to July 2009. After that date the loan can be prepaid in whole, but not in part, and must include a prepayment premium as described in the loan agreement.

We do not have financial covenants related to the mortgage debt.

Lonza Agreement

We have a supply agreement with Lonza Sales AG relating to the manufacture of Soliris, which requires payments to Lonza at the inception of the contract and as product is manufactured. We are required to prepay certain amounts related to the production of Soliris, which are reflected as prepaid manufacturing costs. Once we take title to the inventory produced by Lonza, the amounts are reclassified into inventory. On a quarterly basis, we evaluate our plans to proceed with production under the agreement which depends upon our commercial requirements as well as the progress of our clinical development programs.

In June 2007, we amended our supply agreement to provide for additional purchase commitments of Soliris through 2013 of $30,000 to $35,000. Such commitments may only be cancelled in limited circumstances.

We have agreed to purchase certain minimum quantities of product from Lonza under our existing arrangements. If we terminate the Lonza Agreement without cause, we will be required to pay for batches of product scheduled for manufacture under our arrangement.

Item 3. Quantitative and Qualitative Disclosure about Market Risks

Interest Rate Market Risk

As of September 30, 2007, we held 83.7% of our cash and investments in financial instruments with original maturity dates of three months or less which includes restricted cash, 2.9% in financial instruments with original maturity dates of greater than three months and less than one year, and the remaining 13.4% 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 $28 in the fair value of our cash and investments.

Our outstanding long-term liabilities as of September 30, 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 September 30, 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 $321,000.

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Through July 2007, we borrowed $44,000 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.

Foreign Exchange Market Risk

As a result of our European operations, we may face exposure to adverse movements in foreign currency exchange rates, primarily to the Euro. These exposures arise primarily from monetary instruments, primarily accounts receivable and intercompany receivables and payables denominated in foreign currencies.

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 (i) information required to be disclosed by us in the reports that we file under the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and (ii) information relating to us and required to be included in the reports we file under the Exchange Act is accumulated and communicated to our management, including 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 control 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

As previously reported in Alexion's filings with the SEC, Oklahoma Medical Research Foundation, or OMRF, and PDL BioPharma, Inc., or PDL, each filed a civil action against Alexion in federal district court.

On March 15, 2007, OMRF filed a civil action against Alexion in the U.S. District Court for the Northern District of Oklahoma. OMRF subsequently amended its complaint to, among other things, allege (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, (ii) willful infringement by Alexion of an OMRF patent, and (iii) fraud and constructive fraud under Oklahoma law. OMRF seeks, among other things, declaratory judgment, judicial accounting, and actual, compensatory, consequential and punitive damages, plus attorney's fees. Alexion has denied OMRF's claims and has filed counterclaims. Alexion alleges breach of contract by OMRF of the 1992 license agreement, and also seeks declarations of non-infringement and invalidity of U.S patent no. 5,635,178. Alexion believes it has good and valid defenses to OMRF's claims and intends to vigorously defend the case and pursue its counterclaims.

On March 16, 2007, 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 has denied PDL's claims. In addition, we filed counterclaims seeking declarations of non-infringement and invalidity of PDL patents U.S. no. 5,693,761, no. 5,693,762 and no. 6,180,370 B1.

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 occurs, 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, Soliris, which was approved in the United States and in Europe in March 2007 and June 2007, respectively. If we are unable to successfully commercialize Soliris or if we are significantly delayed or limited in doing so, our business will be materially harmed.

Our ability to generate revenues will depend on successful commercialization of Soliris in the United States and 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 Europe and successfully continuing commercial sales in the United States;
- 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; and
- establishing commercial manufacturing capabilities ourselves or through third-party manufacturers.

We obtained marketing approval for Soliris in Europe in June 2007 and engaged the appropriate authorities in major markets on the operational, reimbursement, price approval and funding processes that are separately required by each European country. We expect to achieve commercial status during the fourth quarter of 2007 in Germany and the United Kingdom. We cannot guarantee that reimbursement and other processes will be concluded by such time and, as a result, commercial sales in Europe may be delayed. If we are not successful in commercializing Soliris in the United States and in Europe, or are significantly delayed or limited in doing so, 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 otherwise 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 are marketing and selling Soliris ourselves in the United States and through our subsidiaries in Europe, but have only limited experience thus far with marketing, sales or distribution of drug products. We have hired sales representatives for the commercialization of Soliris in the United States and have established commercial capability in Europe. If we are unable to establish and maintain capabilities to sell, market and distribute our product, either through our own capabilities or by 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 establish 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 successfully conclude the necessary processes and commercialize Soliris in every country in Europe. Reimbursement sources are different in each European country and in each country may include a combination of distinct potential payers, including private insurance and governmental payers. 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, on our own, until such time as we have requested and received the required regulatory approvals for our manufacturing facility in Rhode Island. 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 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 supplier for Soliris, in addition to loss of sales, we may also incur significant costs in establishing a new arrangement.

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We are dependent upon a small number of customers for a significant portion of our revenue, and the loss of, or significant reduction or cancellation in sales to, any one of these customers could adversely affect our operations and financial condition.

We sell Soliris to distributors who in turn sell to patient health-care providers. We do not promote Soliris to these distributors and they do not set or determine demand for Soliris. However, for the quarter ended September 30, 2007, our three top customers accounted for approximately 19.8%, 16.1% and 9.2% of our net product sales, and we expect such customer concentration to continue for the foreseeable future. Our ability to successfully commercialize Soliris will depend, in part, on the extent to which we are able to provide adequate distribution of Soliris to patients. Although a number of specialty pharmacies, physician buying groups and governmental organizations distribute Soliris, they generally carry a very limited inventory and may be reluctant to distribute Soliris or increase their inventory in the future if demand for the product does not increase. Further, it is possible that our distributors could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to distribute smaller volume products such as Soliris, or cause higher product distribution costs, lower margins or the need to find alternative methods of distributing our product. Although we believe we can find alternative distributors on a relatively short notice, our revenue during that period of time may suffer and we may incur additional costs in switching from one distributor to another. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us or any failure to pay for the products we have shipped to them could materially and adversely affect our results of operations and financial condition.

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 and Europe, it does not guarantee future revenue. 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 in the United States, 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. In the United States, 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 or other parties at adequate levels, if at all. We also 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.

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. We are currently engaging the appropriate authorities in major European markets on the operational, reimbursement, price approval and funding processes that are separately required by each European country. Our results of operations may suffer if we are unable to successfully and timely conclude such processes and begin 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 approvals could be revoked or otherwise negatively impacted 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 and potentially life-threatening health risks, including for example bone marrow failure. 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 other countries, or impact and limit the type of regulatory approvals Soliris receives.

Some patients treated with eculizumab for PNH or other diseases, including 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 certain types of infection, including 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 and Europe are required by prescribing guidelines to be vaccinated prior to receiving the first dose; however, vaccination does not eliminate all risk of becoming infected with Neisseria bacteria. Some patients treated with eculizumab for PNH, including patients who have participated in our trials of eculizumab for the treatment of PNH and other diseases and who had been vaccinated, have become infected with 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. We acquired a commercial-scale manufacturing plant in Smithfield, Rhode Island in July 2006. However, that plant is not currently approved by the FDA or other regulatory agencies to manufacture Soliris or our other drug candidates. We expect that it will be at least eighteen to twenty-four months before product from the plant is approved for commercial sale in the United States. 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 facility 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. 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. 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 marketing 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 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 minimis 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 September 30, 2007, we had an accumulated deficit of approximately $717 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 expect commercial sales in Europe to begin during the fourth quarter of 2007. We cannot guarantee that we will be successful in commercializing Soliris in the United States and Europe and we do not know when we will have products available for sale in other countries and regions, 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 in the United States and Europe, on receiving regulatory approval of Soliris in other countries, 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 the commercialization of Soliris or 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 products and product candidates. We are currently preparing for the commercialization of Soliris in several countries 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 throughout Europe, and as we initiate new clinical trials for our product candidates.

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 Europe 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 announced the termination of 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.

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

Both the FDA and the European Medicines Evaluation Agency, or 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 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, Potentia Pharmaceuticals, Inc., Ophthotech Corporation 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 to 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 Soliris or 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, we may not be able to implement our business strategy.

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 biopharmaceutical 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 are unable to retain and recruit highly qualified personnel, our ability to execute our business plan 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.

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We are significantly leveraged.

On September 30, 2007, we had outstanding $150 million principal amount of 1.375% convertible senior notes which will mature on February 1, 2012. Our subsidiary Alexion Manufacturing borrowed $44 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 9.12%. The loan principal is required to be repaid in equal monthly installments of $489, starting March 2010 and until August 2017, at which time all outstanding balances are due. 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.

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 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 thereunder, 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 approvals in the United States or in Europe, we will not be able to sell Soliris in such market.

We and our partners cannot sell or market our products without regulatory approval. We obtained marketing approval of Soliris in the United States and in Europe for PNH. We cannot guarantee that we will be able to maintain our regulatory approvals for Soliris. If we do not maintain our regulatory approvals for Soliris, the value of our company and our results of operations will be materially 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. Governments in Europe 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 jurisdictions in Europe, we are required to finalize operational, reimbursement, price approval and funding processes prior to marketing our products. As of September 30, 2007, such processes have not been finalized for Soliris in any country in the European Union. We may not receive regulatory approval for Soliris outside the United States and Europe or for any of our product candidates for at least the next several years, if ever.

ALEXION PHARMACEUTICALS, INC.

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, the FDA or governmental authorities in other countries may require us to conduct additional clinical trials. For example, in connection with the approval of Soliris in the United States, 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 an approved indication. We are required to report any serious and unexpected adverse experiences and certain quality problems with Soliris to the FDA and the EMEA. We, the FDA or the EMEA may have to 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 regulatory 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, the EMEA 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 and Europe, we may be unable to obtain regulatory approval for Soliris in any other territory.

Regulatory agencies may require additional information or data with respect to our submissions for Soliris for PNH. 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 and the E.C., other regulatory agencies 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 those circumstances, we would not be able to obtain regulatory approval in such country on a timely basis, if ever. Even if approval is granted in such country, 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.

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 be materially harmed.

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;
- 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, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish 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. 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, and other intellectual property, 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, 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 or the right to practice 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/or obtain a license to continue the manufacture, sale or development of our drugs. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our drugs, including Soliris, which would adversely affect our business.

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 an OMRF patent. 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, and 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 sales of Soliris. If we cannot successfully defend against these or any other future actions or conflicts, we may be liable for damages, be required to obtain costly licenses or have to stop manufacturing, using or selling Soliris, which would adversely affect our business.

Additional third parties may claim that the manufacture, use or sale of Soliris or other drugs under development 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 by such third parties 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;
- 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; that we would 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 Soliris or 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, and market conditions for biopharmaceutical 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 biopharmaceutical 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, the results of our efforts to obtain regulatory approval for our products and sales of Soliris. 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.

ALEXION PHARMACEUTICALS, INC.

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 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 6. EXHIBITS

(a) Exhibits

10.1	First Amendment to Loan Agreement and Other Loan Documents, dated July 18, 2007, by and between Alexion Manufacturing LLC, as borrower, and iStar Financial Inc., as lender (1)
10.2	Amended and Restated Promissory Note, dated July 18, 2007 issued by Alexion Manufacturing LLC (1)
10.3	First Amendment to Construction Mortgage Deed, Assignment of Leases and Rents, Security Agreement and Fixture Filing, dated July 18, 2007, by Alexion Manufacturing LLC in favor of iStar Financial Inc. (1)
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 September 30, 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 September 30, 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 September 30, 2007.

ALEXION PHARMACEUTICALS, INC.

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 September 30, 2007.

(1) Incorporated by reference to our report on Form 8-K, filed on July 23, 2007.

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: November 9, 2007

By: /s/ Leonard Bell
Leonard Bell, M.D.
Chief Executive Officer, Secretary and Treasurer
(principal executive officer)

Date: November 9, 2007

By: /s/ Vikas Sinha
Vikas Sinha
Senior Vice President and Chief Financial Officer
(principal financial officer)

Exhibit 31.1

I, Leonard Bell, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a – 15(f) and 15d – 15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 9, 2007

/s/ Leonard Bell

Leonard Bell, M.D.
Chief Executive Officer

Exhibit 31.2

I, Vikas Sinha, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a – 15(f) and 15d – 15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 9, 2007

/s/ Vikas Sinha

Vikas Sinha
Senior Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc. (the "Company") for the fiscal quarter ended September 30, 2007 as filed with the Securities and Exchange Commission (the "Report"), I, Leonard Bell M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 9, 2007

/s/ Leonard Bell
Leonard Bell, M.D.
Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Alexion Pharmaceuticals, Inc. (the "Company") for the fiscal quarter ended September 30, 2007 as filed with the Securities and Exchange Commission (the "Report"), I, Vikas Sinha, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 9, 2007

/s/ Vikas Sinha
Vikas Sinha
Senior Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.