

ALEXION PHARMACEUTICALS INC

Form 10-Q

August 07, 2007

[Table of Contents](#)

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 June 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
(State or other jurisdiction of

incorporation or organization)

352 Knotter Drive, Cheshire, Connecticut 06410

(Address of principal executive offices) (Zip Code)

203-272-2596

(Registrant's telephone number, including area code)

13-3648318
(I.R.S. Employer

Identification No.)

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

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
Class**

**37,137,557
Outstanding at August 2, 2007**

Table of Contents

ALEXION PHARMACEUTICALS, INC.

INDEX

	Page
PART I. FINANCIAL INFORMATION	
Item 1. Condensed Consolidated Financial Statements (Unaudited)	
<u>Condensed Consolidated Balance Sheets as of June 30, 2007 and December 31, 2006</u>	2
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2007 and 2006</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2007 and 2006</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	5
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	11
Item 3. Quantitative and Qualitative Disclosures about Market Risk	20
Item 4. Controls and Procedures	21
<u>PART II. OTHER INFORMATION</u>	22
Item 1. Legal Proceedings	22
Item 1A. Risk Factors	22
Item 4. Submission of Matters to a Vote of Security Holders	37
Item 6. Exhibits	38
<u>SIGNATURES</u>	39

Table of Contents

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

(in thousands, except per share amounts)	June 30, 2007	December 31, 2006
Assets		
Current Assets:		
Cash and cash equivalents	\$ 112,764	\$ 166,826
Marketable securities	30,130	49,728
Trade accounts receivable	10,265	
Inventories	14,944	2,314
Prepaid manufacturing costs	13,915	
Prepaid expenses and other current assets	4,842	3,973
Total current assets	186,860	222,841
Property, plant and equipment, net	76,749	39,135
Goodwill, net	19,954	19,954
Prepaid manufacturing costs		13,935
Restricted cash	9,526	33,594
Other assets	3,801	4,078
Total assets	\$ 296,890	\$ 333,537
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 8,041	\$ 10,939
Accrued expenses	15,638	16,228
Deferred revenue		588
Current portion of capital lease obligations	262	67
Total current liabilities	23,941	27,822
Capital lease obligations	638	283
Deferred revenue, less current portion		4,755
Mortgage loan	26,000	26,000
Convertible notes	150,000	150,000
Total liabilities	200,579	208,860
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Preferred stock, \$.0001 par value; 5,000 shares authorized, no shares issued or outstanding		
Common Stock, \$.0001 par value; 145,000 shares authorized; 36,813 and 35,568 shares issued at June 30, 2007 and December 31, 2006, respectively	4	4
Additional paid-in capital	795,260	763,691
Treasury Stock, at cost, 57 shares at June 30, 2007 and December 31, 2006, respectively	(1,260)	(1,260)
Accumulated other comprehensive loss	(827)	(177)
Accumulated deficit	(696,866)	(637,581)
Total stockholders' equity	96,311	124,677

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

Total liabilities and stockholders' equity	\$ 296,890	\$ 333,537
--	------------	------------

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

Page 2

Table of Contents**ALEXION PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(UNAUDITED)

(in thousands, except per share amounts)	Three months ended June 30,		Six months ended June 30,	
	2007	2006	2007	2006
Revenues:				
Product sales	\$ 9,756	\$	\$ 10,731	\$
Contract research revenues		339	5,343	1,107
Total revenues	9,756	339	16,074	1,107
Cost of product sales	1,067		1,152	
Gross profit	8,689	339	14,922	1,107
Operating expenses:				
Research and development	15,195	23,462	36,415	44,676
Selling, general and administrative	22,788	11,421	42,627	19,567
Total operating expenses	37,983	34,883	79,042	64,243
Operating loss	(29,294)	(34,544)	(64,120)	(63,136)
Other income and expense				
Investment income	2,158	1,976	4,928	3,939
Interest expense	(511)	(687)	(1,211)	(1,375)
Foreign currency gain	373		346	
Loss before income tax benefit	(27,274)	(33,255)	(60,057)	(60,572)
Income tax benefit	90	90	180	180
Net loss	\$ (27,184)	\$ (33,165)	\$ (59,877)	\$ (60,392)
Net loss per share - basic and diluted	\$ (0.75)	\$ (1.06)	\$ (1.68)	\$ (1.94)
Shares used in computing basic and diluted net loss per common share	36,031	31,203	35,698	31,098

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

Table of Contents**ALEXION PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(UNAUDITED)

(in thousands)	Six months ended June 30,	
	2007	2006
Cash flows from operating activities:		
Net loss	\$ (59,877)	\$ (60,392)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	1,946	1,752
Share-based compensation expense	10,320	6,841
Changes in operating assets and liabilities:		
Accounts receivable	(10,262)	
Inventories	(12,646)	
Prepaid expenses and other assets	(793)	1,556
Accounts payable	(2,902)	(3,358)
Accrued expenses	(525)	3,318
Deferred revenue	(5,343)	(473)
Net cash used by operating activities	(80,082)	(50,756)
Cash flows from investing activities:		
Purchases of marketable securities	(86,366)	(378,600)
Proceeds from maturity or sale of marketable securities	105,949	436,022
Purchases of property, plant and equipment	(38,705)	(2,664)
Release of (increase in) restricted cash	24,069	(1,000)
Net cash provided by investing activities	4,947	53,758
Cash flows from financing activities:		
Payments under capital leases obligations	(33)	
Net proceeds from issuance of common stock	21,250	6,052
Net cash provided by financing activities	21,217	6,052
Effect of exchange rate changes on cash	(144)	(41)
Net change in cash and cash equivalents	(54,062)	9,013
Cash and cash equivalents at beginning of period	166,826	43,629
Cash and cash equivalents at end of period	\$ 112,764	\$ 52,642

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

Table of Contents

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except share and per share amounts)

1. Business

Alexion Pharmaceuticals, Inc. or Alexion or the Company was incorporated in 1992 and is engaged in the discovery, development and commercialization of biologic therapeutic products for the treatment of severe disease states, including hematologic 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 Medicines Agency, or EMEA, also approved Soliris for the treatment of PNH.

Through June 30, 2007, our product sales have been solely attributable to sales of Soliris and have been generated from two sources: named-patient or pre-approval sales in certain European countries (beginning in the first quarter of 2007) and U.S. commercial sales of Soliris (beginning in April 2007).

We have incurred operating losses since our inception. As of June 30, 2007, we had an accumulated deficit of approximately \$696,866. We expect to incur operating losses and negative cash flow, 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 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 June 30, 2007, the results of our operations for the three and six months ended June 30, 2007 and 2006, and our cash flows for the six months ended June 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 six months ended June 30, 2007 are not necessarily indicative of the results to be expected for the full year.

The financial statements of our foreign subsidiaries are translated into U.S. dollars using period-end exchange rates for assets and liabilities and average 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).

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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except share and per share amounts)

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:

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, physician buying groups and governmental organizations. The product is 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 an agreement with a distributor to distribute Soliris under pre-approval programs existing in certain European Union countries. As commercial approval, or marketing authorization, for Soliris has only recently been granted by the EMEA, all sales in the European Union to date have been made on a named-patient, or pre-approval basis. Such sales have been recorded upon receipt of product by the health-care facility, 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 related to inventory in our sales channel.

We record reserves for rebates payable under governmental programs, including Medicaid, as a reduction of revenue at the time product sales are recorded. Our reserve calculations related to Medicaid rebates 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 quarter ended June 30, 2007, three individual customers each accounted for 39%, 19% and 17% of the accounts receivable balance. For the quarter ended June 30, 2007, three individual customers each accounted for 37%, 20% and 18% of patient sales.

Contract Research Revenue

In January 1999, we and Procter & Gamble Pharmaceuticals, or P&G, entered into an exclusive collaboration to develop and commercialize pexelizumab. We granted P&G an exclusive license to our intellectual property related to pexelizumab, with the right to sublicense. In December 2001, we and P&G entered into an agreement pursuant to which the January 1999 collaboration was revised. We and P&G agreed to share concurrently 50% of the ongoing U.S. pre-production and development manufacturing costs for pexelizumab as well as any acute myocardial infarction or coronary artery bypass graft Phase III clinical trial costs. We had recognized a non-refundable up-front license fee of \$10,000 related to the P&G collaboration as revenue over 17 years beginning in 1999.

In 2006, we completed a final Phase III trial of pexelizumab. After reviewing results from that trial, we along with P&G, determined not to pursue further development of pexelizumab. Effective March 30, 2007, we and P&G mutually agreed to terminate the collaboration agreement. As the relevant agreement has been terminated, the remaining portion of the \$10,000 non-refundable up-front license fee, or \$5,343, was recognized as revenue in March 2007 and is included in contract research revenues.

Table of Contents**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, on a first-in, first-out, or FIFO, basis.

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.

We capitalized inventory costs associated with Soliris subsequent to the filing of the Biologics License Application, or BLA. Product sold during the three and six months ended June 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 approximately 75 patient-years of Soliris inventory that has been previously expensed.

To date, our inventory has been purchased under a third party contract arrangement with Lonza Sales AG. The following table summarizes the components of our inventories:

	June 30,	December 31,
	2007	2006
Raw materials	\$ 710	\$
Work-in-process	\$ 2,665	\$
Finished goods	\$ 11,569	\$ 2,314
	\$ 14,944	\$ 2,314

5. Royalties

Our cost of sales for the three and six months ended June 30, 2007 consisted of estimated royalties owed to third parties related to the sale and commercial manufacture of Soliris and other manufacturing costs. We estimate royalties owed to third parties based on contractual arrangements with certain parties as well as our assessment of potential royalty amounts owed to other third parties. On a periodic basis, we may reassess these estimates, resulting in adjustments to cost of sales.

Table of Contents**ALEXION PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(in thousands, except share and per share amounts)

6. Comprehensive Loss

The following table summarizes components of our comprehensive loss:

	Three months ended June 30,		Six months ended June 30,	
	2007	2006	2007	2006
Net loss	\$ (27,184)	\$ (33,165)	\$ (59,877)	\$ (60,392)
Net unrealized gains on available for sale securities		(22)	25	(14)
Foreign currency translation adjustment	(622)	(14)	(674)	(41)
Comprehensive loss	\$ (27,806)	\$ (33,201)	\$ (60,526)	\$ (60,447)

7. Exit Activities

In December 2006, we initiated an integration plan at our subsidiary, Alexion Antibody Technologies, Inc., to consolidate certain functions and discovery research operations, including the termination of all Alexion Antibody personnel, closure of Alexion Antibody facilities, and impairment of equipment in that facility. These costs have been recognized as liabilities and were included in general and administrative expenses for the year ended December 31, 2006. The following table summarizes the liabilities established for exit activities as of December 31, 2006 and subsequent cash payments and revision of estimates made during the three and six month periods ended June 30, 2007:

	Employee Related Benefits	Facility Lease Costs	Other Exit Activities	Total Exit Activities
Balance at December 31, 2006	\$ 5,358	\$ 1,147	\$ 539	7,044
Revision of estimate	21		(144)	(123)
Payments and other settlements	(5,379)	(309)	(395)	(6,083)
Balance at June 30, 2007	\$	\$ 838	\$	\$ 838

As of June 30, 2007, all remaining costs associated with employee related benefits and other exit activities have been paid. The Company remains obligated for lease payments through 2012 and is actively seeking a sub-lessee.

8. 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.

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

Potentially dilutive securities include:

	June 30,	
	2007	2006
Options to purchase common stock	4,838,905	5,700,688
Unvested restricted stock	458,668	353,559
Common stock issuable under convertible debt	4,768,710	4,768,710
	10,066,283	10,822,957

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

9. Stock Options

During the three and six month periods ended June 30, 2007, we issued approximately 535,000 and 1,056,000 shares of common stock, respectively, with proceeds of \$12,217 and \$21,296, respectively, upon the exercise of outstanding stock options.

During the three and six month periods ended June 30, 2006, we issued approximately 42,000 and 431,000 shares of common stock, respectively, with proceeds of \$554 and \$5,927, respectively, upon the exercise of outstanding stock options.

During the three and six month periods ended June 30, 2007, we recognized compensation expense of \$4,231 and \$8,212, respectively, for stock options and \$1,109 and \$2,108, respectively, for restricted stock. The expenses were charged to our condensed consolidated statement of operations. Due to our net operating loss position, a windfall tax benefit was not recognized during the period.

10. 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 claims, among other things, (i) breach of contract by Alexion under a license agreement entered into by Alexion and OMRF in 1992, relating to intellectual property owned or controlled by OMRF, and (ii) willful infringement by Alexion of an OMRF patent. In May 2007, we filed an answer denying OMRF's claims. In addition, we filed counterclaims alleging breach of contract by OMRF and are seeking declarations of non-infringement and invalidity of certain patents held by OMRF. 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. In June 2007, we filed an answer denying PDL's claims. In addition, we filed counterclaims seeking declarations of non-infringement and invalidity of certain 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.

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

The results of such civil actions cannot be predicted with certainty due to their early stages. We are therefore unable to reasonably estimate any possible range of loss related to such actions due to their uncertain resolution. However, should these legal matters be resolved against the Company, the operating results of the Company could be materially adversely affected.

Supply Agreement

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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except share and per share amounts)

11. Income Taxes

We adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), on January 1, 2007. Under FIN 48, a company can recognize the benefit of an income tax position only if it is more likely than not (greater than 50%) that the position is expected to be sustained upon tax examination. As a result of the implementation of FIN 48, we recognized a benefit of \$591 to the January 1, 2007 retained earnings balance. In addition, we also decreased our fully valued deferred tax assets by \$6,671 as a consequence of implementing FIN 48. The total amount of unrecognized tax benefits as of January 1, 2007, including the cumulative effect of the adoption of FIN 48, is \$6,671. None of the amount, if recognized, would affect the effective tax rate due to our full valuation allowance against deferred tax assets. While we believe we have adequately provided for all tax positions, amounts asserted by tax authorities could differ from our estimate. We 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 after 1992. We are subject to examination by state and local tax authorities generally for the period mandated by statute. These states, and the earliest open period include Connecticut (1999), New York (2003), Rhode Island (2006) and California (2003). Our foreign affiliates are not subject to examination by tax authorities for periods before 2005. Subsequent periods may be examined by the relevant tax authorities.

During the year ended December 31, 2006, and the three and six month periods ended June 30, 2007, we did not recognize any interest and penalties related to unrecognized taxes as additional income tax expense.

12. 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. We will end capitalization and begin depreciating the fixed assets related to the facility when the assets are substantially complete and ready for their intended use. Through June 30, 2007, we have capitalized \$63,999 related to the acquisition and construction of the facility, including commissioning costs and capitalized interest of \$4,976 and \$2,326, respectively.

13. Subsequent Events

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 sold or marketed by Alexion and net sales of any other product covered by the UIRF license agreement shall be subject to royalties.

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 approximately \$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 for other general corporate purposes. The other material terms and conditions of the original loan remain in force and effect.

Table of Contents

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 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, 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 forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled Risk Factors. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in other reports or documents we file from time to time with the Securities and Exchange Commission.

Business

We are a biotechnology company 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 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 distribution and shared service center for Europe, and additional 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 EMEA approval for Soliris was PNH. PNH is a rare, disabling and life-threatening, acquired genetic deficiency blood disorder. Patients with PNH may suffer from chronic hemolysis, or destruction of red blood cells caused by the C5 cleavage product C5b-9. The hemolysis in patients with PNH may be associated with severe anemia and life-threatening blood clots, as well as debilitating fatigue, impaired quality of life, renal insufficiency, pain, and shortness of breath.

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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

(in thousands, except share and per share amounts)

In June 2007, the EMEA 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. We have commenced reimbursement discussions with healthcare systems in major European countries and are planning to introduce Soliris in two major European countries by the end of 2007, with additional countries to follow in 2008. We continue sales through a named-patient program in Europe that we initiated in January 2007, which allows for the sale and distribution of Soliris for the treatment of individual patients based upon physician request and government regulatory approval.

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. We are planning to begin a clinical trial of Soliris for PNH in Japan.

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. The Company is planning to enroll up to 10,000 bone marrow failure patients in the EXPLORE study. We are also conducting the global PNH Patient Registry to study the natural history of PNH.

Due to the marketing approval of Soliris in the United States, the Phase IIb E05-001 trial and the EMBRACE Early Access Program have been terminated in the United States. Our treatment support services and case managers are assisting patients who were enrolled in E05-001 and EMBRACE programs to continue their access to Soliris.

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.

In addition to PNH, we are evaluating other potential indications for Soliris as well as other formulations of eculizumab for additional clinical indications, and we are actively pursuing development of other antibody product candidates in early stages of development. We have initiated activities with the Canadian Health Authority to begin clinical testing of eculizumab in asthma patients which is scheduled to begin in second half of 2007.

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 additional future products. To date, we have incurred \$63,999 related to the acquisition and construction of the facility, including commissioning costs and capitalized interest. We expect that we will begin engineering runs in the second half of 2007, manufacturing for process validation purposes in the first half of 2008 and commercial manufacturing in the first half of 2009.

Recent Developments

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 sold or marketed by Alexion and net sales of any other product covered by the UIRF license agreement shall be subject to royalties.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

(in thousands, except share and per share amounts)

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 approximately \$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 for other general corporate purposes. The other material terms and conditions of the original loan remain in force and effect.

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 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, physician buying groups and governmental organizations. The product is shipped directly from our third party warehouse to the patients' health-care provider, who is not typically 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. Financial instruments that potentially expose the Company to concentrations of credit risk are limited to accounts receivable. For the quarter ended June 30, 2007, three individual customers accounted for 39%, 19% and 17% of the accounts receivable balance. For the quarter ended June 30, 2007, three individual customers accounted for 37%, 20%, and 18% of the patient sales balance.

In Europe, we entered into an agreement with a distributor to distribute Soliris under pre-approval programs existing in certain European countries. As commercial approval, or marketing authorization, for Soliris has only recently been granted by EMEA, all sales in Europe to date have been made on a named-patient or pre-approval basis. Such sales have been recorded upon receipt of product by the health-care facility 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 absence of 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 reserves for rebates payable under governmental programs, including Medicaid, as a reduction of revenue at the time product sales are recorded. Our reserve calculations related to Medicaid rebates require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such

Table of Contents

ALEXION PHARMACEUTICALS, INC.

(in thousands, except share and per share amounts)

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, on a first-in, first-out, or FIFO, basis.

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.

We capitalized inventory costs associated with Soliris subsequent to the filing of the Biologics License Application, or BLA. Product sold during the three and six months ended June 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 approximately 75 patient-years of Soliris inventory that has been previously expensed.

The determination of whether or not inventory costs will be realizable requires estimates by our management. A critical estimate in this determination is the estimate of the future expected inventory requirements, whereby we compare our internal sales forecasts to inventory on hand. Actual results may differ from those estimates and 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 write-offs, which would be recorded as an adjustment to cost of sales.

Results of Operations

Comparison of the Three and Six Months ended June 30, 2007 to the Three and Six Months ended June 30, 2006

Revenues

Product Sales

During the three and six months ended June 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 sales of Soliris for the three and six months ended June 30, 2007 of \$9,756 and \$10,731, respectively.

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

We expect European named-patient revenue to increase as we expand the number of patient programs in the European Union, or E.U. We have also commenced reimbursement discussions with healthcare systems in major European countries and expect to introduce Soliris in one or more

major European countries by the end of 2007, with additional countries to follow in 2008.

Table of Contents**ALEXION PHARMACEUTICALS, INC.**

(in thousands, except share and per share amounts)

Contract research revenue

	Three months ended June 30,		Increase/ (Decrease) % Change	Six months ended June 30,		Increase/ (Decrease) % Change
	2007	2006		2007	2006	
P&G	\$	\$ 147	-100%	\$ 5,343	\$ 294	1717%
U.S. government grants		192	-100%		713	-100%
Other revenue			0%		100	100%
Total revenues	\$	\$ 339	-100%	\$ 5,343	\$ 1,107	383%

We recorded contract research revenues of approximately \$0 and \$339 for the three months ended June 30, 2007 and 2006, respectively, and \$5,343 and \$1,107 for the six months ended June 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 related to our research programs.

During 2006, we completed a final Phase III trial of pexelizumab. After reviewing results from that trial, we along with P&G, determined not to pursue further development of pexelizumab. Effective March 30, 2007, we mutually agreed to terminate the collaboration agreement. As 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.

Financial instruments that potentially expose the Company to concentrations of credit risk are limited to accounts receivable. For the quarter ended June 30, 2007, three individual customers accounted for 39%, 19% and 17% of the accounts receivable balance. For the quarter ended June 30, 2007, three individual customers accounted for 37%, 20% and 18% of the patient sales balance.

Cost of sales

Cost of sales was \$1,067 and \$1,152 for the three and six months ended June 30, 2007, reflecting a gross profit of \$8,689 and \$14,922, respectively. Cost of sales during both periods includes estimated royalty expenses associated with sales of Soliris and 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 six months ended June 30, 2007 was previously expensed prior to submission of our BLA, and therefore is not included in the cost of product sales during this period. We continue to hold approximately 75 patient-years of Soliris inventory that has been previously expensed. When this inventory has been fully exhausted, our cost of sales will then reflect the full manufacturing cost of the inventory, resulting in lower gross margins.

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.

Table of Contents**ALEXION PHARMACEUTICALS, INC.**

(in thousands, except share and per share amounts)

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 June 30,		Increase/ (Decrease) \$ Change	Six months ended June 30,		Increase/ (Decrease) \$ Change
	2007	2006		2007	2006	
Clinical development	\$ 3,080	\$ 9,187	\$ (6,107)	\$ 10,287	\$ 18,316	\$ (8,029)
Product development	2,784	4,568	(1,784)	5,438	6,493	(1,055)
Discovery research	216	1,037	(821)	1,218	1,993	(775)
Payroll and benefits	7,300	6,586	714	16,046	13,902	2,144
Operating and occupancy	1,278	1,482	(204)	2,364	2,759	(395)
Depreciation and amortization	537	602	(65)	1,062	1,213	(151)
Research and development expense	\$ 15,195	\$ 23,462	(8,267)	\$ 36,415	\$ 44,676	(8,261)

Research and development expenses decreased approximately \$8,267 for the three months and \$8,261 for the six months ended June 30, 2007, as compared to the same periods in 2006 respectively.

For the three months ended June 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 \$6,107 in clinical development expense due to decreases in spending for pexelizumab programs. Clinical development expenses related to new eculizumab programs in 2007, including EXPLORE, EMBRACE and the PNH registry were largely offset by reductions in expenses related to our 2006 eculizumab programs, including SHEPHERD.

Decrease of \$1,784 in product development expense. A decrease in manufacturing costs of \$3,552 was related to the capitalization of inventory costs beginning with the filing of the BLA in September 2006. Prior to September 2006, we expensed all manufacturing costs, resulting in lower 2007 expenses compared to 2006. This decrease was offset by an increase of \$800 related to increases in expenditures for 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).

Decrease of \$821 in discovery research expense due to the closure of AAT operations.

For the six months ended June 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 \$8,029 in clinical development expense due largely to decreases in spending for pexelizumab programs and the completion of TRIUMPH and SHEPHERD programs in 2006. This decrease was offset by increases of approximately \$4,688 related to new programs in 2007, including EXPLORE, EMBRACE and the PNH registry.

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

Decrease of \$1,055 in product development expense. A decrease in manufacturing costs of \$3,616 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. This decrease was offset by an increase of \$2,562 related to increases in expenditures for 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).

Page 16

Table of Contents**ALEXION PHARMACEUTICALS, INC.****(in thousands, except share and per share amounts)**

Increase of \$2,144 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 \$775 in non-labor discovery research expense due to the closure of AAT operations.

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 general and administrative expenses during the periods presented (amounts in thousands):

	Three months ended June 30,		Increase/ (Decrease) \$	Six months ended June 30,		Increase/ (Decrease) \$
	2007	2006	Change	2007	2006	Change
Selling, general and administrative expense	\$ 22,788	\$ 11,421	\$ 11,367	\$ 42,627	\$ 19,567	\$ 23,060

Selling, general and administrative expenses increased approximately \$11,367 for the three months ended June 30, 2007 and \$23,060 for the six months ended June 30, 2007, as compared to the same periods of 2006, primarily due to the following:

Increase in salary, benefits and other labor expenses of \$6,858 and \$13,821, respectively, for the three and six months ended June 30, 2007, which included increased share-based compensation cost of \$1,565 and \$2,875, respectively. The increases in these costs were a result of increased headcount related to commercial development activities, including increases in payroll and benefits costs of \$3,353 and \$6,987 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 \$2,664 and \$3,648, respectively, for the three and six months ended June 30, 2007. For the three and six months ended June 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 \$1,846 and \$5,591, respectively, for the three and six months ended June 30, 2007, related to increases in infrastructure costs to support our growth as a commercial entity.

Other Income and Expense

We recognize investment income primarily from our portfolio of short-term marketable securities. Investment income was \$2,158 and \$4,928 for the three and six months ended June 30, 2007, respectively, as compared to \$1,976 and \$3,939 for the same period in 2006. The increase was due primarily to higher market interest rates.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

(in thousands, except share and per share amounts)

We incur interest expense on our convertible notes and our mortgage debt. Our interest expense is net of interest capitalized related to the construction of our Rhode Island manufacturing facility, which was \$802 and \$1,398 for the three and six months ended June 30, 2007, respectively. Interest expense was \$511 and \$1,211 for the three and six months ended June 30, 2007, as compared to \$687 and \$1,375 for the same period in 2006, which reflects the additional capitalization of interest in connection with the acquisition and construction of the Smithfield, Rhode Island manufacturing facility.

Foreign currency transaction gains relating to our operations in Europe increased significantly beginning in 2007. The foreign currency transaction gains totaled \$373 and \$346 for the three and six months ended June 30, 2007 and were primarily a result of the weaker U.S. Dollar compared to the Euro.

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. However, 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 approximately \$90 and \$180 for the three and six months ended June 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 six month periods ended June 30, 2007 of approximately \$27,184 and \$59,877 or \$0.75 and \$1.68 per common share, respectively, versus a net loss of approximately \$33,165 and \$60,392 or \$1.06 and \$1.94 per common share, respectively, for the same periods in 2006.

Liquidity and Capital Resources

As of June 30, 2007, our consolidated cash, cash equivalents, marketable securities and restricted cash totaled \$152,420, a decrease of \$97,728, 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 June 30, 2007, \$9,526 of cash was restricted to be used for the construction and other costs related to our Rhode Island manufacturing facility.

At June 30, 2007, our working capital was \$162,526, compared to \$195,019 at December 31, 2006.

We have incurred operating losses since our inception. As of June 30, 2007, we had an accumulated deficit of approximately \$696,866. 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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

(in thousands, except share and per share amounts)

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 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.

Operating Activities

Net cash used in operating activities was \$80,082 and \$50,756 for the six months ended June 30, 2007 and 2006, respectively, an increase of \$29,326, or 57.8%. 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 six months ended June 30, 2007 are as follows:

Net loss of \$59,877

Non-cash charges, including depreciation and amortization and stock-based compensation of \$12,266

Changes in operating assets of \$23,701, primarily attributable to increase 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 sales from the second quarter of 2007 have not yet been collected.

Investing Activities

Net cash provided by investing activities was \$4,947 and \$53,758 for the six months ended June 30, 2007 and 2006, respectively. For the six months ended June 30, 2007, the net cash used for investing activities consisted of the following:

\$19,583 from the net purchase and sale of marketable securities, which was used to fund our operations

\$38,705 of additions to property, plant and equipment, of which \$35,268 was attributable to the construction of our Rhode Island manufacturing facility, with the remaining attributable to general corporate purposes

\$24,069 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 \$21,217 and \$6,052 for the six months ended June 30, 2007 and 2006, respectively, consisting primarily of proceeds from the issuance of common stock related to the exercise of stock options.

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.

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 (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 debt.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

(in thousands, except share and per share amounts)

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.

As of June 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 \$233,250. The \$16,125 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 instalments of approximately \$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 for 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 June 30, 2007, we held approximately 80% of our cash and investments in financial instruments with original maturity dates of three months or less which includes restricted cash, 15% in financial instruments with original maturity dates of greater than three months and less than one year, and the remaining 5% in financial instruments with original maturity dates of equal to or greater than one year and less than two years. These financial instruments are subject to interest rate risk and will decline in value if interest rates increase. We estimate that a change of 100 basis points in interest rates would result in an increase or decrease of approximately \$44 in the fair value of our cash and investments, which had a weighted average duration of approximately 3 months at June 30, 2007.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

(in thousands, except share and per share amounts)

Our outstanding long-term liabilities as of June 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 June 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 \$233,250.

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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 claims, among other things, (i) breach of contract by Alexion under a license agreement entered into by Alexion and OMRF in 1992, relating to intellectual property owned or controlled by OMRF, and (ii) willful infringement by Alexion of an OMRF patent. OMRF seeks, among other things, declaratory judgment, judicial accounting, and actual, compensatory, consequential and punitive damages, plus attorney's fees. On May 10, 2007, we filed an answer denying OMRF's claims. In addition, we filed counterclaims alleging breach of contract by OMRF of the 1992 license agreement, and we are seeking 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. On June 4, 2007, we filed an answer denying 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. Alexion believes it has good and valid defenses to PDL's claims and intends to vigorously defend the case and pursue its counterclaims.

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 candidate, 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 the United States and in Europe;

acceptance of the product in the medical community;

ability to effectively market and distribute the product in the United States and Europe;

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

receipt of marketing approvals from foreign regulatory authorities; and

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

Page 22

Table of Contents

ALEXION PHARMACEUTICALS, INC.

We obtained marketing approval for Soliris in Europe in June 2007 and commenced reimbursement discussions with healthcare systems in major market countries. We currently expect to commence commercial sales in the fourth quarter of 2007 however we cannot guarantee that reimbursement and pricing discussions 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 pre-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 reimbursement discussions 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, which is not yet complete. 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 costs in establishing a new arrangement.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 June 30, 2007, our three top customers accounted for 39%, 19% and 17% of our revenue, 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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 engaged in reimbursement discussions with healthcare systems in major market countries in Europe. Our results of operations may suffer if we are unable to successfully and timely conclude such discussions 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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 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 in our trials of eculizumab for the treatment of PNH and other diseases have become infected with *Neisseria* bacteria, including PNH patients in the open-label extension trial E05-001 who had been vaccinated against *Neisseria* bacteria. Each such incident has been reported to appropriate regulatory agencies in accordance with relevant regulations.

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

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

We currently have no experience or capacity for manufacturing drug products in volumes that would be necessary to support commercial sales and we can provide no assurance that we will be able to do so successfully. We depend on a few outside suppliers for manufacturing and a single manufacturer for commercial supply. Our small, clinical-scale manufacturing plant cannot manufacture enough of our product candidates for later stage clinical development or commercial supply. We do not have the capacity to produce more than one product candidate at a time in that plant. We acquired a commercial-scale manufacturing plant in Smithfield, Rhode Island in July 2006. However, that plant

Table of Contents

ALEXION PHARMACEUTICALS, INC.

is not currently equipped or approved by the FDA or other regulatory agencies to manufacture Soliris or our other drug candidates. We expect that it will be 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, and even if we are able to find alternatives they may ultimately be insufficient for our needs. As a result, our ability to conduct testing and drug trials and our plans for commercialization would be materially adversely affected. Submission of products and new development programs for regulatory approval, as well as our plans for commercialization, would be delayed or suspended. Our competitive position and our prospects for achieving profitability would be materially and adversely affected.

Manufacture of drug products, including the need to develop and utilize manufacturing processes that consistently produce our drug products to their required quality specifications, is highly regulated by the FDA and other domestic and foreign authorities. Regulatory authorities must approve the facilities in which our products are manufactured prior to granting 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 of those requirements and regulations, which failure would have a materially adverse effect on our business.

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

Due to the nature of the current market for third-party commercial manufacturing, many arrangements require substantial penalty payments by the customer for failure to use the manufacturing capacity for which it contracted. We could owe substantial penalty payments to Lonza if we were not to use the manufacturing capacity for which we contracted. Penalty payments under these agreements typically decrease over the life of the agreement, and may be substantial initially and de 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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

We have incurred losses since we started our company in January 1992. As of June 30, 2007, we had an accumulated deficit of approximately \$697 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 to launch Soliris in Europe during 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, 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 product candidates. We are currently preparing for the commercialization of Soliris in Europe and conducting or evaluating several clinical trials. Funding needs may shift between projects and potentially accelerate and increase, as we get closer to commercialization of Soliris in Europe, or if we initiate new clinical trials for our product candidates.

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;

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

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.

Page 28

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 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, 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 biotechnology industry for qualified scientific and technical personnel. Since our business is very science-oriented and specialized, we need to continue to attract and retain such people. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. We have employment agreements with Dr. Bell, Mr. Keiser, and Dr. Squinto. None of our key personnel is nearing retirement age or to our knowledge, planning to retire. To our knowledge, there is no tension between any of our key personnel and the Board of Directors. If we are unable to retain and recruit highly qualified personnel, our ability to execute our business plan will be materially and adversely affected.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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

We are significantly leveraged.

On June 30, 2007, we had outstanding \$150 million principal amount of 1.375% convertible senior notes. 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%. 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;

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

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.

Page 30

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 obtain pricing approvals prior to marketing our products. We have not obtained pricing approval for Soliris outside the United States. 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.

Table of Contents

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, 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. The FDA, the EMEA or we 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;

finest 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.

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

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.

Page 32

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 EMEA, 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

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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

Edgar Filing: ALEXION PHARMACEUTICALS INC - Form 10-Q

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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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

In recent years, several states and localities, including California, the District of Columbia, Maine, Minnesota, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. We are not aware of any companies against which fines or penalties have been assessed under these special state reporting and disclosure laws to date. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Risks Related to Intellectual Property

If we cannot protect the confidentiality and proprietary nature of our trade secrets, 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

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 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 biotechnology stocks in general could have a significant impact on the future trading prices of our common stock and our convertible senior notes. In particular, the trading price of the common stock of many biotechnology companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. This is due to several factors, including general market conditions, the announcement of the results of our clinical trials or product development, 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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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

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

Our corporate charter and by-law provisions and stockholder rights plan may discourage certain types of transactions involving an actual or potential change of control that might be beneficial to Alexion or its stockholders. Our bylaws provide that special meetings of our stockholders may be called only by the Chairman of the Board, the President, the Secretary, or a majority of the Board of Directors, or upon the written request of stockholders who together own of record 50% of the outstanding stock of all classes entitled to vote at such meeting. Our bylaws also specify that the authorized number of directors may be changed only by resolution of the board of directors. Our certificate does not include a provision for cumulative voting for directors, which may have enabled a minority stockholder holding a sufficient percentage of a class of shares to elect one or more directors. Under our certificate of incorporation, our board of directors has the authority, without further action by stockholders, to designate up to 5,000,000 shares of preferred stock in one or more series. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future.

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

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

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

The Company held its 2007 Annual Meeting of Stockholders on May 3, 2007. The results of such meeting were reported in the Company's Quarterly Report on Form 10-Q for the period ending March 31, 2007, filed with the SEC on May 10, 2007.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 June 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 June 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 June 30, 2007.
- 32.2 Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.

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

Table of Contents

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: August 7, 2007

By: /s/ Leonard Bell, M.D.
Leonard Bell, M.D.
Chief Executive Officer, Secretary and Treasurer

(principal executive officer)

Date: August 7, 2007

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

(principal financial officer)

Page 39