ALEXION PHARMACEUTICALS INC
Form 10-Q
November 09, 2006
Table of Contents

FORM 10-Q

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

x Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended September 30, 2006

OR

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

Commission file number: 0-27756

Alexion Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

352 Knotter Drive, Cheshire, Connecticut 06410

(Address of principal executive offices) (Zip Code)

203-272-2596

(Registrant s telephone number, including area code)

N/A

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

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

Indicate by check mark whether the registrant is a shell company (as defined in rule 12b-2 of the Act) Yes ¨ No x

Class	**Outstanding at November 6, 2006**
Common Stock, $0.0001 par value	**31,851,672**

Table of Contents

ALEXION PHARMACEUTICALS, INC.

INDEX

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(amounts in thousands)

(UNAUDITED)

	September 30, 2006	December 31, 2005
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 39,981	$ 43,629
Restricted cash	33,184	
Marketable securities	70,683	168,827
Prepaid expenses and other current assets	3,650	5,095
Total current assets	147,498	217,551
Property, plant and equipment, net	28,630	10,631
Goodwill, net	19,954	19,954
Prepaid manufacturing costs	10,845	10,000
Other assets	4,074	4,575
Total Assets	$ 211,001	$ 262,711
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 3,479	$ 3,865
Accrued expenses	17,315	20,629
Deferred revenue	588	767
Current portion of obligations under capital lease	121	129
Total current liabilities	21,503	25,390
Obligations under capital lease		88
Deferred revenue, less current portion	4,902	5,343
Mortgage loan	26,000	
Convertible notes	150,000	150,000
Total Liabilities	202,405	180,821
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; 31,717 and 30,980 shares issued at September 30, 2006 and December 31, 2005, respectively	3	3
Additional paid-in capital	607,996	589,250
Stock subscription receivable	54	
Treasury Stock, at cost, 50 shares at September 30, 2006 and December 31, 2005, respectively	(981)	(981)
Accumulated other comprehensive loss	(145)	(315)
Accumulated deficit	(598,331)	(506,067)
Total Stockholders Equity	8,596	81,890

Total Liabilities and Stockholders Equity	$ 211,001	$ 262,711

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

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

and Comprehensive Loss

(amounts in thousands, except per share amounts)

(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2006	2005	2006	2005
REVENUES	$ 263	$ 384	$ 1,370	$ 1,116
OPERATING EXPENSES				
Research and development	21,205	31,788	65,881	81,304
General and administrative	12,121	6,415	31,688	16,816
Total operating expenses	33,326	38,203	97,569	98,120
Operating loss	(33,063)	(37,819)	(96,199)	(97,004)
OTHER INCOME AND EXPENSE				
Investment income	1,801	1,618	5,740	4,696
Interest expense	(687)	(736)	(2,062)	(3,477)
Loss from early extinguishment of convertible notes				(3,184)
Other expense	(13)		(13)	
Loss before state tax benefit	(31,962)	(36,937)	(92,534)	(98,969)
STATE TAX BENEFIT	90	363	270	704
Net Loss	$ (31,872)	$ (36,574)	$ (92,264)	$ (98,265)
OTHER COMPREHENSIVE INCOME/LOSS				
Foreign currency translation	(24)		(65)	
Unrealized losses on marketable securities	249	46	235	90
Comprehensive Loss	$ (31,647)	$ (36,528)	$ (92,094)	$ (98,175)
BASIC AND DILUTED LOSS PER SHARE DATA				
Net loss per share	$ (1.02)	$ (1.24)	$ (2.96)	$ (3.45)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS PER COMMON SHARE	31,264	29,469	31,154	28,466

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

(amounts in thousands)

(UNAUDITED)

	Nine months ended September 30,	
	2006	**2005**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (92,264)	$ (98,265)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	2,651	3,239
Write-off of deferred financing costs		1,212
Share-based compensation expense	11,402	1,908
Changes in operating assets and liabilities		
Prepaid expenses and other assets	595	76
Accounts payable	(386)	(3,442)
Accrued expenses	(3,314)	14,118
Deferred revenue	(620)	(634)
Deferred research and development costs		(1,313)
Net cash used by operating activities	(81,936)	(83,101)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(516,974)	(578,360)
Proceeds from maturity or sale of marketable securities	615,353	590,611
Purchase of property, plant and equipment	(20,238)	(2,388)
Increase in restricted cash	(33,184)	
Net cash provided by investing activities	44,957	9,863
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from convertible debt offering		150,000
Proceeds from mortgage loan	26,000	
Convertible debt issuance costs		(4,758)
Redemption of convertible notes		(120,000)
Exchange of 11,727 common shares in 2005		(325)
Net proceeds from issuance of common stock	7,396	68,190
Net cash provided by financing activities	33,396	93,107
Effect of exchange rate changes	(65)	
Net change in cash and cash equivalents	(3,648)	19,869
Cash and cash equivalents at beginning of period	43,629	35,904
Cash and cash equivalents at end of period	$ 39,981	$ 55,773

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

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements included in this Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in our audited Transition Report on Form 10-K/T for the five month transition period ended December 31, 2005.

In our opinion, the unaudited condensed consolidated financial statements reflect all adjustments (including those that are normal and recurring) that are necessary in the judgment of management for a fair presentation of such statements in conformity with accounting principles generally accepted in the United States (GAAP) for interim reporting. In preparing financial statements in conformity with GAAP, we must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from those estimates.

During the nine month period ended September 30, 2006, we established six new entities to support our planned growth and preparation for commercialization. Alexion Manufacturing, LLC and Alexion Delaware Holding, LLC are wholly owned by Alexion Pharmaceuticals, Inc. and both are Delaware limited liability companies. The partnership of Alexion Bermuda, LP is ninety-nine percent owned by Alexion Pharmaceuticals, Inc. and one percent owned by Alexion Delaware Holding, LLC and was formed under the laws of Bermuda as a limited partnership. Alexion International, Sarl is ninety-five percent owned by Alexion Bermuda, LP and five percent owned by Alexion Pharmaceuticals, Inc. and was formed under the laws of Switzerland as a limited liability company. Alexion Holding B.V. is registered as a corporation in Amsterdam (the Netherlands) and is wholly owned by Alexion Delaware Holding, LLC. Finally, Alexion Pharma France SAS, a simplified joint stock company, is registered under the laws of France and wholly owned by Alexion Holding B.V.. There were no material transactions that occurred in the newly formed entities during the nine month period ending September 30, 2006, except as noted in Note 8 and Note 9 to these condensed consolidated financial statements.

2. Accounting for Share-Based Compensation

A summary of the status of our stock option plans at September 30, 2006 and changes during the nine months then ended is presented in the table and narrative below:

	Options	Weighted-Average Exercise Price
Options outstanding at December 31, 2005	5,092,085	$ 24.16
Options granted	1,297,200	28.16
Options cancelled	(244,459)	23.28
Options exercised	(523,488)	14.13
Options outstanding at September 30, 2006	5,621,338	25.41

During the three and nine month period ended September 30, 2006, we recognized compensation expense of $4,040,241 and $10,009,256, respectively, for stock options and $528,179 and $1,393,188, respectively, for restricted stock, which were charged to our condensed consolidated statement of income. Due to our net loss position, a windfall tax benefit was not realized during the period.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

A summary of the status of our non-vested restricted stock as of September 30, 2006, and changes during the nine months then ended are as follows:

	Restricted Stock
Nonvested at December 31, 2005	133,500
Issued	225,059
Vested	
Cancelled	(11,500)
Nonvested at September 30, 2006	347,059

SFAS 123R requires us to present pro forma information for periods prior to the adoption as if we had accounted for all share-based compensation under the fair value method of SFAS 123. For purposes of pro forma disclosure, the estimated fair value of the options at the date of grant is amortized to expense over the requisite service period, which generally equals the vesting period. The following table illustrates the effect on net loss and earnings per share as if we had applied the fair value recognition provisions of SFAS 123 to our share-based employee compensation.

(amounts in thousands, except per share data)	Three months ended September 30, 2005	Nine months ended September 30, 2005
Net loss, as reported	$ (36,574)	$ (98,265)
Add: Stock-based employee compensation expense included in reported net loss	1,584	1,907
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(2,158)	(6,975)
Pro forma net loss	$ (37,148)	$ (103,333)
Basic and diluted-as reported	$ (1.24)	$ (3.45)

3. Net Loss Per Common Share

Basic net loss per common share is computed by dividing the net loss by the weighted average shares of common stock outstanding during the respective period. Diluted net loss per common share assumes, in addition to the above, the dilutive effect of other potential common shares outstanding during the period. Other potential common shares represent dilutive stock options, unvested restricted stock, and convertible debt. These outstanding stock options, convertible debt, and unvested restricted stock entitled holders to acquire 10,737,107 and 10,023,564 shares of common stock at September 30, 2006 and 2005, respectively. There is no difference in basic and diluted net loss per common share for the three and nine months ended September 30, 2006 and 2005, respectively, as the effect of other potential common shares is anti-dilutive.

4. Capital Structure

During the three and nine month periods ended September 30, 2006, we issued 92,726 and 523,488 shares of common stock, respectively, with proceeds of $1,416,882 and $7,343,937, respectively, upon the exercise of outstanding stock options.

During the three and nine month periods ended September 30, 2005, we issued 140,120 and 277,132 shares of common stock, respectively, with proceeds of $2,025,819 and $3,536,515 respectively, upon the exercise of

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

outstanding stock options. Additionally, during the three month period ended September 30, 2005, we increased our holdings of common stock in treasury by 11,727 shares through stock-based exercises of employee options. The shares were exchanged at fair market value of $325,206 in total.

In August 2005, we issued 2,500,000 shares of common stock in a public offering at $26.75 per share, resulting in gross proceeds from the sale of approximately $66,875,000. We incurred underwriting discounts and commissions of approximately $2,145,000 or $0.86 per share as well as other expenses, resulting in net proceeds of approximately $64,517,000.

6. Income Taxes

The Company has net operating loss and federal and state research and development credit carry forwards of approximately $493,000,000 and $17,800,000 respectively as of December 31, 2005. The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer s ability to utilize net operating loss and tax credit carry forwards in any given year resulting from cumulative changes in ownership interests in excess of 50 percent over a three-year period. We have determined that these limiting provisions were triggered. However, such limitation is not expected to result in the loss of the federal net operating loss and research and development credit carry forward.

7. Commitments and Contingencies

We enter into agreements that contain indemnification provisions under our agreements with other companies in our ordinary course of business, typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, we generally indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to our products, or otherwise in connection with the use or testing of our product candidates. The term of these indemnification agreements is generally perpetual. The potential amount of future payments we could be required to make under these indemnification agreements is unlimited. We have not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements as of September 30, 2006.

8. Property, Plant, and Equipment

In July 2006, our wholly owned affiliate, Alexion Manufacturing, LLC purchased the former Dow manufacturing facility in Smithfield, Rhode Island for $13,000,000. The biopharmaceutical manufacturing facility will be used primarily to produce Soliris (eculizumab). In accordance with the Purchase and Sale Agreement dated April 13, 2006, the Agreement , we deposited into an escrow account $500,000 upon execution of the Agreement on April 13, 2006 and an additional $500,000 upon the completion of the due diligence period, which was ninety days after the agreement date. The deposits were held in escrow until the closing date at which time the escrowed amounts and the remaining balance, net of property taxes owed for the first part of the year, of $11,926,289 was paid to Dow.

9. Debt

In July 2006, our wholly owned affiliate Alexion Manufacturing, LLC, entered into a mortgage loan agreement to borrow $26,000,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility. The mortgage loan bears interest at a fixed annual rate of 9.17% and all obligations under the loan agreement are guaranteed by Alexion Pharmaceuticals, Inc. The loan principal is required to be repaid in equal monthly installments of $288,889, starting March 2009 and until August 2016, at which time all outstanding balances are due. 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. In the event that approval to market Soliris (eculizumab) has not been obtained before December 31, 2007, Alexion Manufacturing LLC must deliver an acceptable letter of credit to the lender for the amount of $13,000,000. Also, included in the loan agreement are certain provisions which, if satisfied, would allow for additional borrowings of up to $9,000,000.

Under the terms of the agreement, among other things, Alexion Manufacturing is restricted with respect to additional borrowings, leasing arrangements and mergers. Alexion Manufacturing also may not modify, amend, or waive

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

material obligations with respect to, or terminate, material agreements or proprietary rights, or engage in any business other than ownership and operation of facility. Alexion Pharmaceuticals, Inc. may not, among other things, liquidate, wind-up or dissolve as long as the guarantee remains in effect.

As a condition of the loan, Alexion Manufacturing, LLC is required to maintain restricted cash accounts. These accounts must be used specifically for the purchase and construction of the manufacturing facility. The lender has a first priority security interest and the right to approve all disbursements from the accounts holding restricted cash. Under the agreement, we are required to, at all times, maintain a balance in the restricted cash accounts sufficient to complete the project.

Recently Issued Accounting Standards

In July 2006, the FASB approved the issuance of FASB Interpretation FIN No. 48, Accounting for Uncertainty in Income Taxes (as amended). This Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. Additionally, this Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Interpretation is effective for reporting periods beginning after December 15, 2006 with earlier application permitted. For Alexion, the effective date will be the first quarter of 2007. The Company is evaluating the impact of adopting this accounting principal on its financial position and results of operations.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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

Note Regarding Forward-Looking Statements

This report 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 (eculizumab), clinical trial results, completion of the SHEPHERD trial for Soliris (eculizumab), prospects for and timing of regulatory approval for Soliris (eculizumab), the uncertainties involved in the drug development process, the safety and efficacy of our product candidates, our future research and development activities, estimates of the potential markets for our products (for example, estimates regarding the number of PNH patients), assessment of competitors and potential competitors, estimates of the capacity of manufacturing and other facilities to support our products, the sufficiency of our existing capital resources and projected cash needs, sales and marketing plans, as well as assumptions relating to the foregoing. Words such as anticipates, expects, intends, may, plans, believes, see estimates, variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this report under the section entitled Risk Factors . Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result 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. The interim financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the Financial Statements and Notes thereto for the five month transition period ended December 31, 2005 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Transition Report on Form 10-K/T for the five month transition period ended December 31, 2005.

Business

We are a biotechnology company working to develop and deliver life-changing drug therapies for patients with serious and life-threatening medical conditions. We are engaged in the discovery and development of therapeutic products aimed at treating patients with a wide array of severe disease states, including hematologic diseases, cancer, and autoimmune disorders. Since our incorporation in January 1992, we have devoted substantially all of our resources to drug discovery, research, and product and clinical development. In September 2005, we formed a wholly-owned subsidiary, Alexion Europe SAS to support commercial and regulatory operations throughout Europe.

In September 2006, we filed a Biologics License Application, or BLA, with the U.S. Food and Drug Administration, or FDA, and a European Marketing Authorization Application, or MAA, in Europe, for Soliris (eculizumab) for the treatment of a rare blood disorder known as Paroxysmal Nocturnal Hemoglobinuria, or PNH. The Phase III clinical development program for Soliris (eculizumab) in PNH is comprised of two Phase III clinical trials, known as TRIUMPH and SHEPHERD. The FDA agreed to the design of the protocols for these two trials under the Special Protocol Assessment, or SPA, process. TRIUMPH is a placebo-controlled efficacy trial and SHEPHERD is an open-label, non-placebo controlled safety trial with efficacy secondary endpoints. In January 2006, we reported positive results from TRIUMPH which were also published in the September 2006 issue of the New England Journal of Medicine. All pre-specified, primary and secondary endpoints in the TRIUMPH trial were achieved with statistical significance. SHEPHERD is a twelve month study with a six month preplanned interim analysis. In June 2006, we reported positive six month results from SHEPHERD. Soliris (eculizumab) appeared to be safe and well tolerated during that six month period. In addition, all pre-specified primary and secondary efficacy endpoints in the trial were achieved with statistical significance for the six month period. The data from TRIUMPH and SHEPHERD served as the primary basis for the BLA and MAA submitted in the United States and Europe, respectively. We have requested priority review designation for the BLA from the FDA. Our MAA has been granted accelerated

Table of Contents

ALEXION PHARMACEUTICALS, INC.

assessment by the European Medicines Evaluation Agency, or EMEA, for Soliris (eculizumab) in Europe. Accelerated Assessment is given by the EMEA for medicinal products of major therapeutic interest and shortens the timeframe for review by that agency. Additionally, we have been notified by the EMEA that the MAA has been validated and that the assessment procedure has commenced.

Our second clinical stage product candidate, pexelizumab, has been evaluated in Phase III clinical trials for two separate indications: (1) coronary artery bypass graft (CABG) surgery patients undergoing cardiopulmonary bypass (CPB) and (2) acute myocardial infarction (AMI) patients undergoing primary percutaneous angioplasty. As previously announced, results from those Phase III clinical trials did not achieve their primary endpoints and will not be sufficient for filing for licensing approval in those indications. Pexelizumab development is conducted in collaboration with Procter & Gamble Pharmaceuticals, or P&GP. We have held discussions with P&GP regarding the pexelizumab program, and we do not currently intend to continue development of pexelizumab in the CABG or AMI indications.

In July 2006, we acquired a manufacturing plant in Smithfield, Rhode Island. We intend to equip and develop the plant in accordance with FDA and other regulatory requirements to manufacture Soliris (eculizumab) and other product candidates.

In addition to our Phase III programs, we are developing a global patient registry for PNH patients and have initiated the EXPLORE trial to investigate the frequency of undiagnosed PNH patients who have been diagnosed with other bone marrow failure diseases such as aplastic anemia and myelodysplasia. We intend to pursue additional indications for Soliris (eculizumab), and have other product candidates in earlier stages of development.

To date, we have not received any revenues from the sale of our products. We have incurred operating losses since our inception. As of September 30, 2006, we had an accumulated deficit of $598,331,000. We expect to incur substantial operating losses for the next several years due to expenses associated with product research and development, pre-clinical studies and clinical testing, regulatory activities, manufacturing development, scale-up and commercial-scale manufacturing, pre-commercialization and commercialization activities, developing a sales and marketing force, establishing European and other regional headquarters, and other infrastructure support costs. We may need to obtain additional financing to cover these costs.

We plan to develop and commercialize on our own those product candidates for which the clinical trials and commercialization requirements can be funded and accomplished by our own resources. For those products which require greater resources, our strategy is to form corporate alliances for product development and commercialization.

Results of Operations

Comparison of the Three and Nine Months ended September 30, 2006 to the Three and Nine Months ended September 30, 2005

Revenues

A summary of revenues recognized is as follows for the periods presented:

	Three months ended September 30,		Increase/ (Decrease)	Nine months ended September 30,		Increase/ (Decrease)
	2006	2005	% Change	2006	2005	% Change
	(amounts in thousands, except percentage data)					
P&G	$ 147	$ 147	0%	$ 441	$ 441	0%
U.S. government grants	116	237	-51%	829	675	23%
Other revenue			0%	100		100%
Total revenues	$ 263	$ 384	-32%	$ 1,370	$ 1,116	23%

Table of Contents

ALEXION PHARMACEUTICALS, INC.

We earned revenues of approximately $263,000 and $384,000 for the three months ended and $1,370,000 and $1,116,000 for the nine months ended September 30, 2006 and 2005, respectively. Revenue reflects the amortization of deferred revenue resulting from cash received from P&G under our collaboration for the development and commercialization of pexelizumab, U.S. government funded research grant revenue related to our research programs, and a nonrefundable fee for exclusive access to our xenotransplantation technologies, a program that was terminated in October 2003.

Research and Development

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

	Three months ended September 30,		Increase/ (Decrease)	Nine months ended September 30,		Increase/ (Decrease)
	2006	2005	% Change	2006	2005	% Change
	(amounts in thousands, except percentage data)					
Clinical development	$ 7,942	$ 14,053	-43%	$ 27,713	$ 39,419	-30%
Manufacturing and development	528	9,036	-94%	5,566	19,429	-71%
Product development	8,470	23,089		33,279	58,848	
Payroll and benefits	7,963	5,290	51%	21,865	14,778	48%
Operating and occupancy	1,207	1,359	-11%	3,966	3,978	0%
Discovery research	2,995	1,311	128%	4,988	1,702	193%
Depreciation and amortization	570	739	-23%	1,783	1,998	-11%
Total research and development expense	$ 21,205	$ 31,788	-33%	$ 65,881	$ 81,304	-19%

Research and development expenses decreased approximately $10,583,000 for the three months and $15,423,000 for the nine months ended September 30, 2006, as compared to the same periods in 2005, respectively, primarily due to:

decrease in clinical development expenses of $6,111,000 and $11,706,000 for the three and nine month periods ended September 30, 2006, respectively, due to the completion of the PRIMO-CABG2 and APEX AMI clinical trials. The decreased cost for the nine month period ended September 30, 2006 was partially offset by clinical cost increases of $4,695,000 for the SHEPHERD and extension studies supporting our development of Soliris (eculizumab);

decrease in manufacturing and manufacturing development costs of $8,508,000 and $13,863,000 for the three and nine month periods ended September 30, 2006, respectively, related primarily to the decreased eculizumab manufacturing costs in 2006, partially offset by the recognition of a liability during the nine months ended September 30, 2006 related to our third party pexelizumab manufacturing agreement;

increase of $1,684,000 and $3,286,000 for the three and nine month periods ended September 30, 2006, respectively, in discovery research costs primarily due to the recognition in the first quarter of 2005 of deferred expense related to our terminated collaboration with XOMA, resulting in a reduction of research and development cost in the first quarter of 2005; and

increase of 2,673,000 and $7,087,000 for the three and nine month periods ended September 30, 2006, respectively, in research and development payroll and benefit costs. The increases resulted from the expensing of share-based compensation as required by SFAS 123R amounting to $2,498,000 and $6,578,000 for the three and nine month periods ended September 30, 2006, respectively, as well as increased headcount to support our research and development activities.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

General and Administrative Expenses

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

	Three months ended September 30,		Increase/ (Decrease)	Nine months ended September 30,		Increase/ (Decrease)
	2006	2005	% Change	2006	2005	% Change
	(amounts in thousands, except percentage data)					
Total general and administrative expense	$ 12,121	$ 6,415	89%	$ 31,688	$ 16,816	88%

General and administrative expenses increased approximately $5,706,000 for the three months ended September 30, 2006 and $14,872,000 for the nine months ended September 30, 2006, as compared to the same periods of 2005, primarily due to:

- higher payroll and benefits costs of $3,921,000 for the three month period and $8,533,000 for the nine month period ended September 30, 2006 primarily resulting from growth of our headcount dedicated to commercial development activities and the expensing of share-based compensation of $2,070,000 and $4,824,000 during the three and nine month periods ended September 30, 2006, respectively;

- increased administrative costs related to Alexion Europe of approximately $2,000,000 for the three month period and $4,800,000 for the nine month period ended September 30, 2006; and

- an increase of $1,029,000 and $2,432,000 for the three and nine month periods ended September 30, 2006, respectively, for professional fees, recruitment expenses, public relations and other items related to commercial development.

Total Operating Expenses

Total operating expenses for the three and nine month periods ended September 30, 2006 were approximately $33,326,000 and $97,569,000 compared to approximately $38,203,000 and $98,120,000 for the same periods ended September 30, 2005, respectively.

Other Income and Expense

Investment income was approximately $1,801,000 and $5,740,000 for the three and nine months ended September 30, 2006 as compared to $1,618,000 and $4,696,000 for the same periods in 2005, respectively. The increase was due primarily to higher interest rates.

Interest expense was approximately $687,000 and $2,062,000 for the three and nine months ended September 30, 2006, respectively, as compared to approximately $736,000 and $3,477,000 for the same period in 2005, respectively. The decrease in interest expense is attributable to the lower interest rate for the 1.375% convertible senior notes as compared to the 5.75% convertible subordinated notes which were repaid in March 2005. During the nine month period ended September 30, 2005, we recorded a loss from early extinguishment of the 5.75% convertible subordinated notes, which consisted of the write-off of the remaining balance of the deferred financing costs of approximately $1,212,000 and the redemption premium of approximately $1,972,000.

Income Taxes

We recorded a state tax benefit of approximately $90,000 and $270,000 for the three and nine months ended September 30, 2006, respectively, compared to approximately $363,000 and $704,000 for the same period in 2005, respectively. The benefit is the result of the exchange for cash of our estimated 2005 and 2006 non-incremental research and development tax credits with the State of Connecticut.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

The company has net operating loss and federal and state research and development credit carry forwards of approximately $493 million and $17.8 million, respectively, as of December 31, 2005. The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer s ability to utilize net operating loss and tax credit carry forwards in any given year resulting from cumulative changes in ownership interests in excess of 50 percent over a three-year period. We have determined that these limiting provisions were triggered, however, such limitation would not result in the loss of the federal net operating loss and research and development credit carry forward.

Net Loss

The company incurred a net loss for the three and nine month periods ended September 30, 2006 of approximately $31,872,000 and $92,264,000 or $1.02 and $2.96 per common share, respectively, versus a net loss of approximately $36,574,000 and $98,265,000 or $1.24 and $3.45 per common share, respectively, for the same periods in 2005.

Liquidity and Capital Resources

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

As of September 30, 2006, cash, cash equivalents, and marketable securities were approximately $143,848,000 compared with $212,456,000 at December 31, 2005. The decrease was primarily due to cash used to fund operating activities. As of September 30, 2006, $33,184,000 of cash was restricted.

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2006 was approximately $81,936,000. The decrease compared to the same period in the previous year is primarily due to decreased clinical trial and research and development activities as compared to the same period in 2005.

Investing Activities

Net cash utilized for investing activities for the nine months ended September 30, 2006 was approximately $44,957,000. This included proceeds of approximately $98,379,000 from marketable securities, net of purchases of marketable securities, approximately $20,238,000 of property, plant and equipment additions, and setting aside $33,184,000 in restricted cash pursuant to the terms of our mortgage loan.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2006 was approximately $33,396,000, consisting of proceeds from our mortgage loan of $26,000,000 and proceeds from the issuance of common stock related to the exercise of stock options of approximately $7,396,000.

Sufficiency of Cash Resources

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

Financial Instruments

As of September 30, 2006, the market value of our $150,000,000 1.375% convertible senior notes due February 1, 2012, based on quoted market prices, was estimated at $188,812,500. The $59,062,500 increase from December 31, 2005 is attributable to the increase in the price of our

common stock.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Contractual Obligations

The following table summarizes our contractual obligations at September 30, 2006 and the effect such obligations is expected to have on liquidity and cash flow in future fiscal years. These do not include milestones and assume non-termination of agreements. These obligations represent payments based on current operating forecasts, which are subject to change:

	(in millions)				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Contractual obligations:					
Convertible notes payable	$ 150.0	$	$	$	$ 150.0
Mortgage loan	26.0		2.9	7.0	16.1
Interest expense	26.4	0.6	13.4	7.8	4.6
Capital and operating leases	24.4	0.6	7.6	5.2	11.0
Total contractual obligations	$ 226.8	$ 1.2	$ 23.9	$ 20.0	$ 181.7

Mortgage Loan

In July 2006, our wholly owned affiliate Alexion Manufacturing, LLC entered into a mortgage loan agreement to borrow $26,000,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility. The mortgage loan bears interest at a fixed annual rate of 9.17% and all obligations under the loan agreement are guaranteed by Alexion Pharmaceuticals, Inc. The loan principal is required to be repaid in equal installments, starting March 2009 and until August 2016, at which time all outstanding balances are due. 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. In the event that approval to market Soliris (eculizumab) is not obtained before December 31, 2007, Alexion Manufacturing LLC must deliver an acceptable letter of credit to the lender for the amount of $13,000,000. Also, included in the loan agreement are certain provisions which, if satisfied would allow for additional borrowings of $9,000,000.

Under the terms of the agreement, among other things, Alexion Manufacturing is restricted with respect to additional borrowings, leasing arrangements and mergers. Alexion Manufacturing also may not modify, amend, or waive material obligations with respect to, or terminate, material agreements or proprietary rights, or engage in any business other than ownership and operation of facility. Alexion Pharmaceuticals, Inc. may not, among other things, liquidate, wind-up or dissolve as long as the guarantee remains in effect.

As a condition of the loan, Alexion Manufacturing, LLC is required to maintain restricted cash accounts. These accounts must be used specifically for the purchase and construction of the manufacturing facility. The lender has a first priority security interest and the right to approve all disbursements from the accounts holding restricted cash. Under the agreement, we are required to, at all times, maintain a balance in the restricted cash accounts sufficient to complete the project.

Property, Plant, and Equipment

In July 2006, our wholly owned affiliate, Alexion Manufacturing, LLC purchased the former Dow manufacturing facility in Smithfield, Rhode Island for $13,000,000. The biopharmaceutical manufacturing facility will be used primarily to produce Soliris (eculizumab). In accordance with the Purchase and Sale Agreement dated April 13, 2006, we deposited into an escrow account $500,000 upon execution of the Agreement on April 13, 2006 and an additional $500,000 upon the completion of the due diligence period, in July 2006. The deposits were held in escrow until the closing date at which time the escrowed amounts and the remaining balance, net of property taxes owed for the first part of the year, of $11,926,289 was paid to Dow.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 our Transition Report on Form 10-K/T for the five-month transition period ended December 31, 2005, in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations under the caption Critical Accounting Policies and the Use of Estimates. We have reviewed those policies and determined that they remain our critical accounting policies for the three and nine month periods ended September 30, 2006, respectively.

Recently Issued Accounting Standards

In July 2006, the FASB approved the issuance of FASB Interpretation FIN No. 48, Accounting for Uncertainty in Income Taxes (as amended). This Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. Additionally, this Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Interpretation is effective for reporting periods beginning after December 15, 2006 with earlier application permitted. For Alexion, the effective date will be the first quarter of 2007. The Company is evaluating the impact of adopting this accounting principal on its financial position and results of operations.

Adoption of New Accounting Pronouncements

In May 2005, the FASB issued FASB 154, Accounting Changes and Error Corrections. The Statement replaces APB Opinion No. 20, Accounting Changes, and FASB Statement No. 3, Reporting Accounting Changes in Interim Financial Statements, and changes the requirements for the accounting for and reporting of a change in accounting principle. The Statement applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. For us, the effective date was the first quarter of 2006. The adoption of this accounting principle did not have a significant impact on our financial position or results of operations.

In March 2004, the EITF reached a consensus on Issue No. 03-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments. EITF 03-1 provides guidance on other-than-temporary impairment models for marketable debt and equity securities accounted for under SFAS 115 and non-marketable equity securities accounted for under the cost method. The EITF developed a basic three-step model to evaluate whether an investment is other-than-temporarily impaired. In November 2005, the FASB approved the issuance of FASB Staff Position FSP FAS No. 115-1 and FAS 124-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments. The FSP addresses when an investment is considered impaired, whether the impairment is other-than-temporary and the measurement of an impairment loss. The FSP also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary. The FSP is effective for reporting periods beginning after December 15, 2005 with earlier application permitted. For us, the effective date was the first quarter of 2006. The adoption of this accounting principle did not have a significant impact on our financial position or results of operations.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Item 3. Quantitative and Qualitative Disclosure about Market Risks

As of September 30, 2006, we held approximately 52% of our cash and investments in financial instruments with original maturity dates of three months or less which includes restricted cash, 22% in financial instruments with original maturity dates of greater than three months and less than one year, and the remaining 26% 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 $423,000 in the fair value of our cash and investments, which had a weighted average duration of approximately 3 months at September 30, 2006.

Our outstanding long-term liabilities as of September 30, 2006 included our $150,000,000, 1.375% Convertible Senior Notes due February 1, 2012. As the notes bear interest at a fixed rate, our results of operations would not be affected by interest rate changes. As of September 30, 2006, the market value of our $150,000,000 1.375% convertible senior notes due February 1, 2012, based on quoted market prices, was estimated at $188,812,500.

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

Item 4. Controls and Procedures.

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

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

Table of Contents

ALEXION PHARMACEUTICALS, INC.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

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

Risks Related to Our Financial Position and Need for Additional Capital

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

We have incurred losses since we started our company in January 1992. As of September 30, 2006, we had an accumulated deficit of approximately $598,331,000. 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. Although we have submitted for filing a BLA with the FDA in the United States and an MAA in Europe for Soliris (eculizumab), we have no products that are available for sale and do not know when we will have products available for sale, if ever. We expect to continue to operate at a net loss for at least the next several years as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. Our future profitability depends on our receiving regulatory approval of our product candidates and our ability to successfully manufacture and market approved drugs. The extent and the timing of our future losses and our profitability, if we are ever profitable, are highly uncertain.

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

We believe that 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 (eculizumab) 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 (eculizumab) 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 time and cost necessary to obtain regulatory approvals;
- the time and cost necessary to develop sales, marketing and distribution capabilities;
- the cost necessary to sell, market and distribute our products, if any are approved;
- 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 existence, terms, maintenance, termination and status of collaborative arrangements and strategic partnerships, such as our collaboration with Procter & Gamble, or P&G;

Table of Contents

ALEXION PHARMACEUTICALS, INC.

- the progress, timing and scope of our research and development programs;
- the progress, timing and scope of our preclinical studies and clinical trials;
- any new collaborative, licensing or other commercial relationships that we may establish.

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

We are significantly leveraged.

On September 30, 2006, we had outstanding $150,000,000 principal amount of 1.375% convertible senior notes. On July 11, 2006, our subsidiary Alexion Manufacturing borrowed $26,000,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility which may not be prepaid in whole or in part prior to July 11, 2009. The loan is guaranteed by us and bears a fixed annual rate of 9.17%. Our 1.375% convertible senior notes and the mortgage loan remain outstanding, and the degree to which we are leveraged could, among other things:

- make it difficult for us to make payments on our notes and our loan;
- make it difficult for us to obtain financing for working capital, acquisitions or other purposes on favorable terms, if at all;
- make us more vulnerable to industry downturns and competitive pressures; and
- limit our flexibility in planning for, or reacting to changes in, our business.

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.

Risks Related to Our Business

We depend heavily on the success of our lead product candidate, Soliris (eculizumab), which is still under development. If we do not obtain FDA approval of Soliris (eculizumab) or if FDA delays approval or narrows the indications for which we may market Soliris (eculizumab), our business will be materially harmed.

We recently submitted for filing a BLA to the FDA in the United States and an MAA in Europe for Soliris (eculizumab) for the treatment of PNH. In the near term our ability to generate revenues will depend on approval and successful commercialization of Soliris (eculizumab). The commercial success of Soliris (eculizumab) will depend on several factors, including the following:

- acceptance of our applications for filing;

successful completion of our ongoing Phase III clinical trial for Soliris (eculizumab);

receipt of marketing approvals from the FDA and similar foreign regulatory authorities;

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

successfully launching commercial sales of the product;

the number of patients with PNH that may be treated with the product; and

Table of Contents

ALEXION PHARMACEUTICALS, INC.

acceptance of the product in the medical community and by third-party payers.

The FDA and other regulatory agencies may refuse to accept our regulatory applications for review and may require additional information or data prior to acceptance. Even if our applications are accepted for review, we may not receive required regulatory approvals on a timely basis or at all. The approval process can involve additional lengthy clinical testing and other costly and time-consuming procedures.

Several biotechnology companies have failed to obtain regulatory approvals because regulatory agencies were not satisfied with the structure or conduct of clinical trials or the formatting or content of regulatory submissions. Similar problems could delay or prevent us from obtaining approvals. Furthermore, regulatory authorities, including the FDA, may not agree with our interpretations of our clinical trial data, which could delay, limit or prevent regulatory approvals. In addition, before a product candidate is approved for marketing, we, or any third-party manufacturing our product, are subject to inspection of the manufacturing facilities and the FDA will not approve the product for marketing if we or our third-party manufacturers are not in compliance with current good manufacturing practices.

Even if the FDA and similar foreign regulatory authorities do grant marketing approval for Soliris (eculizumab), they may narrow the indications for which we are permitted to market the product, may pose other restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. A narrowed indication or other restrictions may limit the market potential for the product and obligation to conduct additional clinical trials would likely result in increased expenditures and lower revenues. If we are not successful in commercializing Soliris (eculizumab), or are significantly delayed or limited in doing so, our business will be materially harmed and we may need to curtail or cease operations.

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 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. Our small, clinical-scale manufacturing plant cannot manufacture enough of our product candidates for later stage clinical development or commercial supply. We do not have the capacity to produce more than one product candidate at a time in that plant. We acquired a commercial-scale manufacturing plant in Smithfield, Rhode Island in July, 2006. However, that plant is not currently equipped or approved by the FDA or other regulatory agencies to manufacture Soliris (eculizumab) or our other drug candidates. We expect that it will be at least two years before the plant is capable of making product for commercial sale. We have no experience in developing commercial-scale manufacturing of the sort anticipated in Smithfield, Rhode Island. We can provide no assurance that we will be able to develop the Smithfield, Rhode Island site into a plant capable of manufacturing our drug products under conditions required by the FDA or foreign regulatory agencies on a timely basis, if at all. Our plant in Smithfield, Rhode Island will be subject to FDA inspection and approval before we can begin manufacturing Soliris (eculizumab) there and 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 begin manufacturing Soliris (eculizumab) there for European sales and will continue to be subject to ongoing European regulatory inspection thereafter.

We have executed a commercial-scale product supply agreement with Lonza for the long-term manufacture of eculizumab. 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 (eculizumab). If eculizumab is approved for sale, we expect that Lonza or we would 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. Our competitive position and our prospects for achieving profitability would be materially and adversely affected.

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

Manufacture of our drug products is highly technical and only a few third-parties have the ability and capacity to manufacture our drug products for our development and commercialization needs. We can not 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, and we could be required to share with P&G, on up to a 50-50 basis, substantial penalty payments owed by P&G for its failure to utilize the manufacturing capacity it contracted for with Chiron Corporation for the supply of pexelizumab. Penalty payments under these agreements typically decrease over the life of the agreement, and may be substantial initially and de minims or non-existent in the final period. The payment of a substantial penalty would harm our financial condition.

If we are unable to establish sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully market and sell future drug products.

We have no experience with marketing, sales and distribution of drug products and have only recently established pre-commercial capability in those areas. If we are unable to establish capabilities to sell, market and distribute our products, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully sell Soliris (eculizumab) or our future drug products. In that event, we will not be able to generate significant revenues. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need. We may not be able to enter into any marketing or distribution agreements with third-party providers on acceptable terms, if at all.

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

Soliris (eculizumab), if commercialized, is likely to be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if we cannot depend on governmental, private third-party payers and other third-party payers, including Medicare and Medicaid, to defray the cost of Soliris (eculizumab) to the consumer. If these entities refuse to provide coverage and reimbursement with respect to Soliris (eculizumab) or determine to provide an insufficient level of coverage and reimbursement, Soliris (eculizumab) may be too costly for general use, and physicians may not prescribe it. 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, which we anticipate Soliris (eculizumab) to be.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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

Since Soliris (eculizumab) will likely be 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 (eculizumab) may be adversely impacted. Any limitation on the use of Soliris (eculizumab) or any decrease in the price of Soliris (eculizumab) will have a material adverse effect on our ability to achieve profitability.

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

If the testing or use of our products harms people, or is perceived to harm patients even when such harm is unrelated to our products, our clinical trials may be adversely affected, our regulatory approval process could be delayed, negatively impacted or abandoned, any 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 (eculizumab) in only a small number of patients. If our applications for marketing Soliris (eculizumab) are approved and more patients begin to use our product, new risks and side effects associated with Soliris (eculizumab) 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 our product if and when regulatory approvals for Soliris (eculizumab) are obtained, 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 (eculizumab) or substantially increase the costs and expenses of commercializing and marketing Soliris (eculizumab).

We may be sued by people who participate in our trials or who use our products. Many patients who participate in our trials or use our products are already very ill. Any informed consents or waivers obtained from people who enroll in our trials or use our products 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 recruit patients for our clinical trials or to market and sell our products. 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.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Our clinical trials are often conducted with patients who have severe and advanced stages of disease when they enter our trials. Patients involved in clinical trials such as ours often have known as well as unknown significant pre-existing health risks. During the course of a trial, patients may suffer adverse events, including death, for reasons that may or may not be related to our products. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients or delay, negatively impact or end our opportunity to receive regulatory approval to market our products. Even in a circumstance in which we do not believe that an adverse event is related to our product, the investigation into the circumstance may be time consuming or may be inconclusive. These investigations may delay our regulatory approval process, impact and limit the type of regulatory approvals our products receive, or end our opportunity to receive regulatory approval. PNH patients in our trials sometimes have additional, pre-existing, potentially life-threatening disease, including for example bone marrow failure.

Some patients who have participated in our PNH trials have died or suffered potentially life-threatening diseases either during or after ending study-specified treatments. In particular, use of C5 Inhibitors, such as eculizumab, is associated with an increased risk for infection with Neisseria bacteria. Serious cases of Neisseria infection can result in severe illness, including but not limited to brain damage, loss of limbs or parts of limbs, kidney failure, or death. PNH patients in our TRIUMPH and SHEPHERD trials all received vaccination against the Neisseria bacteria prior to first administration of eculizumab; 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 (eculizumab) or discontinue their treatment of Soliris (eculizumab). Treatment with Soliris(eculizumab) blocks complement and allows complement-sensitive PNH red blood cells to increase in number. If treatment with Soliris (eculizumab) 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 (eculizumab) 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 (eculizumab) could have a material adverse effect on our ability to sell eculizumab for PNH.

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

We depend upon third-party collaborators to assist us in the development of our product candidates. If any of our existing collaborators breaches or terminates its agreement with us or does not perform its development work under an agreement in a timely manner, or at all, we would experience significant delays in the development or commercialization of our product candidates. We would also experience significant delays if we could not engage additional collaborators when required. In either event, 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:

- our current collaboration arrangements will continue in their current form;
- 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
- current or potential collaborators will not pursue treatments for other diseases or seek other ways of developing treatments for our disease targets.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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

Each of Abbott Laboratories Inc., Adprotech Ltd., Avant Immunotherapeutics, Inc., Baxter International, Inc., Millennium Pharmaceuticals, Inc., Neurogen Corporation, Tanox, Inc., XOMA, Ltd., and Archemix Corporation have publicly announced their intentions to develop drugs which target the inflammatory effects of complement in the immune system. We are also aware that GlaxoSmithKline, plc, Merck & Co., Inc., and Pfizer, Inc. have had programs develop complement inhibitor therapies. Each of AstraZeneca, MorphoSys AG and Dyax Corporation has publicly announced intentions to develop therapeutic human antibodies from libraries of human antibody genes. Additionally, each of Amgen, Inc. and Medarex, Inc. has publicly announced intentions to develop therapeutic human antibodies from mice that have been bred to include some human antibody genes. These and other pharmaceutical companies, many of which have significantly greater resources than we, may develop, manufacture, and market better or cheaper drugs than our product candidates. They may establish themselves in the marketplace even before we are able to finish our clinical trials. Other pharmaceutical companies also compete with us to attract academic research institutions as drug development partners, including for licensing these institutions proprietary technology. If our competitors successfully enter into such arrangements with academic institutions, we will be precluded from pursuing those unique opportunities and may not be able to find equivalent opportunities elsewhere.

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

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

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

We are 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;

Table of Contents

ALEXION PHARMACEUTICALS, INC.

potentially dilutive issuance of equity securities;

incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;

difficulties in assimilating the operations of the acquired companies;

diverting our management s attention away from other business concerns;

risks of entering markets in which we have limited or no direct experience; and

the potential loss of our key employees or key employees of the acquired companies.

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

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

As of December 31, 2005, we had approximately $493 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 there under, increase their aggregate percentage ownership of our stock by more than 50 percentage points over the lowest percentage of our stock owned by these stockholders at any time during the testing period, which is generally the three-year period preceding the potential ownership change. In the event of an ownership change, section 382 imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change NOLs. The limitation imposed by section 382 for any post-change year would be determined by multiplying the value of our stock immediately before the ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Any unused limitation may be carried over to later years, and the limitation may under certain circumstances be increased by built-in gains which may be present with respect to assets held by us at the time of the ownership change that are recognized in the five-year period after the ownership change. Our use of NOLs arising after the date of an ownership change would not be affected.

Risks Related to Our Industry

We are subject to extensive government regulation, and, if we do not obtain and maintain regulatory approvals, we will not be able to sell our drug products.

We and our partners cannot sell or market our products without regulatory approval. If we or our partners do not obtain and maintain regulatory approval for our products, the value of our company and our results of operations will

Table of Contents

ALEXION PHARMACEUTICALS, INC.

be harmed. In the United States, we or our partners must obtain and maintain approval from the FDA for each indication for each drug that we intend to sell and for each facility where such drug is manufactured. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed outside the United States and facilities outside the United States where such drugs are manufactured, and obtaining their approvals can also be lengthy, expensive and highly uncertain. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country. In certain foreign jurisdictions we would be required to obtain pricing approvals prior to marketing our products. None of our product candidates has received regulatory approval to be marketed and sold in the United States or any other country. We may not receive regulatory approval for any of our product candidates for at least the next several years, if ever.

We and our 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 apply both before and after approval of our product candidates, if our product candidates are ever approved, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, 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. Our manufacturing and other facilities and those of any third parties manufacturing our products will be subject to inspection prior to grant of marketing approval and subject to continued review and periodic inspections by the regulatory authorities. Any third party we would use to manufacture our products for sale must also be licensed by applicable regulatory authorities. Failure to comply with the laws, including statutes and regulations, administered by the FDA or other agencies could result in:

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

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

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

The FDA has granted orphan drug designation for eculizumab in the treatment of PNH and membranous nephritis. Orphan drug designation does not convey any advantage in, or shorten the duration of, the FDA review and approval process. If a product which has an orphan drug designation is the first drug of its type to receive FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

If our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our products.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval for our products. We need to conduct both preclinical animal testing and clinical human trials. These tests and trials may not achieve favorable results. The FDA typically requires two well controlled clinical trials that demonstrate efficacy in order to obtain FDA approval to market a product candidate. The special protocol assessment for our development of Soliris (eculizumab) for PNH provides for only a single efficacy trial and the FDA has indicated that the trials should provide compelling evidence of clinically meaningful benefit in order to warrant consideration for marketing approval. The FDA has noted that a study that is merely statistically positive may not provide the evidence necessary to support filing or approval of a product candidate.

The FDA and other regulatory agencies may require additional information or data prior to and after acceptance of our BLA and MAA for Soliris (eculizumab) for PNH. We may have to conduct additional lengthy clinical testing and other costly and time-consuming procedures. Inconclusive or negative final data from our 12 month Phase III SHEPHERD trial would have a significant negative impact on our prospects. Even if we view the data as positive, the FDA may not agree with our interpretations of our clinical trial data for Soliris (eculizumab) and may decide that our results are not adequate to support approval for marketing of Soliris (eculizumab). In those circumstances, we would not be able to obtain regulatory approval on a timely basis, if ever. Even if approval is granted, 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. Whether or not we obtain FDA approval for a product, 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.

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

Completion of clinical trials does not guarantee that we will initiate additional trials for our product candidates, that if the trials are initiated what the scope and phase of the trial will be or that they will be completed, or that if the trials are completed, that the results will provide a sufficient basis to proceed with further trials or to apply for or receive regulatory approvals or to commercialize products. Results of 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 trial to achieve its pre-specified primary endpoint generally increases the likelihood that additional studies 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. Also, to ensure safety and effectiveness, the effect of drugs often must be studied over a long period of time, especially for the chronic diseases that we are studying. Unfavorable results or insufficient patient enrollment in our clinical trials could delay or cause us to abandon a product development program. We may decide to abandon development of a product candidate at any time, or we may have to spend considerable resources repeating clinical trials or conducting additional trials, either of which would increase costs and delay any revenue from those product candidates, if any.

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

- slow patient enrollment, including for example due to the rarity of the disease being studied;

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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.

Risks Related to Intellectual Property

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

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

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

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

Parts of our technology, techniques and proprietary compounds and potential drug candidates, including those which are in-licensed, may be found to infringe patents owned by or granted to others. If we cannot resolve these conflicts, we may be liable for damages, be required to obtain costly licenses or be stopped from manufacturing, using or selling our products or conducting other activities. For example, 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. Many of our product candidates, including our lead product candidate, eculizumab, are either genetically engineered antibodies, including recombinant humanized antibodies, recombinant humanized single chain antibodies, recombinant human antibodies, or recombinant human single chain antibodies.

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 some of our drug candidates, including eculizumab. We are also aware of other patents owned by third parties that might be claimed to be infringed by the development and commercialization of some of our drug candidates, including eculizumab. In respect to some of these patents, we have obtained licenses, or expect to obtain licenses. However, with regard to other patents, we have either determined in our judgment that:

- we believe our products do not infringe the patents;

Table of Contents

ALEXION PHARMACEUTICALS, INC.

- we do not believe the patents are 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.

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; will be able to obtain a license to any third-party patent on commercially reasonable terms; successfully develop non-infringing alternatives on a timely basis; or license alternative non-infringing technology, if any exists, on commercially reasonable terms. Any impediment to our ability to manufacture or sell approved forms of our product candidates could have a material adverse effect on our business and prospects.

Risks Related to Our Common Stock

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

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

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

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

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

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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 5. Other Information

Purchase of Manufacturing Facility

As described in Item 2 of Part I, on July 13, 2006, our wholly owned affiliate, Alexion Manufacturing LLC purchased a manufacturing facility in Smithfield, Rhode Island from Dow Chemical Company for $13,000,000. The biopharmaceutical manufacturing facility will be used primarily to produce Soliris (eculizumab). Pursuant to the Purchase and Sale Agreement dated April 13, 2006, or the purchase agreement, we acquired rights to approximately a 55,000 square foot facility, certain equipment located at, or used in connection with, the facility and certain rights under service contracts related to the facility. We deposited into an escrow account $500,000 upon execution of the purchase agreement on April 13, 2006 and an additional $500,000 upon the completion of the due diligence period in July 2006. The deposits were held in escrow until the closing date at which time the escrowed amounts and the remaining balance, net of property taxes owed for the first part of the year, of $11,926,289 was paid to Dow.

Mortgage Loan Agreement

As described in Item 2 of Part I, on July 11, 2006, Alexion Manufacturing entered into certain loan contracts, including the Loan and Security Agreement, or the loan agreement, and the Promissory Note, or the promissory note, with iStar Financial, Inc., as a lender, to borrow $26,000,000 to finance the purchase and construction of our Smithfield, Rhode Island manufacturing facility. On the closing date, Alexion Manufacturing paid iStar a commitment fee of $390,000.

The mortgage loan is evidenced by the promissory note and all obligations under the loan are guaranteed by Alexion Pharmaceuticals, Inc. pursuant to the Completion, Payment, and Performance Guaranteed entered into on July 11, 2006. To further secure its performance of its obligations under the loan agreement, Alexion Manufacturing entered into the Construction Mortgage Deed, Assignment of Leases and Rents, Security Agreement on July 11, 2006 which, among other things, grants the lender a security interest in the facility and the inventory, accounts and other property of Alexion Manufacturing.

The loan bears interest at a fixed annual rate of 9.17%, and in the event of default, as described below, the rate increases to 14.17%. Interest-only payments are due monthly beginning with the closing of the transaction, and the loan principal plus interest payments are due in equal installments monthly beginning March 2009 and until August 2016, at which time all outstanding balances are due. The loan may not be prepaid in whole or in part prior to July

Table of Contents

ALEXION PHARMACEUTICALS, INC.

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. In the event that approval to market Soliris (eculizumab) in the United States or Europe has not been obtained before December 31, 2007, Alexion Manufacturing is obligated to deliver an acceptable letter of credit to the lender for the amount of $13,000,000.

Under the terms of the agreement, among other things, Alexion Manufacturing is restricted with respect to additional borrowings, leasing arrangements and mergers. Alexion Manufacturing also may not modify, amend, or waive material obligations with respect to, or terminate, material agreements or proprietary rights, or engage in any business other than ownership and operation of the Smithfield, Rhode Island facility. Alexion Pharmaceuticals, Inc. may not, among other things, liquidate, wind-up or dissolve as long as the guarantee remains in effect.

As a condition of the loan, Alexion Manufacturing is required to maintain restricted cash accounts. These accounts are restricted as to use specifically for the purchase and construction of the manufacturing facility. The lender has a first priority security interest and the right to approve all advances from the accounts holding restricted cash. We are required to, at all times, maintain a balance in the restricted cash accounts sufficient to complete the project. On the date of closing of the transaction, the balance of restricted cash was $35,807,244.

Lender has a right to approve all disbursements from the accounts to pay construction and development costs in connection with the facility and to require that certain conditions be satisfied prior to making disbursements, including sufficiency of funds to pay the remaining costs of the project. Prior to receiving a disbursement, Alexion Manufacturing is required to, among other things, comply with all conditions reasonably imposed by iStar and also confirm that all representations and warranties are still true; certify all expenses to be verified by the lender; represent that all work complies with applicable legal requirements and all necessary licenses and approvals have been obtained.

Lender also has a right from time to time to estimate the costs associated with completion of construction and to determine whether the amounts held in the restricted cash accounts are sufficient. Should it be determined that the funds are insufficient, Alexion Manufacturing would have ten business days to make a deposit of sufficient funds. Failure to do so would be considered an event of default.

The loan agreement specifies a number of other events of default (some of which are subject to applicable cure periods), including the failure to make payments when due; breach of representations and warranties; failure to deliver a $13,000,000 letter of credit if marketing approval for Soliris (eculizumab) is not received in the United States or Europe prior to December 31, 2007; default in performance of or compliance with any term contained in the loan agreement or other loan contracts; voluntary or involuntary bankruptcy; change in control of Alexion Manufacturing; and noncompliance with covenants and defaults under other agreements or instruments of indebtedness by Alexion Manufacturing or Alexion. Upon the occurrence of an event of default, the lender may take one or more actions, including declaring all amounts outstanding to be immediately due and payable, taking possession of the facility, applying all funds contained in the restricted cash accounts to satisfy obligations; discontinuing any construction work; causing construction work to be completed; and ceasing loan disbursements.

Alexion manufacturing is required to indemnify the lender in connection with a variety of claims, including related to or out of (i) any breach by Alexion Manufacturing or Alexion Pharmaceuticals, Inc. of any representation, warranty, covenant or other agreement contained in the loan agreement or other contracts, (ii) actual or threatened spill, leakage or clean-up of hazardous material affecting the facility or any violation of any applicable environmental law, and (iii) use of proceeds of the loan. In addition, in connection with the loan agreement, Alexion Manufacturing entered into an Environmental Indemnity Agreement on July 11, 2006 to specifically indemnify the lender against claims arising from the presence or release of hazardous materials at the facility.

Provided that no event of default exists and approval to market Soliris (eculizumab) in the US or Europe is obtained prior to or on December 31, 2007, Alexion Manufacturing may request a loan for an additional $9,000,000 on the terms described in the loan agreement.

Table of Contents

ALEXION PHARMACEUTICALS, INC.

Item 6. EXHIBITS

(a) Exhibits

10.1 Purchase and Sale Agreement by and between The Dow Chemical Company and Alexion Manufacturing LLC, dated as of April 13, 2006, as amended.

10.2 Loan and Security Agreement between Alexion Manufacturing LLC and iStar Financial Inc., dated as of July 11, 2006.

10.3 Completion, Payment, and Performance Guarantee by Alexion Pharmaceuticals, Inc. in favor of iStar Financial Inc., dated as of July 11, 2006.

10.4 Construction Mortgage Deed, Assignment of Leases and Rents, Security Agreement and Fixture Filing, dating as of July 11, 2006 by Alexion Manufacturing LLC in favor of iStar Financial Inc.

10.5 Environmental Indemnity Agreement by and among Alexion Manufacturing LLC, Alexion Pharmaceuticals, Inc. in favor of iStar Financial Inc., dated as of July 11, 2006.

31.1 Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.

31.2 Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.

32.1 Certification by Leonard Bell, Chief Executive Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.

32.2 Certification by Vikas Sinha, Senior Vice President and Chief Financial Officer of Alexion Pharmaceuticals, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in connection with Alexion Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.

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: November 8, 2006

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

Date: November 8, 2006

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