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NOVADEL PHARMA INC  
Form 10QSB  
March 10, 2003

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-QSB  
X QUARTERLY REPORT UNDER SECTION 13 OR 15(D) OF  
--- THE SECURITIES EXCHANGE ACT OF 1934

For the six month period ended JANUARY 31, 2003

\_\_\_ TRANSITION REPORT UNDER SECTION 13 or 15 (d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_ to \_\_\_

Commission file number 000-23399

NOVADEL PHARMA INC.  
(Exact name of small business issuer as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

22-2407152  
(I.R.S. Employer  
Identification No.)

31 State Highway 12  
Flemington, New Jersey  
(Address of Principal Executive Offices)

08822  
(Zip Code)

(908)782-3431  
(Issuer's telephone number)

Check whether the issuer (1) filed all reports required to be filed by  
Section 13 or 15(d) of the Exchange Act during the past 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  
--- ---

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY  
PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Check whether the registrant filed all documents and reports required  
to be filed by Sections 12, 13 or 15(d) of the Exchange Act after the  
distribution of securities under a plan confirmed by a court. Yes \_\_\_ No \_\_\_

APPLICABLE ONLY TO CORPORATE ISSUERS:

State the number of shares outstanding of each of the issuer's classes  
of common equity, as of the latest practicable date. 14,548,509 shares of common  
stock outstanding as of January 31, 2003.

TRANSITIONAL SMALL BUSINESS DISCLOSURE FORMAT (CHECK ONE):

YES NO X  
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NOVADEL PHARMA INC.

BALANCE SHEETS

	January 31 2003	July 31, 2002
	----- (Unaudited)	----- (Note 1)
ASSETS		
CURRENT ASSETS:		
Cash	\$1,524,000	\$ 3,314,000
Accounts receivable - trade, less allowance for doubtful accounts of \$88,000 at January 31, 2003 and July 31, 2002	-	1,000
Prepaid expenses and other current assets	161,000	96,000
	-----	-----
Total Current Assets	1,685,000	3,411,000
	-----	-----
FURNITURE, FIXTURES, AND EQUIPMENT, LESS ACCUMULATED DEPRECIATION	441,000	406,000
OTHER ASSETS	26,000	22,000
	-----	-----
	\$2,152,000	\$ 3,839,000
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable-trade	\$ 368,000	\$ 125,000
Accrued expenses and other current liabilities	529,000	191,000
	-----	-----
Total Current Liabilities	897,000	316,000
	-----	-----
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIENCY):		
Preferred stock, \$.01 par value:		
Authorized 1,000,000 shares, none issued		
Common stock, \$.001 par value:		
Authorized - 50,000,000 shares		
Issued and outstanding 14,548,509 and 14,448,817; respectively	15,000	14,000
Additional paid-in capital	14,536,000	13,322,000
Accumulated Deficit	(13,296,000)	(9,813,000)
	-----	-----
Total Stockholders' Equity (Deficiency)	1,255,000	3,523,000
	-----	-----
	\$2,152,000	\$ 3,839,000
	=====	=====

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See accompanying notes to financial statements.

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NOVADEL PHARMA INC.  
STATEMENTS OF OPERATIONS  
(Unaudited)

	Three Months Ended January 31,	
	2003	2002
CONSULTING REVENUES	-	\$183,000
CONSULTING, SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	1,871,000	548,000
LOSS FROM OPERATIONS	(1,871,000)	(365,000)
BUY-OUT OF CONSULTANT'S CONTRACT	-	(33,000)
INTEREST INCOME	18,000	10,000
NET LOSS BEFORE TAXES	(1,853,000)	(388,000)
DEFERRED INCOME TAX BENEFIT	84,000	88,000
NET LOSS	\$ (1,769,000)	\$ (300,000)
BASIC AND DILUTED LOSS PER SHARE	\$ (.12)	\$ (.03)
SHARES USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	14,542,821	9,942,291

See accompanying notes to financial statements.

NOVADEL PHARMA INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)  
(Unaudited)

	Common Stock		
	Shares	Par Value	Paid-in Capital
BALANCE, JULY 31, 2002	14,448,817	\$ 14,000	\$13,322,000
SIX MONTHS ENDED JANUARY 31, 2003 -			
Shares issued for Warrants exercised	99,692	1,000	9,000
Options issued for services	-	-	1,198,000
Warrants issued for services	-	-	7,000
Net Loss	-	-	-
BALANCE, JANUARY 31, 2003	14,548,509	\$ 15,000	\$14,536,000

See accompanying notes to financial statements.

NOVADEL PHARMA INC.

STATEMENT OF CASH FLOWS  
(Unaudited)

	Six Months January 3
	2003
CASH FLOW FROM OPERATING ACTIVITIES:	
Net (loss)	\$(3,483,000)
Adjustments to reconcile net income (loss) to net cash flows from operating activities:	
Warrants issued for Services	7,000
Options Issued for Services	1,198,000
Shares issued for Warrants exercised	10,000
Depreciation & Amortization	74,000
Allowance for Doubtful Accounts	-
Changes in operating assets and liabilities:	
Accounts receivable	1,000

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Prepaid expenses and other current assets	(65,000)
Demand note receivable, officer	-
Due from joint venture partner for reimbursable expenses	-
Other Assets	(4,000)
Accounts payable - trade	243,000
Accrued expenses and other current liabilities	338,000
	-----
Net cash flows from operating activities	(1,681,000)
	-----
CASH FLOWS FROM INVESTING ACTIVITIES -	
Purchase of property and equipment	(109,000)
	-----
CASH FLOWS FROM FINANCING ACTIVITIES - Proceeds received from issuance of common stock through	
a private placement offering	-
	-----
NET CHANGE IN CASH	(1,790,000)
CASH, BEGINNING OF PERIOD	3,314,000
	-----
CASH, END OF PERIOD	\$1,524,000
	=====
SUPPLEMENTAL CASH FLOW INFORMATION:	
Interest paid	\$ -
	=====
Income taxes paid	\$ -
	=====

See accompanying notes to financial statements.

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NOVADEL PHARMA INC.  
NOTES TO FINANCIAL STATEMENTS

NOTE 1 - BASIS OF PRESENTATION:

The balance sheet at the end of the preceding fiscal year has been derived from the audited balance sheet contained in the Company's Form 10-KSB and is presented for comparative purposes. All other financial statements are unaudited. In the opinion of management, all adjustments, which include only normal recurring adjustments necessary to present fairly the financial position, results of operations and cash flows for all periods presented, have been made in the interim statements. Results of operations for interim periods are not necessarily indicative of the operating results for a full year.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company believes that its current cash levels will be sufficient to satisfy its cash requirements for the next three (3) months. However, beyond this point there is substantial doubt about the Company's ability to continue operations without obtaining additional financing and/or consummating a strategic alliance with a well-funded business partner. There are a number of risks and uncertainties related to the Company's attempt to

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complete a financing or strategic partnering arrangement that are outside the control of the Company. We may not be able to successfully obtain additional financing on terms acceptable to the Company, or at all. These uncertainties raise substantial doubt as to the Company's ability to continue as a going concern.

Footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted in accordance with the published rules and regulations of the Securities and Exchange Commission. The financial statements in this report should be read in conjunction with the financial statements and notes thereto included in the Form 10-KSB of NOVADEL PHARMA INC. (the "Company"), for the year ended July 31, 2002.

### NOTE 2 - PREPAID EXPENSES AND OTHER CURRENT ASSETS:

Approximately \$94,000 of prepaid supplies; \$62,000 of prepaid insurance and \$5,000 of employee loan are included in the \$161,000 total.

### ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES:

Approximately \$201,000 of accrued employee vacation; \$264,000 of accrued payroll, related payroll taxes and guaranteed bonus (see Note 5); \$51,000 of accrued clinical study costs and \$10,000 of accrued legal and professional fees are included in the \$529,000 total. The remainder is other accrued expenses and other current liabilities.

### NOTE 3- STOCK OPTIONS AND WARRANTS:

In October 2002, the Company issued 75,000 options under the 1998 option plan and 200,000 non-plan options to its president. These options vest immediately, have an exercise price of \$1.30 and expire during October 2007.

In November 2002, the Company decided to extend for one year the expiration date of its publicly traded warrants (i.e. to November 18, 2003). All other provisions of the warrants remain unchanged.

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In December 2002, pursuant to an employment agreement with Gary A. Shangold, M.D. (see Note 5, below) 1,000,000 options were issued at an exercise price of \$1.93 per share with a 5 year life. The options vest and become exercisable in three equal annual installments commencing December 1, 2003

### NOTE 4 - DEFERRED INCOME TAX BENEFIT:

During December 2002, the Company received approximately \$84,000 as consideration for transferring approximately \$1,116,000 of New Jersey net operating loss tax benefit to a third party corporation buyer. The Technology Tax Certificate Transfer Program for transferring net operating loss and R & D tax benefits is the responsibility of New Jersey Economic Development Authority.

### NOTE 5 - CONTRACTS:

In December 2002, the Company entered into a three-year employment agreement with Gary A. Shangold, M.D. pursuant to which he agreed to

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serve as the Company's President and Chief Executive Officer. The Company agreed to pay Dr. Shangold an annual base salary of \$350,000 and a guaranteed bonus of \$150,000. In addition, Dr. Shangold is eligible to receive: (i) an annual discretionary bonus of up to \$262,500, which shall be determined at the sole discretion of the Board; and (ii) an investment and fee bonus equal to 5% of all amounts up to an aggregate of \$7,500,000 (i.e., \$375,000) invested in, or earned by, the Company during his term. The Company is obligated to pay Dr. Shangold at least \$200,000 on or before June 30, 2003. Such investment and fee bonus shall be reduced by certain proceeds received by Dr. Shangold from his former employer. Pursuant to the agreement, Dr. Shangold was also granted non-plan options (see Note 3, above) to purchase 1,000,000 shares of the Company's common stock (at an exercise price of \$1.93 per share) which vest over a three year period.

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### NOVADEL PHARMA INC.

#### Part I, Item 2. Management's Discussion and Analysis

Novadel Pharma inc., a Delaware corporation (the "Company"), is engaged in development of novel application drug delivery systems for presently marketed prescription and over-the-counter ("OTC") drugs and has been a consultant to the pharmaceutical industry. Since 1992, the Company has used its consulting revenues to fund its own product development activities.

Since its inception, substantially all of the Company's revenues have been derived from its consulting activities. The Company has had a history of recurring losses from operation, giving rise to an accumulated deficit at January 31, 2003 of approximately \$13,296,000. For the 6 months ending January 31, 2003, the Company has had no revenue from consulting as the Company has shifted its emphasis away from product development consulting for its clients and to development of its own products.

For the reasons stated above, the Company anticipates that it will incur substantial operating expenses in connection with the testing and approval of its proposed delivery systems, and expects these expenses will result in continuing and significant operating losses until such time, if ever, that the Company is able to achieve adequate sales levels.

In view of the Company's very limited resource, its anticipated expenses and the competitive environment in which the Company operates, there can be no assurance that its operations will be sustained for the duration of the current fiscal year.

#### RESULTS OF OPERATIONS

THE SIX MONTHS ENDED JANUARY 2003 [THE "2003 PERIOD"] AND JANUARY 2002 [THE "2002 PERIOD"]

Operating revenues for the 2003 Period decreased approximately \$255,000 to \$0 from \$255,000 for the 2002 Period.

Total costs and expenses for the 2003 Period increased approximately \$2,728,000 or 313% to \$3,600,000 from \$872,000 for the 2002 Period. This increase includes approximately: \$1,498,000 in consultants fees primarily due to a non-cash charge

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of approximately \$1,205,000 for options and warrants issued to consultants; \$520,000 in payroll expense primarily due to the establishment of a vacation pay accrual and hiring of additional employees; \$320,000 in legal & professional fees; \$147,000 in laboratory testing and clinical studies costs; \$51,000 in employee recruiting; \$47,000 in insurance expenses due to additional employees and generally increased premiums; \$46,000 in depreciation and amortization expense due to the earlier purchases of internal laboratory equipment; \$29,000 in inside laboratory supplies expenses; \$29,000 in trade show and conference expenses; \$29,000 in travel expenses; \$14,000 in office expenses due to additional employees and \$12,000 in automobile expenses.

Costs and expenses decreases for the 2003 period, as compared to the 2002 period, includes approximately: \$33,000 in buy-out of contract with a consultant and \$17,000 in public company expenses due primarily to a decrease in printing costs.

Interest income increased approximately \$18,000 or 120% to \$33,000 for the 2003 Period from \$15,000 for the 2002 Period due to an increased average cash balance.

Deferred income tax benefit for the 2003 period was approximately \$84,000 compared to approximately \$88,000 for the 2002 period. These benefits resulted from the sale of the Company's New Jersey net operating losses.

The resulting net loss for the 2003 Period was \$3,483,000 compared to a net loss of \$547,000 for the 2002 Period.

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THE THREE MONTHS ENDED JANUARY 2003 [THE "2003 PERIOD"] AND JANUARY 2002 [THE "2002 PERIOD"]

Operating revenues for the 2003 Period decreased approximately \$183,000 to \$0 from \$183,000 for the 2002 Period.

Total costs and expenses for the 2003 Period increased approximately \$1,323,000 or 241% to \$1,871,000 from \$548,000 for the 2002 Period. This increase includes approximately: \$716,000 in consultants fees primarily due to a non-cash charge of approximately \$599,000 for options and warrants issued to consultants; \$372,000 in payroll expense primarily due to the establishment of a vacation pay accrual and hiring of additional employees; \$113,000 in legal & professional fees; \$49,000 in employee recruiting; \$25,000 in insurance expenses due to additional employees and increased premiums; \$21,000 in depreciation and amortization expense due to the earlier purchases of internal laboratory equipment; \$20,000 in travel expenses; \$10,000 in inside laboratory supplies expenses; \$9,000 in laboratory testing and clinical studies costs and \$8,000 in automobile expenses.

Costs and expenses decreases for the 2003 period, as compared to the 2002 period, includes approximately: \$33,000 in buy-out of contract with a consultant; \$18,000 in public company expenses due primarily to decreased printing costs and \$6,000 in bad debt expense.

Interest income increased approximately \$8,000 or 80% to \$18,000 for the 2003 Period from \$10,000 for the 2002 Period due to an increased average cash balance.

Deferred income tax benefit for the 2003 period was approximately \$84,000 compared to approximately \$88,000 for the 2002 period. These benefits resulted



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from the sale of the Company's New Jersey net operating losses.

The resulting net loss for the 2003 Period was \$1,769,000 compared to a net loss of \$300,000 for the 2002 Period.

### LIQUIDITY AND CAPITAL RESOURCES

Net cash used in operating activities approximated \$1,681,000 for the 2003 Period compared to net cash used in operating activities of approximately \$242,000 for the 2002 Period. Net cash used in operating activities for both the 2003 and 2002 periods was primarily attributable to the net loss of \$3,483,000 and \$547,000, respectively. For the 2003 period, \$109,000 was used for investing activities compared to \$81,000 for the 2002 Period. For the 2002 period, \$2,984,000 was received from financing activities. Total cash flow for the 2003 period decreased approximately \$1,790,000 as compared to a \$2,661,000 increase for the 2002 period.

The Company believes that it currently has sufficient cash to satisfy its cash requirements for at least the next three (3) months. However, beyond this point there is substantial doubt about the Company's ability to continue operations without obtaining additional financing and/or consummating a strategic alliance with a well-funded business partner. There are a number of risks and uncertainties related to the Company's attempt to complete a financing or strategic partnering arrangement that are outside the control of the Company. We may not be able to successfully obtain additional financing on terms acceptable to the Company, or at all. These uncertainties raise substantial doubt as to the Company's ability to continue as a going concern. The Company's auditors have qualified their audit opinion with regard to the Company's ability to continue as a going concern.

### INFLATION

The Company does not believe that inflation has had a material effect on its results of operations during the past three fiscal years. There can be no assurance that the Company's business will not be affected by inflation in the future.

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### Part 1, Item 3. Controls and Procedures

Within the 90-day period prior to the date of this report, our Chief Executive Officer and Chief Financial Officer performed an evaluation of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. They concluded that the controls and procedures were effective. Since the date of the evaluation, we have made no significant changes in our internal controls or in other factors that could significantly affect our internal controls.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

None

### Item 2. Changes in Securities

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In August 2002, the Company issued 85,922 common shares to satisfy the cashless exercise of 136,482 warrants.

In December 2002 the Company issued 13,770 common shares to satisfy the exercise of 13,770 warrants.

### Item 3. Defaults Upon Senior Securities

N/A

### Item 4. Submissions of Matters to a Vote of Security Holders

N/A

### Item 5. Other Information

N/A

### Item 6. Exhibits List and Reports on Form 8-K

#### (a) List of Exhibits

\*\* Exhibit 10.26 Employment Agreement Dated December 3, 2002, between the Company and Gary A. Shangold, M.D.

\*\* Exhibit 10.27 Amendment #1 of Employment Agreement Dated December 22, 2002, between the Company and Gary A. Shangold, M.D.

Exhibit 11. Statement re: computation of earnings per share for the six months ended January 31, 2003

Exhibit 99.1. Certification of Chief Executive Officer and Chief Financial Officer

#### b) Reports on Form 8-K None

\*\* Filed herewith

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## SIGNATURES

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

NOVADEL PHARMA INC

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Dated: March 10, 2003  
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By: /s/ Gary Shangold, M.D.  
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Gary Shangold, M.D., President  
(Principal Executive Officer)

Dated: March 10, 2003  
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By: /s/ Donald J. Deitman  
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Donald J. Deitman  
Chief Financial Officer

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CERTIFICATION

I, Gary Shangold, M.D., certify that:  
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1. I have reviewed this quarterly report on Form 10-QSB of NovaDel Pharma Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) Presented in this quarterly report our conclusions about the

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effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date.

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors and material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 10, 2003

Gary Shangold, M.D.  
President & Chief Executive Officer

/s/ Gary Shangold, M.D.  
-----  
(Signature)

CERTIFICATION

I, Donald J. Deitman, certify that:

- 
1. I have reviewed this quarterly report on Form 10-QSB of NovaDel Pharma Inc.;
  2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
  3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
  4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
    - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

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b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date.

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors and material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 10, 2003  
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Donald J. Deitman  
Chief Financial Officer

/s/ Donald J. Deitman  
-----

(Signature)

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P STYLE="margin-top:6px;margin-bottom:0px;text-indent:4%">The DEA limits the quantity of certain Schedule I and II controlled substances that may be produced in the United States in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem and JZP-6, sodium oxybate, is a Schedule I controlled substance, our supplier of the active pharmaceutical ingredient and our product manufacturers must obtain DEA quotas in order to supply us with sodium oxybate, Xyrem and JZP-6. Since the DEA typically grants quotas on an annual basis and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process. If our commercial or clinical requirements for sodium oxybate, Xyrem or JZP-6 exceed our supplier's and contract manufacturer's DEA quotas, our supplier and contract manufacturer would need quota increases from the DEA, which could be difficult and time consuming to obtain and might not ultimately be obtained on a timely basis, or at all. In cooperation with our manufacturing partners, we sought and received significant increases in their 2007 quotas from the DEA for sodium oxybate, Xyrem and JZP-6 to satisfy the forecasted demand for Xyrem and to conduct our clinical studies of JZP-6. We did not succeed in obtaining the entire quota we requested for 2007. The quotas issued by the DEA for 2008 were greater than initially issued for 2007; however, we believe that the quota for 2008 may not be sufficient to satisfy all of our commercial and clinical needs. In the future and in cooperation with our procurement and manufacturing partners, we will continue to seek increased quotas to satisfy our clinical and commercial needs. However, we may not be successful in obtaining increased quotas from the DEA, and without sufficient DEA quotas, there could be shortages of Xyrem for the marketplace or JZP-6 for use in our clinical studies, or both.

*We depend on single source suppliers and manufacturers for each of our products and product candidates. The loss of any of these suppliers or manufacturers, or delays or problems in the supply or manufacture of our products for commercial sale or our product candidates for use*

*in our clinical trials, could materially and adversely affect our business, financial condition, results of operations and growth prospects.*

We do not have, and do not intend to establish in the near term, our own manufacturing or packaging capability for our products or product candidates, or their active pharmaceutical ingredients. Accordingly, we have entered into manufacturing and supply agreements with single source suppliers and manufacturers for our commercialized products and product candidates. Our suppliers

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and contract manufacturers may not be able to manufacture our products or product candidates without interruption, or may not comply with their obligations to us under our supply and manufacturing arrangements. We may not have adequate remedies for any breach and their failure to supply us could result in a shortage of our products or product candidates.

The availability of our products for commercial sale is dependent upon our ability to procure the ingredients, packaging materials and finished products we need. If one of our suppliers or product manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or product manufacturers could require us to obtain regulatory clearance in the form of a prior approval supplement and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product manufacturing process. We believe that it could take as long as two years to qualify a new supplier or manufacturer, and we may not be able to obtain active pharmaceutical ingredients, packaging materials or finished products from new suppliers or manufacturers on acceptable terms and at reasonable prices, or at all. Should we lose either an active pharmaceutical ingredient supplier or a product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA approval of a new active pharmaceutical ingredient supplier or product manufacturer.

For Xyrem, JZP-6 or sodium oxybate, the new supplier or manufacturer would also need to be registered with the DEA and obtain a DEA quota. In addition, the FDA must approve suppliers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products, as well as suppliers of finished products. The qualification of new suppliers and manufacturers could potentially delay the manufacture of our products and product candidates and result in shortages in the marketplace or for our clinical trials, or both, particularly since we do not have secondary sources of supply of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates. If there are delays in qualifying the new manufacturer or the new manufacturer is unable to obtain a sufficient quota from the DEA, there could be a shortage of Xyrem for the marketplace.

Due to FDA-mandated dating requirements, DEA quotas relating to Xyrem and JZP-6, and the limited market size for our approved products, we are subject to complex manufacturing logistics and minimum order quantities that could result in excess inventory as determined under our accounting policy, unsalable inventory as a result of product expiring prior to use, and competition with others for manufacturing services when needed or expected. We have adopted a production planning program to assess and manage manufacturing logistics among the vendors supplying our requirements of active pharmaceutical ingredient, drug product and packaging; however, unexpected market requirements or problems with vendors' facilities, among other things, could result in shortages of one or more of our products for the marketplace or product candidates for use in our clinical studies, or both.

Failure by our third party manufacturers to comply with regulatory requirements could adversely affect their ability to supply products to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with cGMP requirements. In complying with cGMP requirements, our suppliers must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that our products and product candidates meet applicable specifications and other requirements for product safety, efficacy and quality. DEA regulations also govern facilities where controlled substances such as sodium oxybate are manufactured. Manufacturing facilities are subject to periodic unannounced inspection by the FDA, the DEA and other regulatory authorities, including state authorities. Failure to comply with applicable legal requirements subjects the suppliers to possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with the ingredients or finished products we need.

Any delay in supplying, or failure to supply, products by any of our suppliers could result in our inability to meet the commercial demand for our products or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects. For example, if Lonza is unable to timely provide fluvoxamine in the quantities we need there could be an interruption in the supply of Luvox CR to the market. In addition, under our agreement with UCB, we are responsible for the supply of Xyrem and JZP-6 to UCB. Our failure to meet our contractual obligations to supply UCB with adequate quantities of Xyrem and JZP-6 would result in lost revenues to us and, if material, could result in termination of our agreements by UCB.

***Our product candidates have never been manufactured on a commercial scale and there are risks associated with scaling up manufacturing to commercial scale. Luvox CR has only recently been manufactured on a commercial scale and the NDA for Luvox CR was previously withdrawn as a result of difficulties encountered during the scale-up of manufacturing.***

Our product candidates have never been manufactured on a commercial scale and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. If our manufacturers are unable to produce

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sufficient quantities of our products for commercialization or at a cost that we expect, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Luvox CR, for which we have obtained the exclusive rights to market and distribute in the United States from Solvay and which was recently approved for commercial sale, is being manufactured for us by Elan in exchange for royalty and milestone payments and supply price payments. Luvox CR has never previously been produced on a commercial scale, and the NDA for Luvox CR was withdrawn in June 2001 by Solvay and Elan as a result of difficulties encountered during the scale-up of manufacturing of Luvox CR. Although the FDA has approved Luvox CR, there is no assurance that Elan will be able to manufacture Luvox CR without a higher batch failure rate than we expect or in sufficient quantities to meet potential future demand.

*We could be materially adversely affected if we or our products are subject to negative publicity. For example, sodium oxybate, the active pharmaceutical ingredient in Xyrem and JZP-6, is a derivative of gamma hydroxybutyrate, or GHB, which has been a drug of abuse and may not be sold legally in the United States. If physicians and patients perceive Xyrem and JZP-6 to be the same as or similar to GHB, sales of Xyrem and JZP-6 could be adversely affected.*

From time to time, there is negative publicity about GHB and its effects, including with respect to illegal use, overdoses, serious injury and death and because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. Because sodium oxybate is a derivative of GHB, patients, physicians and regulators may view Xyrem as the same as or similar to GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally. Xyrem's label includes information about adverse events from GHB, and we anticipate that if JZP-6 is approved, its label will include similar information. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers. Because of our dependence upon patient and physician perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could materially and adversely affect our business, financial condition, results of operations and growth prospects.

*The investigation by the U.S. Attorney's Office for the Eastern District of New York concerning the sales and marketing of Xyrem creates additional compliance-related operating costs and could result in additional fines, penalties or other adverse consequences.*

In April 2006, we and our subsidiary Orphan Medical received subpoenas from the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem. In April 2006, a physician who was a speaker for Orphan Medical, and for a short time for us, was indicted by a federal grand jury in the U.S. District Court for the Eastern District of New York. The indictment includes allegations that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. In March 2007, in the same federal court, a former Orphan Medical regional sales manager, who also worked for a short time for us, pled guilty based on similar allegations to introducing a misbranded drug into interstate commerce.

We and Orphan Medical have settled this matter with the United States, acting through the Department of Justice, the U.S. Attorney's Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services. Orphan Medical pled guilty to one felony count of introducing a misbranded drug into interstate commerce. A total of approximately \$20.0 million in civil and criminal payments will be paid in connection with this matter, of which \$1.0 million was paid in July 2007 and \$2.0 million was paid in January 2008; the remaining will be paid over the next four years. We agreed to guarantee payment of amounts payable by Orphan Medical.

While we were not prosecuted, as part of the settlement we entered into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services. That agreement requires us to maintain a comprehensive compliance program, and we will have additional ongoing compliance-related operating costs related to this compliance program and the corporate integrity agreement. In the event of an uncured material breach or deliberate violation, as the case may be, of the corporate integrity agreement or the other definitive settlement agreements we entered into, we could be excluded from participation in Federal healthcare programs and/or subject to prosecution.

Even though we have executed definitive settlement agreements, we might still be subject to regulatory and/or enforcement action by federal agencies that are not parties to the settlement, private insurers and states' attorneys general with respect to the activities covered by the settlement. We cannot predict whether this additional action will occur, nor can we reasonably estimate the amount of any fines or penalties that might result from an adverse outcome.





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In addition, there is no assurance that we will not be subject to future investigations. Many pharmaceutical companies have announced government investigations of their sales and marketing practices for many of their products. Even with compliance training and a company culture of compliance, our current or future practices may nonetheless become the subject of an investigation. A number of laws, often referred to as whistleblower statutes, provide for financial rewards to employees and others for bringing to the attention of the government sales and marketing practices that the government views as illegal or fraudulent. The costs of investigating any claims, responding to subpoenas of investigators, and any resulting fines, can be significant and could divert the attention of our management from operating our business.

*Xyrem cannot be advertised directly to consumers, which could limit sales.*

The FDA has required that Xyrem's label include a box warning regarding the risk of abuse. A box warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A box warning also means, among other things, that the product cannot be advertised directly to consumers. Provigil, the only other product approved by the FDA specifically for the treatment of excessive daytime sleepiness in patients with narcolepsy, does not have a box warning and can be advertised directly to consumers. In addition, Xyrem's type of FDA approval under the FDA's Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. Unlike Xyrem, Provigil was not approved under the FDA's Subpart H regulations and is not subject to the pre-review requirements. Accordingly, promotional materials for Provigil are not subject to the same delays that we experience with respect to new promotional materials for Xyrem.

Since JZP-6 contains the same active pharmaceutical ingredient as Xyrem, we anticipate that the label for JZP-6, if approved by the FDA, will also include a box warning. The FDA recently approved a product for the treatment of fibromyalgia. This product is not, and future competing products may not be, subject to this restriction, and the box warning may negatively affect potential JZP-6 sales if competing products can be advertised directly to consumers.

*We face substantial competition from companies with greater resources than we have.*

With respect to all of our existing and future products, we may compete with companies selling or working to develop products that may be more effective, safer or less costly than our products. The markets for which we are developing products are competitive and include generic and branded products, some of which are marketed by major pharmaceutical companies that have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing and marketing and selling approved products than we do. While Xyrem is the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy, cataplexy is often treated with tricyclic antidepressants and selective serotonin reuptake inhibitors, although none of these compounds has been approved by the FDA for the treatment of cataplexy. Other treatments for excessive daytime sleepiness in patients with narcolepsy consist primarily of stimulants and wakefulness promoting agents, including Provigil (modafinil), the only other FDA-approved product for the treatment of excessive daytime sleepiness in patients with narcolepsy.

We are marketing Luvox CR in the United States for the treatment of obsessive compulsive disorder and social anxiety disorder. Selective serotonin reuptake inhibitors are the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. Five other branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, including four selective serotonin reuptake inhibitors: Paxil, which is marketed by GlaxoSmithKline, Zoloft, which is marketed by Pfizer, Prozac, which is marketed by Eli Lilly and Luvox which is not currently marketed. Anafranil, the other branded product approved by the FDA for the treatment of obsessive compulsive disorder, is a tricyclic antidepressant marketed by Mallinckrodt in the United States. Each of these products currently has generic equivalents. Generic products are generally sold at significantly lower prices than branded products, tending to both take market share away from branded products and put downward pricing pressure on branded products. Four other products are currently approved by the FDA for the treatment of social anxiety disorder, including three selective serotonin reuptake inhibitors: Zoloft, Paxil and Paxil CR, an extended release version of Paxil, and one serotonin-norepinephrine reuptake inhibitor, Effexor XR. Effexor XR, developed and sold by Wyeth, does not have generic competitors, whereas Paxil, Paxil CR and Zoloft have generic competitors.

We are developing JZP-6 for the treatment of fibromyalgia. In June 2007, the FDA approved Lyrica, an anticonvulsant marketed by Pfizer for the treatment of partial seizures, post herpetic neuralgia and diabetic peripheral neuropathy, for the treatment of fibromyalgia. There are currently no other products approved by the FDA for the treatment of fibromyalgia. In clinical practice, a variety of drugs are often prescribed to address individual symptoms of fibromyalgia, including antidepressants, pain medications, muscle relaxants, hypnotics and anticonvulsants. Eli Lilly submitted a sNDA for Cymbalta in August 2007 seeking FDA approval for the treatment of fibromyalgia, and Forest Laboratories (with Cypress Bioscience) filed an NDA for milnacipran in December 2007.

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seeking FDA approval for the treatment of fibromyalgia. These are large pharmaceutical companies with far greater resources than we have.

Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with other large, established companies. Our commercial opportunities may be reduced or eliminated if our competitors develop and commercialize generic or branded products that are safer or more effective, have fewer side effects or are less expensive than our products.

Our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we may. For example, other major pharmaceutical companies are conducting, or have completed, Phase III clinical trials of product candidates for the treatment of fibromyalgia. These product candidates may reach the market before JZP-6, or may be better accepted by physicians and patients. Thus, even if we successfully complete our Phase III clinical trials for JZP-6 for the treatment of fibromyalgia and achieve FDA approval, JZP-6 may not result in significant commercial revenues for us.

Our competitors may market their products more effectively than we do. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to other therapies, we may not generate meaningful revenues from the sales of our products.

*If generic products that compete with any of our products are approved, sales of our products may be adversely affected.*

Our products are or may become subject to competition from generic equivalents because there is no proprietary protection for some of our products or because our protection has expired or is not sufficiently broad. The FDA has granted orphan drug exclusivity for Xyrem until July 2009 for cataplexy in patients with narcolepsy, and until November 2012 for excessive daytime sleepiness in patients with narcolepsy. Once our orphan drug exclusivity periods for Xyrem expire, other companies could introduce generic equivalents of Xyrem if the generic equivalents do not infringe our existing patents covering Xyrem. Once our orphan drug exclusivity period for Xyrem for the treatment of cataplexy expires in July 2009, prescriptions for Xyrem, or if approved by the FDA, JZP-6, could possibly be filled with generic equivalents that have been approved for the treatment of cataplexy in patients with narcolepsy, even if the patient is diagnosed with excessive daytime sleepiness or fibromyalgia.

A generic form of fomepizole was introduced into the market in December 2007; other generic forms of fomepizole have been approved by the FDA. We expect sales of Antizol to decline significantly for the remainder of 2008 and thereafter as a result of this competition. We have filed a patent application covering Antizol, but no patent has yet issued and we cannot know when, or if, a patent will issue or if issued, if it would prevent or inhibit generic competition. Patent protection is not available for the active pharmaceutical ingredient in most of our products and product candidates, including Xyrem, Luvox CR and JZP-6. Although Xyrem is covered by patents expiring in 2019 with claims covering the formula and process for manufacturing our commercial formulation of Xyrem, it is possible that other companies could manufacture generic equivalents of Xyrem in ways that are not covered by the claims of these patents.

Part of our business strategy includes the ongoing development of proprietary product improvements to Xyrem, including new and enhanced dosage forms. However, we may not be successful in developing or obtaining FDA and other regulatory approvals of these improvements. Although the active pharmaceutical ingredient in Xyrem and JZP-6 is a DEA scheduled compound for which a quota is required and the FDA has required a risk management program for its distribution, and therefore generic competition may be more difficult and expensive than it might be for other products not requiring a risk management program for distribution, our competitors will not be prevented from introducing a generic equivalent. We have filed a patent application with claims covering the method for distributing sodium oxybate using a centralized distribution system, but we cannot assure you that this patent will issue or, if issued, whether it will provide any significant protection of Xyrem from generic competition.

Luvox CR is covered by a patent application filed by Elan with claims covering the orally administered extended release formulation of fluvoxamine. This patent may not issue, and even if this patent issues, it is possible that other companies could manufacture similar or therapeutically equivalent products in ways that are not covered by the claims of the patent. There may be other patents that we are not aware of that cover some aspect of the Luvox CR formulation and that would prevent us from commercializing Luvox CR or that would require us to pay royalties or other forms of consideration.

After the introduction of a generic competitor, a significant percentage of the prescriptions written for a product generally may be filled with the generic version at the pharmacy, resulting in a loss in sales of the branded product, including for indications for which the generic version has not been approved for marketing by the FDA. Generic competition often results in decreases in the prices at which branded products can be sold. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the use of generic products rather than branded products



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where a generic equivalent is available. Generic competition for our products earlier than expected could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***We may not be able to enter into acceptable agreements to commercialize our products in international markets.***

If appropriate regulatory approvals are obtained, we generally intend to commercialize our products in most markets outside of the United States through arrangements with third parties. If we decide to sell our products in markets outside of the United States, we may not be able to enter into any arrangements on acceptable terms, or at all. In addition, these arrangements could result in lower levels of income to us than if we promoted our products directly in international markets. If we choose to market our products directly in markets outside of the United States, we may not be able to develop an effective international sales force. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenues outside of the United States would be limited. In either case, our marketing efforts (and those of our partners) outside of the United States may be subject to regulatory requirements and politico-economic climates that are dissimilar to those in the United States and which could impose unforeseen costs or restrictions on us or our partners.

***We may not be able to successfully acquire or in-license additional products or product candidates as part of growing our business.***

In order to grow our business, we intend to acquire or in-license additional products and product candidates that we believe have significant commercial potential. Any growth through acquisitions or in-licensing will be dependent upon the continued availability of suitable acquisition or in-license products and product candidates at favorable prices and upon advantageous terms and conditions. Even if such opportunities are present, we may not be able to successfully identify products or product candidates suitable for potential acquisition or in-licensing. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for the right to acquire and in-license such products or product candidates.

***We currently have a relatively small sales organization compared with most other pharmaceutical companies with marketed products. If we are unable to appropriately expand our specialty sales force and sales organization in the United States to adequately promote our current and potential future products, the commercial opportunity for our products may be diminished.***

We recently expanded our sales force significantly in anticipation of the launch of Luvox CR. We cannot be sure that we will retain these new sales representatives, or that they will be effective at promoting our commercial products. Our potential future commercial products, including JZP-6, may require further expansion of our sales force and sales support organization, and we will need to commit significant additional management and other resources to the growth of our sales organization before the commercial launch of those product candidates. We may not be able to achieve the necessary growth in a cost-effective manner or realize a positive return on our investment. We will also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel. If we elect to rely on third parties to sell our products in the United States, we may receive less revenue or incur more expense than if we sold our products directly. In addition, we may have little or no control over the sales efforts of those third parties. If we are unable to appropriately expand our sales force or collaborate with third parties to sell our products, our ability to generate revenues would be adversely affected.

***If we fail to retain key personnel, or to retain our executive management team, we may be unable to successfully develop or commercialize our products.***

Our success depends in part on our continued ability to retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team. The loss of services of any one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our key activities. We do not carry key person insurance. Although the members of our executive management team have employment contracts with us through February 2009, each member of our executive management team and each of our other key employees may terminate his or her employment at any time without notice and without cause or good reason.

We recently reduced the number of non-sales employees in our company in connection with efforts to focus, in the near term, on our commercial products and later-stage product candidates. Competition for qualified personnel in the life sciences industry is intense, and it is particularly difficult to recruit new employees to the San Francisco Bay Area, where our offices are located, in large part due to high housing costs. If we need to hire additional personnel to expand our development, clinical and commercial activities, or to support those activities, we may not be able to attract and retain quality personnel on acceptable terms.

If we need to accelerate our activities or expand our business, and cannot recruit qualified employees when we need them, our key activities could be delayed. Our future financial performance and our ability to commercialize our products and to compete



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effectively will depend, in part, on our ability to manage our personnel resources effectively, and our failure to do so could adversely affect our business, financial condition, results of operations and growth prospects.

*Our offices are located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could damage our facilities, which could adversely affect our operations.*

Our offices are located in the San Francisco Bay Area, near known earthquake fault zones and are therefore vulnerable to damage from earthquake. In October 1989, a major earthquake in our area caused significant property damage and a number of fatalities. We are also vulnerable to damage from other disasters such as power loss, fire, floods and similar events. If a significant disaster occurs, our ability to continue our operations could be seriously impaired and we may not have adequate insurance to cover any resulting losses. Any significant unrecoverable losses could seriously impair our operations and financial conditions.

## **Risks Related to Our Intellectual Property**

*It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.*

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, their use and the methods used to manufacture them, as well as successfully defending these patents against third party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties is dependent upon the extent to which we have rights under valid and enforceable patents, or have trade secrets that cover these activities.

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. The existence of a patent will not necessarily prevent other companies from developing similar or therapeutically equivalent products or protect us from claims of third parties that our products infringe their issued patents, which may require licensing and the payment of significant fees or royalties. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or manufacture products in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents, our licensed patents or in third party patents.

The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;

we or our licensors or partners might not have been the first to make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;

we or our licensors or partners might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative products without infringing our intellectual property rights;

our pending patent applications may not result in issued patents;

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our issued patents and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;

we may not develop additional proprietary products that are patentable; or

the patents of others may have an adverse effect on our business.

We also may rely on trade secrets and other unpatented proprietary information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets and other unpatented proprietary information, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures. If our employees, consultants, advisors and partners develop inventions or processes independently, or jointly with us, that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Enforcing a claim that a third party illegally obtained and is using any of our inventions or trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less



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willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. While the ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to contractual limitations, these contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our innovations and other confidential information, then our ability to obtain patent protection or protect our proprietary information may be jeopardized. Moreover, a dispute may arise with our research and development collaborators over the ownership of rights to jointly developed intellectual property. Such disputes, if not successfully resolved, could lead to a loss of rights and possibly prevent us from pursuing certain new products or product candidates.

***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or commercialize, our products.***

Our ability, and that of our partners, to commercialize any approved products will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. We have filed multiple U.S. patent applications and foreign counterparts, and may file additional U.S. and foreign patent applications related thereto. There can be no assurance that any issued patents we own or control will provide sufficient protection to conduct our business as presently conducted or as proposed to be conducted. Moreover, in part because of prior research performed and patent applications submitted in the same manner or similar fields, there can be no assurance that any patents will issue from the patent applications owned by us, or that we will remain free from infringement claims by third parties.

If we choose to go to court to stop someone else from pursuing the inventions claimed in our patents or in or our licensed patents or those of our partners, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party's activities do not infringe our rights to these patents or that it is in the public interest to permit the infringing activity.

A third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. Patent infringement lawsuits are costly and could affect our results of operations and divert the attention of management and development personnel. There is a risk that a court could decide that we or our partners are infringing third party patent rights. In the event that we or our partners are found to infringe any valid claim of a patent held by a third party, we may, among other things, be required to:

pay damages, including up to treble damages and the other party's attorneys' fees, which may be substantial;

cease the development, manufacture, use and sale of our products that infringe the patent rights of others through a court-imposed sanction such as an injunction;

expend significant resources to redesign our products so they do not infringe others' patent rights, which may not be possible;

discontinue manufacturing or other processes incorporating infringing technology; or

obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

The pharmaceutical and life sciences industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the

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interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the United States.

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Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for inventions covered by our licensors or our issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to ours. Any such patent application may have priority over our or our licensors' patents or applications and could further require us to obtain rights to issued patents covering such subject matter. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

### **Risks Related to Our Industry**

***The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our partners from obtaining approvals for the commercialization of some or all of our product candidates.***

The research, testing, manufacturing, selling and marketing of pharmaceutical products are subject to extensive regulation by FDA and other regulatory authorities in the United States and other countries, and regulations differ from country to country. Approval in the United States, or in any jurisdiction, does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain approval for our products. We are not permitted to market our product candidates in the United States until we receive approval from the FDA, generally of an NDA. The NDA must contain, among other things, data to demonstrate that the drug is safe and effective for its intended uses and that it will be manufactured to appropriate quality standards. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process, and the FDA has substantial discretion in the approval process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including warning letters, untitled letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve pending NDAs or supplements to approved NDAs. If we are unable to obtain regulatory approval of our product candidates, we will not be able to commercialize them and recoup our research and development costs.

The FDA recently announced that, in light of staffing issues, it has given its managers discretion to miss Prescription Drug User Fee Act, or PDUFA, deadlines for completing reviews of NDAs. If the FDA were to miss a PDUFA deadline for one of our products, delaying the approval and launch, the delay could have a material adverse effect on our business.

***Even if we receive regulatory approval for our product candidates, we will be subject to ongoing significant regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.***

If we receive regulatory approvals to sell our products, the FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses or marketing of our products, or impose requirements for burdensome post-approval study commitments. The terms of any product approval, including labeling, may be more restrictive than we desire and could affect the marketability of the product or otherwise reduce the size of the potential market for that product. Following any regulatory approval of our products, we will be subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, if the FDA approves any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with any of our products in the United States or overseas or at our contract manufacturers facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to, or obtain re-approvals of, our contract manufacturers' facilities, or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products and our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits, including class action suits. The FDA and other governmental authorities also actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.



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We are also subject to regulation by regional, national, state and local agencies, including the DEA, the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we commercialize our products. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. Our manufacturing partners are subject to the same requirements, which include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate. These statutes and regulations include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting identified common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and the reporting of gifts to individual physicians in the states. Other states require the posting of information relating to clinical studies. In addition, California requires pharmaceutical companies to implement a comprehensive compliance program that includes a limit on expenditures for or payments to individual prescribers. Currently, several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we or any of our partners fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our or our partners' ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

***If we fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

We participate in the federal Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program for our products that are reimbursed by those programs. The minimum amount of the rebate for each unit of product is set by law at 15.1% of the average manufacturing price of that product, or if it is greater, the difference between the average manufacturing price and the best price we make available to any customer. The rebate amount also includes an inflation adjustment, if necessary.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to the Centers for Medicare & Medicaid Services at the U.S. Department of Health and Human Services of our current average manufacturing price and best prices for the quarter. If we become aware that our reporting for prior quarters was



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incorrect, or changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected average manufacturing price or best price for that quarter. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. In addition to retroactive rebates (and interest, if any), if we are found to have knowingly submitted false information to the government, we may be liable for civil monetary penalties in the amount of \$100,000 per item of false information. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid.

Federal law requires that any company that participates in the Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Services pharmaceutical pricing program requiring us to sell our products at prices lower than we otherwise might be able to charge. The Public Health Services pricing program extends discounts comparable to the Medicaid rebates to a variety of community health clinics and other entities that receive health services grants from the Public Health Services, as well as hospitals that serve a disproportionate share of poor patients and children.

***Reimbursement may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably.***

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract strategic partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third party payors decide which drugs they will pay for and establish reimbursement levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement policies. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third party payors may not provide coverage and reimbursement for our products, in whole or in part. We cannot predict actions third party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. For example, because Luvox CR is competing in a market with both branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to effectively commercialize our products. Since Luvox CR has only recently been approved, we do not yet know what the reimbursement levels and other requirements will be for that product.

There have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. These proposals include prescription drug benefit proposals for Medicare beneficiaries and measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides a new Medicare prescription drug benefit that became effective in January 2006, and mandates other reforms. Although we cannot predict the full effect on our business of the implementation of this new legislation, it is possible that the new benefit, which is managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues. Currently, there are legislative proposals that would permit the U.S. Secretary of Health and Human Services to negotiate directly with pharmaceutical companies to obtain lower prices for drugs covered under Medicare Part D.

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed. During the presidential primary campaign, various candidates have been discussing healthcare reform proposals which, if enacted, could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

***Sales of our products in the United States may be adversely affected by consolidation among wholesale drug distributors and the growth of large retail drug store chains.***

The market participants to whom we sell Antizol and Luvox CR, and the market participants to whom we expect to sell most of our future products, have undergone significant consolidation, marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the





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market, and the number of independent drug stores and small drugstore chains has decreased. In addition, excess inventory levels held by large distributors can lead to periodic and unanticipated reductions in our revenues and cash flows. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug manufacturers, including us.

***Prescription drug importation from Canada and other countries could increase pricing pressure on our products and could decrease our revenues and profit margins.***

Under current U.S. law, there is a general prohibition on imports of unapproved products. The FDA has published internal guidance that sets forth the agency's enforcement priorities for imported drugs. Under this policy, the FDA allows its personnel to use their discretion in permitting entry into the United States of personal use quantities of FDA-regulated products in personal baggage and mail when the product does not present an unreasonable risk to the user. Thus, individuals may import prescription drugs that are unavailable in the United States from Canada and other countries for their personal use under specified circumstances. Other imports, although illegal under U.S. law, also enter the country as a result of the resource constraints and enforcement priorities of the FDA and the U.S. Customs Services. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 will permit pharmacists and wholesalers to import prescription drugs into the United States from Canada under specified circumstances. These additional import provisions will not take effect until the Secretary of Health and Human Services makes a required certification regarding the safety and cost savings of imported drugs and the FDA has promulgated regulations setting forth parameters for importation. These conditions have not been met to date and the law has therefore not taken effect. However, legislative proposals have been introduced to remove these conditions and implement changes to the current import laws, or to create other changes that would allow foreign versions of our products priced at lower levels than in the United States to be imported or reimported to the United States from Canada, Europe and other countries. If these provisions take effect, the volume of prescription drug imports from Canada and elsewhere could increase significantly and our products could face competition from lower priced imports.

Even if these provisions do not take effect and alter current law, the volume of prescription drug imports from Canada and elsewhere could increase due to a variety of factors, including the further spread of internet pharmacies and actions by a number of state and local governments to facilitate Canadian and other imports. These imports may harm our business.

We licensed Xyrem to Valeant to distribute in Canada. Due to government price regulation in Canada, products are generally sold in Canada for lower prices than in the United States. Due to the risk management program for Xyrem and our agreement with Valeant, we believe that it is unlikely that Xyrem will be imported from Canada to the United States.

***Product liability and product recalls could harm our business.***

The development, manufacture, testing, marketing and sale of pharmaceutical products entail significant risk of product liability claims or recalls. Our products and product candidates are designed to affect important bodily functions and processes. Side effects of, or manufacturing defects in, the products sold by us could result in exacerbation of a patient's condition, further deterioration of a patient's condition or even death. This could result in product liability claims and/or recalls of one or more of our products. For example, studies and publications suggest that selective serotonin reuptake inhibitors, including the active pharmaceutical ingredient in Luvox CR and its immediate release formulation Luvox, may increase the risk of suicidal behavior in adults and adolescents. In addition, the current selective serotonin reuptake inhibitor products used to treat obsessive compulsive disorder and social anxiety disorder, particularly those formulated for immediate release, all have significant adverse side effects. Side effects associated with selective serotonin reuptake inhibitors include sexual dysfunction, adverse drug interaction and risk of hypertension. Claims may be brought by individuals seeking relief for themselves or by groups seeking to represent a class. While we have not had to defend against any product liability claims to date, as sales of our products increase, we believe it is likely product liability claims will be made against us. We cannot predict the frequency, outcome or cost to defend any such claims.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, if at all. Partly as a result of product liability lawsuits related to pharmaceutical products, product liability and other types of insurance have become more difficult and costly for pharmaceutical companies to obtain. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products. In addition, we may not continue to be able to obtain insurance on satisfactory terms or in adequate amounts.

A successful claim or claims brought against us in excess of available insurance coverage could subject us to significant liabilities and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Such claims could also harm our reputation and the reputation of our products, adversely affecting our ability to market our products successfully. In addition, defending a product liability lawsuit is expensive and can divert the attention of key employees from operating our business.



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Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation.

**Risks Relating to Our Financial Condition**

*We have a history of net losses, which we expect to continue for at least several years and, as a result, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.*

We have a limited operating history and have incurred significant net losses since our inception in 2003, and we expect to continue to incur net losses for the next several years. Our net loss for the year ended December 31, 2007 and the three months ended March 31, 2008 was \$138.8 million and \$46.7 million, respectively, and we had an accumulated deficit of \$363.2 million at March 31, 2008. We expect our operating expenses to continue at similar rates, and they could increase, over the next several years as we continue to market Luvox CR, develop, acquire or in-license additional products or product candidates, conduct clinical trials for our product candidates, undertake research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We may need to expand our commercial organization to launch additional products. It is very expensive to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

*Our operations have generated negative cash flows, and if we are unable to secure additional funding when we need it, we may be required to further reduce operations.*

As of March 31, 2008, we had approximately \$105.2 million in cash, cash equivalents and marketable securities. Our net cash used in operations for the three months ended March 31, 2008, and the year ended December 31, 2007 was approximately \$38.2 million and \$81.1 million, respectively. Substantially all of our net product sales resulted from sales of Xyrem and Antizol. Sales of Antizol are likely to decrease substantially in 2008 due to generic competition, and sales of Xyrem could decrease due to adverse market conditions, negative publicity or other events outside our control. We recently reduced our activities to focus on our commercial products and later stage product candidates, including a reduction in the size of our work force. Even with this change, we must continue to commit substantial resources to costly and time-consuming product development and clinical trials of our product candidates and significant funds to our commercial operations. We believe that our current cash and cash equivalents and interest earned thereon, together with future financings, the proceeds available under the CEFF and anticipated revenues from product sales and royalties, will be sufficient to satisfy our current operations for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

the amount of sales and other revenues from our commercial products, including selling prices for products that we may begin selling and price increases for our current products;

market acceptance of and the number of prescriptions written for our products;

selling and marketing costs associated with Luvox CR and Xyrem in the United States;

revenues from current and potential future development and/or commercial collaboration partners;

the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;

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the number and characteristics of product candidates that we pursue;

the cost and timing of establishing clinical and commercial supplies of our product candidates;

the cost and timing of obtaining regulatory approval;

payments of milestones to third parties;

increased expenses associated with our current employees and new employees hired to support our continued growth;

the cost of investigations, litigation and/or settlements related to regulatory activities;

the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and

the extent to which we acquire, in-license or invest in new businesses, products or product candidates.

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Although we generate product revenues, since our inception in 2003 we have financed our operations primarily through the sale of preferred stock, the issuance of senior secured notes and warrants, a line of credit, development financing related to one of our previous product candidates, our collaboration with UCB related to Xyrem and JZP-6 and the sale of common stock in our initial public offering.

We will need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and commercial operations. We may also be required to license to third parties products and product candidates that we would prefer to develop and commercialize ourselves or to sell the rights to one or more commercial products to third parties. We may seek to raise additional funds through development financings, collaborations, or public or private debt or equity financings. If we exercise our right to draw down amounts under the CEFF, Kingsbridge will not be obligated to purchase shares of our common stock under the CEFF unless certain conditions are met, which include: a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; and the effectiveness of a registration statement that we have filed with the SEC registering for resale the shares of common stock to be issued under the CEFF and the shares underlying the warrant that we issued to Kingsbridge. If we raise funds through collaborations, we may be required to relinquish, on terms that are not favorable to us, rights to some of our products or product candidates that we would otherwise seek to develop or commercialize ourselves. If we raise additional funds through the issuance of debt securities, these securities could have rights that are senior to holders of our common stock and could contain covenants that restrict our operations. Any additional equity financing may be dilutive to our stockholders. In addition, if we raise additional funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. The terms of future financings may restrict our ability to raise additional capital, which could delay or prevent the further development or commercialization of our products. Our failure to raise capital when needed may harm our business and operating results.

We are launching Luvox CR and, as is the case with new product launches, we cannot predict with certainty the timing or level of Luvox CR sales. If sales of Luvox CR do not reach the levels we expect and if we do not generate additional cash resources from financings or partnering activities, we may be unable to meet our cash requirements under our current operating plan. If product sales do not meet our expectations and we do not raise additional funds, we will need to reduce our planned expenditures, perhaps significantly, to preserve our cash. We recently implemented plans to reduce our expenditures by focusing on our commercial products and later stage product candidates and eliminating some jobs. If necessary, we would implement, beginning as early as the third quarter of 2008, appropriate plans and additional measures to quickly reduce discretionary spending and capital expenditures, terminate or slow additional product development programs, further reduce headcount, license or sell some of our product candidates or products, or implement a combination of these and other cost cutting measures.

***We have a substantial amount of debt, which may adversely affect our cash flows and our ability to operate our business.***

On March 17, 2008, we incurred \$40.0 million of additional secured indebtedness in connection with the expansion of our senior debt to \$120.0 million at face value. Our substantial debt combined with our other financial obligations and contractual commitments could have other important consequences. For example, it could:

make us more vulnerable to adverse changes in general economic, industry and competitive conditions and adverse changes in government regulation;

require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flows to fund working capital, capital expenditures, acquisitions and other general corporate purposes;

limit our flexibility in planning for, or reacting to, changes in our business and our industry;

place us at a competitive disadvantage compared to our competitors who have less debt; and

limit our ability to borrow additional amounts for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other purposes.

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Any of these factors could materially adversely affect our business, financial condition, results of operations and growth prospects. In addition, under specified circumstances, our lenders could demand repayment of all or a portion of our debt, including if annualized net sales of our products fall below certain specified levels, which would have a material adverse effect on our business, financial condition and results of operations. If we do not have sufficient earnings to service our debt, we may be required to refinance all or part of our existing debt, sell assets, borrow more money or sell securities, none of which we can assure you that we would be able to do in a timely manner or at all.

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*The terms of our debt could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions.*

Our senior secured debt contains, and any future indebtedness would likely contain, a number of restrictive covenants that impose significant operating and financial restrictions on us, including restrictions on our ability to take actions that may be in our best interests. Our existing debt includes covenants, including requirements that we:

generally not borrow additional amounts without the approval of our lenders;

dispose of certain assets only in accordance with the terms of our existing senior secured debt;

not impair our lenders' security interests in our assets;

repay a portion of the debt early under certain circumstances; and

maintain restricted cash balances under certain circumstances.

## **Risks Relating to Ownership of Our Common Stock**

*The market price of our common stock may be volatile, and the value of your investment could decline significantly.*

Investors who purchase our common stock may not be able to sell their shares at or above the purchase price. Security prices for companies similar to us experience significant price and volume fluctuations. The following factors, in addition to other risks described herein, may have a significant effect on our common stock market price:

the success of Luvox CR in the United States;

the success of our development efforts and clinical trials;

negative publicity concerning one of our products or product candidates;

announcement of FDA approval or non-approval of our product candidates, or specific label indications for their use, or delays in the FDA review process;

the failure or delay by the DEA in providing sufficient quotas for sodium oxybate, Xyrem or JZP-6;

actual or expected fluctuations in our operating results, including as a result of fluctuating demand for our commercial products as a result of purchases by wholesalers in connection with product launches, stockpiling or inventory drawdowns by our customers, or otherwise;

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changes in the market prices for our products;

the success of our efforts to acquire or in-license additional products or product candidates;

introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

announcements of product innovations by us, our partners or our competitors;

changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements;

actions taken by regulatory agencies with respect to our products, clinical trials, manufacturing process or sales and marketing terms;

developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;

our ability or inability to raise additional capital and the terms on which we raise it;

actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

conditions or trends in the pharmaceutical industry, the financial markets or the economy in general;

actual or expected changes in our growth rates or our competitors' growth rates;



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changes in the market valuation of similar companies;

trading volume of our common stock; and

sales of our common stock by us or our stockholders.

In addition, the stock market in general and the market for life sciences companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

***Future sales of our common stock in the public market could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, including shares issued under the CEFF, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. In addition, the perceived risk of dilution from sales of our common stock to or by Kingsbridge in connection with the CEFF may cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. As of May 9, 2008, we had 24,622,636 shares of common stock outstanding. The 6,000,000 shares of common stock sold in our initial public offering are freely tradable without restrictions or further registration under the Securities Act of 1933, as amended. The remaining 18,622,636 shares of common stock outstanding as of May 9, 2008, less shares subject to a repurchase option in our favor tied to the holders' continued service to us (which will be eligible for sale upon lapse of the repurchase option), are now eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144.

As of May 9, 2008, the holders of up to approximately 19,306,128 shares of common stock, based on shares outstanding as of that date, including 1,787,920 shares underlying outstanding warrants, were entitled to certain rights with respect to the registration of such shares under the Securities Act of 1933, as amended, under an amended and restated investor rights agreement that we entered into with these holders. In addition, upon exercise of outstanding options by our executive officers, our executive officers will be entitled to rights under the amended and restated investor rights agreement with respect to registration of the shares of common stock acquired on exercise. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement and include shares held by these holders pursuant to the exercise of their registration rights, these sales may impair our ability to raise capital. On March 17, 2008, we entered into a registration rights agreement pursuant to which we agreed to file, on or before June 6, 2008, a registration statement covering the resale of the 562,192 shares underlying the warrants that we issued in connection with the expansion of our senior secured debt in March 2008, and the shares underlying the warrants we may issue in a further expansion of that debt and use our reasonable best efforts to cause such registration statement to become and remain effective. The registration rights agreement entered into in connection with the CEFF requires that we use commercially reasonable efforts to have the registration statement of which this prospectus is a part declared effective and ensure that it remains effective for the term of such agreement. In addition, we have filed registration statements on Form S-8 under the Securities Act of 1933, as amended, to register the shares of our common stock reserved for issuance under our stock option and employee stock purchase plans, and intend to file additional registration statements on Form S-8 to register the shares automatically added each year to the share reserves under these plans.

***The CEFF may result in dilution to our stockholders.***

Pursuant to the CEFF, Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of \$75.0 million of our common stock or 4,922,064 shares of our common stock over a three-year period. We are entitled in certain circumstances to deliver a "blackout" notice to Kingsbridge to suspend the use of the registration statement that we have filed with the SEC registering for resale the shares of common stock to be issued under the CEFF and the shares underlying the warrant we issued to Kingsbridge. If we deliver a blackout notice in the 15 trading days following a settlement of a draw down, then we must make a blackout payment to Kingsbridge, or issue Kingsbridge additional shares of our common stock in lieu of this payment. If we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of any blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down amounts under the CEFF, we will issue shares to Kingsbridge at a discount of up to ten percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.



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***Our executive officers and directors, together with their respective affiliates, own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.***

As of May 9, 2008, our executive officers and directors, together with their respective affiliates, beneficially owned 64.0% of our capital stock, of which 7.9% is beneficially owned by our executive officers. Accordingly, our executive officers and directors are able to determine the composition of our board of directors, retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on the market value of our common stock, and may prevent attempts by our stockholders to replace or remove our board of directors or management.

***We incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules of the Securities and Exchange Commission and The NASDAQ Stock Market LLC have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel must continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may incur substantial costs to maintain the same or similar coverage.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, beginning with our annual report on Form 10-K for the fiscal year ending December 31, 2008. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we have hired and will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

***Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, or for a change in the composition of our board of directors or management to occur, even if doing so would benefit our stockholders. These provisions include:

authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

dividing our board of directors into three classes;

limiting the removal of directors by the stockholders;

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eliminating cumulative voting rights and therefore allowing the holders of a majority of the shares of our common stock to elect all of the directors standing for election, if they should so choose;

prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

eliminating the ability of stockholders to call a special meeting of stockholders; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

***We have never declared or paid dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.***

Our business requires significant funding, and we currently invest more in product development than we earn from sales of our products. In addition, the agreements governing our debt restrict our ability to pay dividends on our common stock. Therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently plan to invest all available funds and future earnings in the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

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**DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the documents incorporated by reference into this prospectus contain certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 with respect to our financial condition, results of operations and business. Words such as anticipates, expects, intends, plans, predicts, believes, seeks, estimates, could, would, will, potential, should, and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this prospectus and the other documents incorporated by reference that are not historical facts are hereby identified as forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this prospectus, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 in Item 1A under Risk Factors as well as in Item 7A Qualitative and Quantitative Disclosures About Market Risk, our Quarterly Report on Form 10-Q for the period ended March 31, 2008 in Part II, Item 1A under Risk Factors as well as in Part I, Item 3 Qualitative and Quantitative Disclosures About Market Risk and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

the launch of Luvox CR and our anticipated sales and marketing efforts;

the future performance from Xyrem sales efforts;

the progress and results of our research and development programs;

our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;

the results and timing of our clinical trials and the commencement of future clinical trials; and

submission and timing of applications for regulatory approval.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this prospectus or, in the case of documents incorporated by reference, as of the date of such documents. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

**USE OF PROCEEDS**

We will not receive any of the proceeds from the sale of shares of our common stock by the selling stockholder pursuant to this prospectus. Any sale of shares by us to Kingsbridge under the common stock purchase agreement or in connection with the exercise of the Kingsbridge warrant will be made pursuant to an exemption from the registration requirements of the Securities Act. We will use the proceeds from these sales for general corporate purposes, including clinical trials, manufacturing and supply activities, sales and marketing activities, milestone payments under current or future agreements with strategic partners, research and development activities, regulatory affairs expenses and general and administrative expenses. The amounts and timing of our actual expenditures will depend on numerous factors, such as the progress of our product development and commercialization efforts and the amount of cash used by our operations. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we currently are not planning or negotiating any such transactions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from the sale of shares to Kingsbridge. Accordingly, we will retain broad discretion over the use of these proceeds, if any.

**Table of Contents****SELLING STOCKHOLDER**

This prospectus relates to the possible resale by the selling stockholder, Kingsbridge Capital Limited, or Kingsbridge, of shares of common stock that we may issue pursuant to the common stock purchase agreement we entered into with Kingsbridge on May 7, 2008, or upon exercise of the warrant that we issued to Kingsbridge on May 7, 2008. We are filing the registration statement of which this prospectus is a part pursuant to the provisions of the registration rights agreement we entered into with Kingsbridge on May 7, 2008.

The selling stockholder may from time to time offer and sell pursuant to this prospectus any or all of the shares that it acquires under the common stock purchase agreement or upon exercise of the warrant.

The following table presents information regarding Kingsbridge, as the selling stockholder, and the shares that it may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholder, and reflects holdings as of May 31, 2008. As used in this prospectus, the term "selling stockholder" includes Kingsbridge and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from the selling stockholder as a gift, pledge, or other non-sale related transfer. The number of shares in the column "Number of Shares Being Offered" represents all of the shares that the selling stockholder may offer under this prospectus. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, as amended. The percentage of shares of common stock beneficially owned prior to the offering shown in the table below is based both on an aggregate of 24,898,024 shares of our common stock outstanding on May 31, 2008, and on the assumption that all shares of common stock issuable under the common stock purchase agreement with Kingsbridge and all shares of common stock issuable upon exercise of the warrant are outstanding as of that date.

Stockholders	Shares of Common Stock Beneficially Owned Prior to Offering		Number of Shares Being Offered	Shares of Common Stock Beneficially Owned After Offering	
	Number	Percent		Number	Percent
Kingsbridge Capital Limited(1)	5,142,064(2)	17.12%	5,142,064	0	*

\* Less than one percent.

- (1) The business address of Kingsbridge Capital Limited is PO Box 1075, Elizabeth House, 9 Castle Street, St. Helier, Jersey, JE42QP, Channel Islands.
- (2) Consists of 4,922,064 shares of common stock, the maximum number of shares of common stock issuable under the common stock purchase agreement we entered into with Kingsbridge on May 7, 2008, and 220,000 shares of common stock issuable upon exercise of the warrant we issued to Kingsbridge on May 7, 2008, which warrant is not exercisable before November 7, 2008. For the purposes hereof, we assume the issuance of all 5,142,064 shares. Adam Gurney, Tony Gardner-Hillman and Maria O Donoghue have shared voting and investment control of the securities held by Kingsbridge.

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**PLAN OF DISTRIBUTION**

We are registering 5,142,064 shares of common stock under this prospectus on behalf of Kingsbridge. Except as described below, to our knowledge, the selling stockholder has not entered into any agreement, arrangement or understanding with any particular broker or market maker with respect to the shares of common stock offered hereby, nor, except as described below, do we know the identity of the brokers or market makers that will participate in the sale of the shares.

The selling stockholder may decide not to sell any shares. The selling stockholder may from time to time offer some or all of the shares of common stock through brokers, dealers or agents who may receive compensation in the form of discounts, concessions or commissions from the selling stockholder and/or the purchasers of the shares of common stock for whom they may act as agent. In effecting sales, broker-dealers that are engaged by the selling stockholder may arrange for other broker-dealers to participate. Kingsbridge is an underwriter within the meaning of the Securities Act. Any brokers, dealers or agents who participate in the distribution of the shares of common stock may also be deemed to be underwriters, and any profits on the sale of the shares of common stock by them and any discounts, commissions or concessions received by any such brokers, dealers or agents may be deemed to be underwriting discounts and commissions under the Securities Act. Kingsbridge has advised us that it may effect resales of our common stock through any one or more registered broker-dealers. To the extent the selling stockholder may be deemed to be an underwriter, the selling stockholder will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

The selling stockholder will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made over the NASDAQ Global Market, on the over-the-counter market, otherwise, or in a combination of such methods of sale, at then prevailing market prices, at prices related to prevailing market prices or at negotiated prices. The shares of common stock may be sold according to one or more of the following methods:

a block trade in which the broker or dealer so engaged will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus;

an over-the-counter distribution in accordance with the rules of NASDAQ;

ordinary brokerage transactions and transactions in which the broker solicits purchasers;

privately negotiated transactions;

a combination of such methods of sale; and

any other method permitted pursuant to applicable law.

Any shares covered by this prospectus which qualify for sale pursuant to Rule 144 of the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus. In addition, the selling stockholder may transfer the shares by other means not described in this prospectus.

Any broker-dealer participating in such transactions as agent may receive commissions from Kingsbridge (and, if they act as agent for the purchaser of such shares, from such purchaser). Broker-dealers may agree with Kingsbridge to sell a specified number of shares at a stipulated price per share, and, to the extent such a broker-dealer is unable to do so acting as agent for Kingsbridge, to purchase as principal any unsold shares at the price required to fulfill the broker-dealer commitment to Kingsbridge. Broker-dealers who acquire shares as principal may thereafter resell such shares from time to time in transactions (which may involve crosses and block transactions and which may involve sales to



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and through other broker-dealers, including transactions of the nature described above) on the NASDAQ Global Market, on the over-the-counter market, in privately-negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, and in connection with such resales may pay to or receive from the purchasers of such shares commissions computed as described above. To the extent required under the Securities Act, an amendment to this prospectus, or a supplemental prospectus will be filed, disclosing:

the name of any such broker-dealers;

the number of shares involved;

the price at which such shares are to be sold;

the commission paid or discounts or concessions allowed to such broker-dealers, where applicable;

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that such broker-dealers did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, as supplemented; and

other facts material to the transaction.

Underwriters and purchasers that are deemed underwriters under the Securities Act may engage in transactions that stabilize, maintain or otherwise affect the price of the securities, including the entry of stabilizing bids or syndicate covering transactions or the imposition of penalty bids. Kingsbridge and any other persons participating in the sale or distribution of the shares will be subject to the applicable provisions of the Exchange Act and the rules and regulations thereunder including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of, purchases by the selling stockholder or other persons or entities. Furthermore, under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to such securities for a specified period of time prior to the commencement of such distributions, subject to special exceptions or exemptions. Regulation M may restrict the ability of any person engaged in the distribution of the securities to engage in market-making and certain other activities with respect to those securities. In addition, the anti-manipulation rules under the Exchange Act may apply to sales of the securities in the market. All of these limitations may affect the marketability of the shares and the ability of any person to engage in market-making activities with respect to the securities.

We have agreed to pay the expenses of registering the shares of common stock under the Securities Act, including registration and filing fees, printing expenses, administrative expenses and certain legal and accounting fees, as well as certain fees of counsel for the selling stockholder incurred in the preparation and negotiation of the CEFF agreements and the registration statement of which this prospectus forms a part. The selling stockholder will bear all discounts, commissions or other amounts payable to underwriters, dealers or agents, as well as transfer taxes and certain other expenses associated with the sale of securities.

Under the terms of the Kingsbridge common stock purchase agreement and the registration rights agreement, we have agreed to indemnify the selling stockholder and certain other persons against certain liabilities in connection with the offering of the shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute toward amounts required to be paid in respect of such liabilities.

At any time a particular offer of the shares of common stock is made, a revised prospectus or prospectus supplement, if required, will be distributed. Such prospectus supplement or post-effective amendment will be filed with the SEC, to reflect the disclosure of required additional information with respect to the distribution of the shares of common stock. We may suspend the sale of shares by the selling stockholder pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

## **LEGAL MATTERS**

The validity of the securities being offered hereby will be passed upon by Carol A. Gamble, our Senior Vice President, General Counsel and Corporate Secretary. As of the date of this prospectus, Ms. Gamble beneficially owns 33,408 shares of our common stock, including 104,420 shares of common stock issuable upon the exercise of outstanding options that are exercisable within 60 days of June 11, 2008.

## **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements and schedule included in our Annual Report on Form 10-K for the year ended December 31, 2007, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

## **WHERE YOU CAN FIND ADDITIONAL INFORMATION**

**This prospectus is part of a registration statement we filed with the Securities and Exchange Commission. You should rely only on the information contained in this prospectus or incorporated by reference. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not**

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**permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of common stock.**

We file reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any reports, proxy statements or other information filed by us at the Securities and Exchange Commission's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at (800) SEC-0330. The Securities and Exchange Commission maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the Securities and Exchange Commission, including Jazz Pharmaceuticals. The address of the Securities and Exchange Commission website is <http://www.sec.gov>.

### **Important Information Incorporated By Reference**

The Securities and Exchange Commission allows us to incorporate by reference information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the Securities and Exchange Commission. The SEC file number for the documents incorporated by reference in this prospectus is 001-33500. The documents incorporated by reference into this prospectus contain important information that you should read about us.

The following documents are incorporated by reference into this document:

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 and filed with the SEC on March 31, 2008;

The information specifically incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 from our definitive proxy statement on Schedule 14A filed with the SEC on April 28, 2008;

Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 and filed with the SEC on May 15, 2008;

Our Current Reports on Form 8-K, filed on January 8, 2008, January 31, 2008, February 29, 2008, March 18, 2008, April 8, 2008, May 9, 2008 and June 11, 2008; and

The description of our common stock, which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A, filed with the SEC on May 25, 2007, including any amendments or reports filed for the purpose of updating such description.

We also incorporate by reference into this prospectus all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the Securities and Exchange Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial registration statement and prior to effectiveness of the registration statement, or (ii) from the date of this prospectus but prior to the termination of the offering. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits which are specifically incorporated by reference into such documents. Requests should be directed to: Jazz Pharmaceuticals, Inc., Attn: Investor Relations, 3180 Porter Drive, Palo Alto, CA 94304, telephone: (650) 496-3777.

Any statement contained herein or in a document incorporated or deemed to be incorporated by reference into this document will be deemed to be modified or superseded for purposes of the document to the extent that a statement contained in this document or any other subsequently filed document that is deemed to be incorporated by reference into this document modifies or supersedes the statement.



**Table of Contents****PART II****INFORMATION NOT REQUIRED IN THE PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth the estimated costs and expenses payable by the registrant in connection with the common stock being registered. The selling stockholder will not bear any portion of such expenses. All the amounts shown are estimates, except for the SEC registration fee.

SEC registration fee	\$ 1,419
Accounting fees and expenses	15,000
Legal fees and expenses	25,000
Printing and miscellaneous expenses	10,000
<b>Total</b>	<b>\$ 51,419</b>

**Item 15. Indemnification of Directors and Officers.**

The registrant's amended and restated certificate of incorporation contains provisions permitted under Delaware law relating to the liability of directors. These provisions eliminate a director's personal liability for monetary damages resulting from a breach of fiduciary duty, except in circumstances involving wrongful acts, such as:

any breach of the director's duty of loyalty to the registrant or its stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of the law;

any act related to unlawful stock repurchases, redemptions or other distribution or payments of dividends; or

any transaction from which the director derived an improper personal benefit.

These provisions do not limit or eliminate the registrant's rights or any stockholder's rights to seek non-monetary relief, such as an injunction or rescission, in the event of a breach of a director's fiduciary duty. These provisions will not alter a director's liability under federal securities laws.

As permitted by Section 145 of the Delaware General Corporation Law, or DGCL, the registrant's amended and restated bylaws require the registrant to indemnify its directors and officers to the fullest extent not prohibited by the DGCL or any other applicable law. The registrant may modify the extent of such indemnification by individual contracts with the registrant's directors and officers. Further, the registrant may decline to indemnify any director or officer in connection with any proceeding (or part thereof) initiated by such person, unless such indemnification is expressly required to be made by law, the proceeding was authorized by the registrant's board of directors, such indemnification is provided by the registrant, in its sole discretion, pursuant to the powers vested in the registrant under the DGCL or any other applicable law, or otherwise required under the registrant's amended and restated bylaws.

The registrant has entered into indemnity agreements with each of its directors, executive officers and vice presidents that require it to indemnify such persons against any and all expenses (including attorneys' fees), witness fees, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding or alternative dispute resolution mechanism, inquiry hearing or investigation, whether threatened, pending or completed, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of the registrant or any of its affiliated enterprises, provided that such person's conduct

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did not constitute a breach of his or her duty of loyalty to the registrant or its stockholders, and was not an act or omission not in good faith or which involved intentional misconduct or a knowing violation of laws. The indemnity agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder. At present, there is no pending litigation or proceeding involving any of the registrant's directors, officers or employees for which indemnification is sought, nor is the registrant aware of any threatened litigation that may result in claims for indemnification by the registrant.

The registrant has the power to indemnify its other employees and other agents, as permitted by the DGCL or any other applicable law, but the registrant is not required to do so.

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The registrant maintains directors' and officers' liability insurance. The policy insures the registrant's directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses the registrant for those losses for which the registrant has lawfully indemnified the directors and officers. The policy contains various exclusions, none of which apply to any offerings pursuant to this registration statement.

The amended and restated investors' rights agreement between the registrant and certain investors provides for cross-indemnification in connection with registration of the registrant's common stock on behalf of such investors. In connection with the expansion of our senior debt on March 17, 2008, we also entered into a registration rights agreement with the purchasers of the \$40.0 million of additional secured indebtedness that provides for cross-indemnification in connection with registration of the registrant's common stock on behalf of such purchasers. In addition, the common stock purchase agreement and the registration rights agreement between the registrant and Kingsbridge provides for cross-indemnification in connection with the registration of the registrant's common stock on behalf of Kingsbridge and the entering into of the transactions contemplated by the common stock purchase agreement and the registration rights agreement.

**Item 16. Exhibits.**

<b>Exhibit Number</b>	<b>Description of the Document</b>
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock Certificate.(3)
4.3A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between the Registrant and the other parties named therein.(4)
4.3B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between the Registrant and the other parties named therein.(5)
4.3C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between the Registrant and the other parties named therein.(6)
4.4A	Form of Series BB Preferred Stock Warrant of the Registrant.(7)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended.(5)
4.5A#	Senior Secured Note and Warrant Purchase Agreement, dated as of March 14, 2008, by and among the Registrant, JPI Commercial, LLC and the Purchasers named therein.(5)
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.(5)
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.(5)
4.5D	Form of Common Stock Warrant of the Registrant.(5)
4.5E#	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.(5)
4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008.(6)
4.6B	Registration Rights Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated May 7, 2008.(6)
5.1	Opinion of Registrant's General Counsel.
10.70	Common Stock Purchase Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated May 7, 2008.(6)
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Registrant's General Counsel (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page).





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- # Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.
- (1) Incorporated herein by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.
  - (2) Incorporated herein by reference to Exhibit 3.4 to the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.
  - (3) Incorporated herein by reference to the same numbered exhibit to the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.
  - (4) Incorporated herein by reference to Exhibit 4.3 to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.
  - (5) Incorporated herein by reference to the same numbered exhibit to the Registrant's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
  - (6) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.
  - (7) Incorporated herein by reference to Exhibit 4.6 to the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 9, 2007.

**Item 17. Undertakings.**

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and
  - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;  
*provided, however,* that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
  
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
  - (i) If the registrant is relying on Rule 430B:
    - (A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

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- (B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or
- (ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (5) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Palo Alto, State of California, on June 11, 2008.

**Jazz Pharmaceuticals, Inc.**

(Registrant)

/s/ MATTHEW K. FUST  
Matthew K. Fust

(Duly Authorized and Principal Accounting and  
Financial Officer)

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KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints **BRUCE C. COZADD, SAMUEL R. SAKS, M.D., MATTHEW K. FUST** and **CAROL A. GAMBLE**, and each or any one of them, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement and to sign any and all additional registration statements relating to the Registration Statement and filed pursuant to Rule 462(b) of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ SAMUEL R. SAKS, M.D.  <b>Samuel R. Saks, M.D.</b>	Chief Executive Officer and Director  <i>(Principal Executive Officer)</i>	June 11, 2008
/s/ MATTHEW K. FUST  <b>Matthew K. Fust</b>	Executive Vice President and  Chief Financial Officer  <i>(Principal Accounting and Financial Officer)</i>	June 11, 2008
/s/ SAMUEL D. COLELLA  <b>Samuel D. Colella</b>	Director	June 11, 2008
/s/ BRUCE C. COZADD  <b>Bruce C. Cozadd</b>	Director	June 11, 2008
/s/ BRYAN C. CRESSEY  <b>Bryan C. Cressey</b>	Director	June 11, 2008
/s/ MICHAEL W. MICHELSON  <b>Michael W. Michelson</b>	Director	June 11, 2008
/s/ JAMES C. MOMTAZEE  <b>James C. Momtazee</b>	Director	June 11, 2008
/s/ KENNETH W. O KEEFE  <b>Kenneth W. O Keefe</b>	Director	June 11, 2008
/s/ JAIMIN R. PATEL	Director	June 11, 2008

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**Jaimin R. Patel**

/s/ ALAN M. SEBULSKY

Director

June 11, 2008

**Alan M. Sebulsky**

/s/ JAMES B. TANANBAUM, M.D.

Director

June 11, 2008

**James B. Tananbaum, M.D.**

/s/ NATHANIEL M. ZILKHA

Director

June 11, 2008

**Nathaniel M. Zilkha**

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**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of the Document</b>
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock Certificate.(3)
4.3A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between the Registrant and the other parties named therein.(4)
4.3B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between the Registrant and the other parties named therein.(5)
4.3C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between the Registrant and the other parties named therein.(6)
4.4A	Form of Series BB Preferred Stock Warrant of the Registrant.(7)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended.(5)
4.5A#	Senior Secured Note and Warrant Purchase Agreement, dated as of March 14, 2008, by and among the Registrant, JPI Commercial, LLC and the Purchasers named therein.(5)
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.(5)
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.(5)
4.5D	Form of Common Stock Warrant of the Registrant.(5)
4.5E#	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.(5)
4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008.(6)
4.6B	Registration Rights Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated May 7, 2008.(6)
5.1	Opinion of Registrant's General Counsel.
10.70	Common Stock Purchase Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated May 7, 2008.(6)
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Registrant's General Counsel (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page).

- # Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.
- (1) Incorporated herein by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.
  - (2) Incorporated herein by reference to Exhibit 3.4 to the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.
  - (3) Incorporated herein by reference to the same numbered exhibit to the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.
  - (4) Incorporated herein by reference to Exhibit 4.3 to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.
  - (5) Incorporated herein by reference to the same numbered exhibit to the Registrant's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
  - (6)

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Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.

- (7) Incorporated herein by reference to Exhibit 4.6 to the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 9, 2007.