SOMAXON PHARMACEUTICALS, INC.

FORM 10-Q
(Quarterly Report)

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Address	12750 HIGH BLUFF DRIVE, SUITE 310
	SAN DIEGO, California 92130
Telephone	(858) 509-3670
CIK	0001339455
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2006

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 000-51665

Somaxon Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware *(State or other jurisdiction of incorporation or organization)*	**20-0161599** *(I.R.S. Employer Identification No.)*
12750 High Bluff Drive, Suite 310, San Diego, CA *(Address of principal executive offices)*	**92130** *(Zip Code)*

(858) 509-3670
(Registrant's telephone number, including area code)

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☑

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

Yes ☐ No ☑

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of May 2, 2006 was 18,045,366.

SOMAXON PHARMACEUTICALS, INC.

FORM 10-Q — QUARTERLY REPORT
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2006

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Somaxon Pharmaceuticals, Inc.
(A development stage company)

BALANCE SHEETS
(unaudited)

	March 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 83,142,538	$100,918,088
Short-term investments	10,513,204	3,047,086
Other current assets	1,871,733	1,923,466
Total current assets	95,527,475	105,888,640
Property and equipment, net	194,454	190,045
Other assets	177,259	177,259
Total assets	$ 95,899,188	$106,255,944
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 14,408,283	$ 11,881,616
Accrued liabilities	676,992	919,090
Total current liabilities	15,085,275	12,800,706
Commitments and contingencies: (Note 4)		
Stockholders' equity:		
Preferred stock, $.0001 par value; 10,000,000 shares authorized, none issued and outstanding	—	—
Common stock, $.0001 par value; 100,000,000 shares authorized; 18,045,366 shares issued and outstanding at March 31, 2006 and December 31, 2005	1,804	1,804
Additional paid-in capital	147,924,444	150,802,850
Deferred compensation	—	(3,801,897)
Deficit accumulated during the development stage	(67,088,179)	(53,547,519)
Accumulated other comprehensive loss	(24,156)	—
Total stockholders' equity	80,813,913	93,455,238
Total liabilities and stockholders' equity	$ 95,899,188	$106,255,944

The Accompanying Notes are an Integral Part of these Financial Statements

Somaxon Pharmaceuticals, Inc.
(A development stage company)

STATEMENTS OF OPERATIONS
(unaudited)

	Three months ended March 31, 2006	Three months ended March 31, 2005	Period from August 14, 2003 (inception) through March 31, 2006
Operating expenses			
License fees	$ 153,750	$ 113,710	$ 5,193,815
Research and development	12,294,125	2,046,084	48,988,654
Marketing, general and administrative expense	2,200,073	888,470	9,935,330
Remeasurement of Series C warrant liability	—	—	5,648,612
Total operating expenses	14,647,948	3,048,264	69,766,411
Loss from operations	(14,647,948)	(3,048,264)	(69,766,411)
Interest and other income	1,107,288	59,614	2,678,232
Net loss	(13,540,660)	(2,988,650)	(67,088,179)
Accretion of redeemable convertible preferred stock to redemption value	—	—	(86,102)
Net loss applicable to common stockholders	$(13,540,660)	$(2,988,650)	$ (67,174,281)
Basic and diluted net loss applicable to common stockholders per share	$ (0.75)	$ (5.85)	
Shares used to calculate net loss applicable to common stockholders per share	17,936,113	510,999	

The Accompanying Notes are an Integral Part of these Financial Statements

Somaxon Pharmaceuticals, Inc.
(A development stage company)

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS
For the period from August 14, 2003 (inception) through March 31, 2006 (unaudited)

	Series C Redeemable Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Stock Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Loss	Total
	Shares	Amount	Shares	Amount	Shares	Amount					
Issuance of common stock for cash to founders at $0.0006 per share in August.	—	$ —	—	$ —	583,333	$ 58	$ 292	$ —	$ —	$ —	$ 350
Issuance of Series A convertible preferred stock for cash at $1.00 per share in August, November, and December	—	—	2,281,538	2,281,538	—	—	—	—	—	—	2,281,538
Net Loss	—	—	—	—	—	—	—	—	(1,463,182)	—	(1,463,182)
Balance at December 31, 2003	**—**	**—**	**2,281,538**	**2,281,538**	**583,333**	**58**	**292**	**—**	**(1,463,182)**	**—**	**818,706**
Issuance of Series A convertible preferred stock for cash at $1.00 per share in January	—	—	18,462	18,462	—	—	—	—	—	—	18,462
Issuance of Series B convertible preferred stock for cash at $1.00 per share in April and June, net of issuance costs of $97,295	—	—	23,000,000	22,902,705	—	—	—	—	—	—	22,902,705
Issuance of common stock in April at $1.20 per share for license agreement	—	—	—	—	84,058	8	100,862	—	—	—	100,870
Common stock issued from exercise of stock options	—	—	—	—	55,833	6	3,494	—	—	—	3,500
Deferred compensation associated with stock option grants	—	—	—	—	—	—	110,917	(110,917)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	—	13,425	—	—	13,425
Expense related to non-employee stock options	—	—	—	—	—	—	14,205	—	—	—	14,205
Net Loss	—	—	—	—	—	—	—	—	(13,597,770)	—	(13,597,770)
Balance at December 31, 2004	**—**	**—**	**25,300,000**	**25,202,705**	**723,224**	**72**	**229,770**	**(97,492)**	**(15,060,952)**	**—**	**10,274,103**

Somaxon Pharmaceuticals, Inc.
(A development stage company)

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS
For the period from August 14, 2003 (inception) through March 31, 2006 (unaudited)

	Series C Redeemable Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Stock Compensation	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Loss	Total
	Shares	Amount	Shares	Amount	Shares	Amount					
Issuance of Series C redeemable convertible preferred stock for cash at $1.35 per share in June and September, net of issuance costs of $152,712	48,148,455	64,847,703	—	—	—	—	—	—	—	—	—
Series C proceeds allocated to warrant instrument	—	(647,684)	—	—	—	—	—	—	—	—	—
Additional paid-in capital from the exercise of the Series C warrant instrument.	—	—	—	—	—	—	6,296,296	—	—	—	6,296,296
Accretion of Series C redeemable convertible preferred stock to redemption value	—	86,102	—	—	—	—	(86,102)	—	—	—	(86,102)
Issuance of common stock in initial public offering at $11.00 per share in December 2005, net of issuance costs of $5,179,780	—	—	—	—	5,000,000	500	49,819,720	—	—	—	49,820,220
Conversion of redeemable convertible preferred stock into common stock	(48,148,455)	(64,286,121)	—	—	8,024,721	802	64,285,319	—	—	—	64,286,121
Conversion of convertible preferred stock into common stock	—	—	(25,300,000)	(25,202,705)	4,216,661	422	25,202,283	—	—	—	—
Common stock issued from exercise of stock options	—	—	—	—	80,760	8	176,672	—	—	—	176,680
Deferred compensation associated with stock option grants	—	—	—	—	—	—	4,741,609	(4,741,609)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	—	1,037,204	—	—	1,037,204
Expense related to non-employee stock options	—	—	—	—	—	—	137,283	—	—	—	137,283
Net loss	—	—	—	—	—	—	—	—	(38,486,567)	—	(38,486,567)
Balance at December 31, 2005	**—**	**$ —**	**—**	**$ —**	**18,045,366**	**$ 1,804**	**$150,802,850**	**$ (3,801,897)**	**$(53,547,519)**	**$ —**	**$ 93,455,238**
Net loss	—	—	—	—	—	—	—	—	(13,540,660)	—	(13,540,660)
Change in unrealized loss on available-for-sale investments	—	—	—	—	—	—	—	—	—	(24,156)	(24,156)
Comprehensive loss											(13,564,816)
Elimination of deferred stock compensation upon adoption of SFAS No. 123R	—	—	—	—	—	—	(3,801,897)	3,801,897	—	—	—

Stock option expense under SFAS No. 123R	—	—	—	—	—	—	867,333	—	—	—	867,333
Expense related to non-employee stock options	—	—	—	—	—	—	34,597	—	—	—	34,597
Vesting of early exercised stock options	—	—	—	—	—	—	21,561	—	—	—	21,561
Balance at March 31, 2006	**—**	**$ —**	**—**	**$ —**	**18,045,366**	**$ 1,804**	**$147,924,444**	**$ —**	**$(67,088,179)**	**$ (24,156)**	**$(80,813,913)**

The Accompanying Notes are an Integral Part of these Financial Statements

Somaxon Pharmaceuticals, Inc.
(A development stage company)

STATEMENTS OF CASH FLOWS
(unaudited)

	Three Months Ended March 31, 2006	Three Months Ended March 31, 2005	Period from August 14, 2003 (inception) through March 31, 2006
Cash flows from operating activities			
Net loss	$ (13,540,660)	$ (2,988,650)	$ (67,088,179)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	19,795	8,537	96,320
Expense related to stock option issuance	901,930	137,160	2,104,047
Issuance of stock for license agreement	—	—	100,870
Remeasurement of Series C warrant	—	—	5,648,612
Loss on disposal of equipment	—	—	1,782
Changes in operating assets and liabilities			
Other current assets	51,733	(32,503)	(1,871,733)
Other assets	—	10,018	(177,259)
Accounts payable	2,526,667	(983,474)	14,408,283
Accrued liabilities	(220,537)	(633,558)	629,326
Net cash used in operating activities	(10,261,072)	(4,482,470)	(46,147,931)
Cash flows from investing activities			
Purchases of property and equipment	(24,204)	(10,249)	(292,556)
Purchases of short-term investments	(7,552,024)	—	(10,599,110)
Sales and maturities of short-term investments	61,750	—	61,750
Net cash used in investing activities	(7,514,478)	(10,249)	(10,829,916)
Cash flows from financing activities			
Issuance of common stock, net of issuance costs	—	—	49,820,570
Issuance of preferred stock, net of issuance costs	—	—	90,050,408
Exercise of stock options	—	—	249,407
Net cash provided from financing activities	—	—	140,120,385
Increase (Decrease) in cash and cash equivalents	(17,775,550)	(4,492,719)	83,142,538
Cash and cash equivalents at beginning of the period	100,918,088	12,835,318	—
Cash and cash equivalents at end of the period	$ 83,142,538	$ 8,342,599	$ 83,142,538
Supplemental disclosure of noncash investing and financing activities			
Accretion to redemption value of redeemable convertible preferred stock	$	$ —	$ 86,102
Conversion of preferred stock into common stock upon completion of initial public offering	$	$ —	$ 89,487,602

The Accompanying Notes are an Integral Part of these Financial Statements

Somaxon Pharmaceuticals, Inc.
(A development stage company)

Notes to Financial Statements
(unaudited)

Note 1. Organization and Summary of Significant Accounting Policies

Business

Somaxon Pharmaceuticals, Inc. ("Somaxon" or the "Company") is a Delaware corporation founded on August 14, 2003. The Company is a specialty pharmaceutical company focused on the in-licensing and development of proprietary product candidates for the treatment of diseases and disorders in the fields of psychiatry and neurology.

To date, the Company has in-licensed three product candidates. The lead product candidate, SILENOR™ (doxepin hydrochloride), is in Phase III clinical trials for the treatment of insomnia. The product candidate nalmefene hydrochloride is in a Phase II/III clinical trial for the treatment of pathological gambling and a Phase II clinical trial for smoking cessation. The Company is also developing a new formulation of acamprosate calcium for the treatment of certain movement disorders. The Company intends to continue to build a portfolio of product candidates that target psychiatric and neurological diseases and disorders, focusing on products that are currently commercialized outside the United States, approved in the United States but with significant commercial potential for proprietary new uses, new dosages, alternative delivery systems, or in late stages of clinical development.

Capital Resources

The Company expects to continue to incur losses and have negative cash flows from operations in the foreseeable future as it continues to engage in development and clinical trial activities for its product candidates and build a sales organization. The Company may be required to raise additional funds through public or private financings, strategic relationships, or other arrangements and cannot assure that the funding will be available on attractive terms, or at all. Also, additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. The Company's failure to raise capital as and when needed could have a negative impact on the financial condition and the ability to implement the Company's business strategy, including completing current clinical development programs, commercializing products, and in-licensing other products.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles and the rules and regulations of the Securities and Exchange Commission related to a quarterly report on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by U.S. generally accepted accounting principles for complete financial statements. The balance sheet at December 31, 2005 has been derived from the audited financial statements at that date, but does not include all disclosures required by accounting principles generally accepted in the United States. However, the Company believes that the disclosures are adequate to make the information presented not misleading. The interim financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair statement of the financial condition and results of operations for the periods presented. All such adjustments are of a normal recurring nature.

Operating results for the three months ended March 31, 2006 are not necessarily indicative of the results that may be expected for any future periods. For further information, please see the financial statements and related disclosures included in the Company's Form 10-K for the year ended December 31, 2005.

Share-Based Compensation Expense

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R), *Share-Based Payment*, which requires the measurement and recognition of compensation expense in the Statement of Operations for all share-based payment awards made to employees and directors, including employee stock options, based on estimated fair values. Prior to adoption of SFAS No. 123(R), the Company accounted for stock-

based awards to employees and directors using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25 *Accounting for Stock Issued to Employees* ("APB 25") as allowed under SFAS No. 123 *Accounting for Stock-Based Compensation* . Under the intrinsic value method, deferred stock compensation was recognized to the extent that the price of the underlying common stock, as determined in the retrospective fair value analysis performed in conjunction with the Company's initial public offering, exceeded the exercise price of the stock options at the date of grant.

In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin ("SAB") No. 107 relating to SFAS No. 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS No. 123(R). The Company has two share-based payment plans: the employee stock purchase plan and the stock option plan. SFAS No. 123(R) is applicable only to the Company's stock options as the terms of the Company's employee stock purchase plan make it non-compensatory under the provisions of SFAS No. 123(R).

The Company adopted SFAS No. 123(R) using the modified prospective transition method. Under the modified prospective method, prior period financial statements are not restated for the impact of SFAS No. 123(R). Stock options granted prior to the adoption of SFAS No. 123(R), but not yet fully vested at the time of adoption, are included in compensation expense based on the grant date fair value estimated in accordance with the pro-forma provisions of SFAS No. 123. SFAS No. 123(R) requires compensation expense to be reduced for an estimate of forfeitures such that expense is recognized for those stock options which ultimately vest. This is consistent with the Company's pro-forma accounting under SFAS No. 123; however the Company did not use an estimated forfeiture rate when recognizing compensation expense under APB 25. The cumulative effect from adopting SFAS No. 123(R), with the forfeiture rate applied to the compensation expense recorded under APB 25, was immaterial.

SFAS No. 123(R) requires the fair value of share-based payment awards to be estimated on the date of grant using an option-pricing model. The Company uses the Black-Scholes valuation model to estimate the fair value of employee stock options. One of the inputs required in the Black-Scholes valuation model is a measure of expected future volatility. The Company's stock did not have a readily available market prior to its initial public offering in December 2005, causing a relatively short history of data for determining volatility. Consequently, the Company made an estimate of its volatility based on comparable companies to arrive at its grant date calculated value for stock options.

The Company recognizes the calculated value of the portion of the awards that are ultimately expected to vest over the requisite service period, which is the vesting period for the Company's stock options, on a straight line basis. Stock-based compensation expense recognized under SFAS No. 123(R) for employees and directors for the three months ended March 31, 2006 was $867,333 of which $182,800 was included in research and development expense and $684,533 was included in marketing, general and administrative expense. Pro-forma stock based compensation as determined under FAS No. 123 was $194,032 for the three month period ended March 31, 2005. See Note 3 for additional information.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

Comprehensive Income (Loss)

SFAS No. 130, *Reporting Comprehensive Income (Loss),* requires that all components of comprehensive income (loss) be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is net income (loss), plus certain other items that are recorded directly to stockholders' equity, which

Somaxon Pharmaceuticals, Inc.
(A development stage company)

Notes to Financial Statements
(unaudited)

for Somaxon consists specifically of changes in unrealized gains and losses on securities classified as available-for-sale. The Company reports comprehensive income (loss) in the statement of redeemable convertible preferred stock and stockholders' equity.

Segment Information

Management has determined that the Company operates in one reportable segment which is the development and commercialization of pharmaceutical products.

Net Loss per Share

Net loss applicable to common stockholders per share is calculated in accordance with SFAS No. 128, *Earnings Per Share,* and SAB No. 98. Basic earnings per share ("EPS") is calculated by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding for the period, reduced by the weighted average number of unvested common shares subject to repurchase. Basic EPS excludes the effects of common stock equivalents. Diluted EPS is computed in the same manner as basic EPS, but includes the effects of common stock equivalents using the treasury-stock method to the extent they are dilutive. Common stock equivalents include convertible preferred stock, options, and warrants. The Company incurred a net loss in all periods presented, causing inclusion of any potentially dilutive securities to have an anti-dilutive affect, resulting in basic and dilutive loss per share applicable to common stockholders to be equivalent. The Company did not have any common shares issued for nominal consideration as defined under the terms of SAB No. 98, which would be included in EPS calculations. The following table summarizes the Company's EPS calculations.

	Three months ended March 31,	
	2006	2005
Numerator:		
Net loss	$(13,540,660)	$(2,988,650)
Denominator:		
Weighted average common shares	18,009,030	670,721
Weighted average unvested common shares subject to repurchase	(72,917)	(159,722)
Denominator for basic and diluted net loss per share	17,936,113	510,999
Basic and diluted net loss per share	$ (0.75)	$ (5.85)
Outstanding anti-dilutive securities not included in diluted net loss per share calculation:		
Convertible preferred shares	—	4,216,661
Options to purchase common stock	2,167,922	429,250
Common stock subject to repurchase	100,867	194,652
Total outstanding anti-dilutive securities not included in diluted net loss per share calculation	2,268,789	4,840,563

At March 31, 2005, the Company had 2,300,000 and 23,000,000 shares of Series A and Series B convertible preferred stock issued and outstanding. During the Company's initial public offering in December 2005, these shares were converted into 4,216,661 shares of common stock at a ratio of six shares of preferred stock into one share of common stock. No preferred shares were issued and outstanding at March 31, 2006.

Somaxon Pharmaceuticals, Inc.
(A development stage company)

Notes to Financial Statements
(unaudited)

As discussed above, the Company adopted SFAS No. 123(R) on January 1, 2006, which requires stock option expense to be recognized in the Statement of Operations. Prior to adoption of SFAS No. 123(R), stock based compensation was accounted for using the intrinsic value method prescribed under APB 25. The pro-forma net loss disclosed pursuant to requirements of SFAS No. 123 approximated the net loss and net loss per share that would have resulted had the Company applied the provisions of SFAS No. 123(R) in prior periods. The following table provides pro-forma net loss and pro-forma net loss per share under SFAS No. 123 for periods prior to the adoption of SFAS No. 123(R) for comparative purposes.

	Three months ended March 31,	
	2006	2005
Net loss applicable to common stock holders as reported	$(13,540,660)	$(2,988,650)
Add: Stock-based employee compensation expense included in net loss	N/A	130,065
Less: Stock-based employee compensation expense using fair value method	N/A	(194,032)
Pro-forma net loss applicable to common stockholders	$(13,540,660)	$(3,052,617)
Basic and diluted net loss applicable to common stockholders per share as reported	$ (0.75)	$ (5.85)
Pro-forma basic and diluted net loss applicable to common stockholders per share	$ (0.75)	$ (5.97)

Note 2. Composition of Certain Balance Sheet Items

Other Current Assets

Other current assets consist of the following:

	March 31, 2006	December 31, 2005
Deposits	$ 682,519	$ 768,275
Prepaid clinical research fees	543,720	952,282
Prepaid insurance	497,876	72,387
Other current assets	147,618	130,522
Total other current assets	$1,871,733	$ 1,923,466

Property and Equipment

Property and equipment consists of the following:

	March 31, 2006	December 31, 2005
Office furniture and equipment	$170,438	$ 169,002
Computer equipment	119,610	96,842
Property and equipment, at cost	290,048	265,843
Less: accumulated depreciation	(95,594)	(75,798)
Property and equipment, net	$194,454	$ 190,045

Somaxon Pharmaceuticals, Inc.
(A development stage company)

Notes to Financial Statements
(unaudited)

Depreciation expense was $19,795, and $8,537 for the three month periods ended March 31, 2006 and 2005, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	March 31, 2006	December 31, 2005
Accrued license fees	$127,500	$ 138,750
Accrued compensation and benefits	327,674	610,863
Refundable proceeds from unvested exercised stock options	47,666	69,227
Accrued professional fees	168,902	95,000
Other accrued liabilities	5,250	5,250
Total accrued liabilities	$676,992	$ 919,090

Note 3. Share-based compensation

Employee Stock Purchase Plan

On December 15, 2005, the Company implemented its employee stock purchase plan (the “ESPP”) which allows employees to contribute up to 20% of their cash earnings, subject to certain maximums, to be used to purchase shares of the Company’s common stock on each semi-annual purchase date. The purchase price is equal to 95% of the market value per share on each purchase date. The Company has initially reserved 300,000 shares of common stock for issuance under the ESPP and it contains an “evergreen provision” that allows for annual increases in the number of shares available for issuance on the first day of each fiscal year beginning January 1, 2007 and ending January 1, 2015 equal to the lesser of: (i) 300,000 shares, (ii) 1% of the outstanding capital stock on each January 1, or (iii) an amount determined by the Company’s board of directors. As of March 31, 2006, no shares were issued under the ESPP.

Stock Options

The Company has stock options outstanding under two stock option plans for the benefit of its eligible employees, consultants, and independent directors. The Somaxon Pharmaceuticals, Inc. 2004 Equity Incentive Award Plan (the “2004 Plan”) allowed for a maximum issuance of up to 1,250,000 shares. As a result of the Company’s IPO in December 2005, no additional options will be granted under the 2004 Plan and all options that are repurchased, forfeited, cancelled or expire will become available for grant under the 2005 Equity Incentive Award Plan (the “2005 Plan”).

In November 2005, the stockholders approved the 2005 Plan. As of March 31, 2006, 2,000,000 shares of common stock were reserved for issuance under the 2005 Plan, plus an additional 25,073 shares from stock options which were available for issuance under the 2004 Plan. In addition, the 2005 Plan contains an “evergreen provision” that allows for an annual increase in the number of shares available for issuance on the first day of each fiscal year beginning January 1, 2007 and expiring January 1, 2015 equal to the lesser of: (i) 2,000,000 shares, (ii) 5% of the outstanding capital stock on each January 1, or (iii) an amount determined by the Company’s board of directors.

The Company’s stock options generally vest over a period of between one and four years and have a ten year term. Certain of the stock options were exercised in advance of becoming vested. Unvested shares obtained from

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the early exercise of stock options are subject to repurchase by the Company at the original exercise price in the event of termination or separation. The Company recognized a liability for the proceeds received from the exercise of unvested options of $47,666 and $69,227 at March 31, 2006 and December 31, 2005, respectively. No unvested shares have been repurchased by the Company as of March 31, 2006.

The following table summarizes the Company's stock option activity for employee and director stock options.

	Shares	Weighted Average Exercise Price	Weighted Average Grant Date Calculated Value per Share
Outstanding at December 31, 2004	**260,333**	**$ 1.20**	
Stock options granted during 2005:			
Quarter ended March 31, 2005	147,250	$ 2.40	$ 3.47
Quarter ended June 30, 2005	54,167	2.40	4.00
Quarter ended September 30, 2005	676,166	3.04	7.54
Quarter ended December 31, 2005	331,243	11.08	6.52
Total stock options granted during 2005	1,208,826	$ 5.13	$ 6.60
Stock options exercised during 2005:			
Quarter ended March 31, 2005	—	$ —	
Quarter ended June 30, 2005	(20,000)	2.40	
Quarter ended September 30, 2005	(37,500)	2.82	
Quarter ended December 31, 2005	(19,094)	1.20	
Total 2005 stock options exercised	(76,594)	$ 2.32	
Stock options forfeited during 2005:			
Quarter ended June 30, 2005	(26,736)	$ 1.20	
Outstanding at December 31, 2005	**1,365,829**	**$ 4.62**	
Stock options granted during 2006:			
Quarter ended March 31, 2006	764,590	$ 11.13	$ 7.84
Total stock options granted through March 31, 2006	764,590	$ 11.13	$ 7.84
Outstanding at March 31, 2006	**2,130,419**	**$ 6.95**	

There were no stock options exercised by employees and directors, and therefore no intrinsic value for exercised stock options during the three month periods ended March 31, 2006 and 2005. The intrinsic value of director and employee stock options outstanding at March 31, 2006, based on a closing stock price of $16.01 per share, was $19.3 million.

Of the 2,130,419 outstanding options to employees and directors, 254,374 were vested and 1,876,045 were unvested. The weighted average remaining vesting term at March 31, 2006 was 3.1 years and the total calculated value of outstanding stock options awarded to employees and directors expected to be recognized in future periods over this weighted average remaining vesting term is $11.9 million. The intrinsic value of exercisable stock options at March 31, 2006 was $3.2 million.

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The calculated value of employee stock options was determined using the Black-Scholes option pricing model with the following assumptions:

	Three months ended March 31,	
	2006	2005
Risk free interest rate	4.31% to 4.82%	4.18%
Expected term	6.25 years	6 years
Expected volatility	76% to 78%	63%
Weighted average volatility	76%	63%
Expected dividend yield	0%	0%
Fair value of underlying stock	$10.60 to $19.00	$4.68

In accordance with EITF Issue 96-18 *Accounting for Equity Investments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services* , the Company periodically re-measures the fair value of stock option grants to non-employees and recognizes the related income or expense during their vesting period.

The following table summarizes the Company's stock option activity for stock options granted to consultants.

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2004	**15,833**	**$ 1.20**
Stock options granted during 2005:		
Quarter ended March 31, 2005	7,500	1.60
Quarter ended December 31, 2005	20,003	13.62
Total 2005 stock options granted	27,503	10.34
Stock options exercised during 2005:		
Quarter ended September 30, 2005	(4,167)	1.20
Total 2005 stock options exercised	(4,167)	1.20
Stock options forfeited during 2005:		
Quarter ended March 31, 2005	(1,666)	1.20
Outstanding at December 31, 2005	**37,503**	**$ 7.90**
Stock options granted during 2006 to date:	—	$ —
Stock options exercised during 2006 to date:	—	—
Outstanding at March 31, 2006	**37,503**	**$ 7.90**

There was no stock option activity for consultants during the three month period ended March 31, 2006. Stock options granted to consultants resulted in expense of $34,597 and $7,096 for the three month periods ended March 31, 2006 and 2005, respectively. Stock option expense for consultants is included within research and development expense.

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A summary of all stock options outstanding at December 31, 2005 is as follows:

	Options Outstanding			Vested Options		
Exercise Price	Number	Weighted Average Remaining Life	Weighted Average Exercise Price	Number	Weighted Average Remaining Life	Weighted Average Exercise Price
$1.20	229,502	8.5 Years	$ 1.20	96,405	8.5 Years	$ 1.20
$2.40	173,917	9.2 Years	$ 2.40	42,917	9.2 Years	$ 2.40
$3.00	644,246	9.6 Years	$ 3.00	31,109	9.6 Years	$ 3.00
$8.40	7,334	9.7 Years	$ 8.40	—	9.7 Years	$ 8.40
$11.00 to $13.62	348,333	10.0 Years	$ 11.25	14,306	10.0 Years	$ 12.02
Total stock options outstanding	1,403,332	9.4 Years	$ 4.71	184,737	9.4 Years	$ 2.62

A summary of all stock options outstanding at March 31, 2006 is as follows:

	Options Outstanding			Vested Options		
Exercise Price	Number	Weighted Average Remaining Life	Weighted Average Exercise Price	Number	Weighted Average Remaining Life	Weighted Average Exercise Price
$1.20	229,502	8.2 Years	$ 1.20	111,687	8.2 Years	$ 1.20
$2.40	173,917	8.6 Years	$ 2.40	77,953	8.6 Years	$ 2.40
$3.00	644,246	9.3 Years	$ 3.00	39,651	8.8 Years	$ 3.00
$8.40 to $10.99	708,424	9.8 Years	$ 10.58	—	9.8 Years	$ 10.58
$11.00 to $13.62	348,333	9.7 Years	$ 11.25	44,722	9.7 Years	$ 11.57
$13.63 to $19.00	63,500	10.0 Years	$ 16.93	—	10.0 Years	$ 16.93
Total stock options outstanding	2,167,922	9.3 Years	$ 6.97	274,012	9.0 Years	$ 3.49

Shares Available for Future Grant

The following table summarizes the number of shares available for issuance under the Company's equity compensation plans.

	Stock Options	ESPP
Shares available for issuance at December 31, 2004	**84,668**	**—**
Increase in authorized shares	2,833,333	300,000
Grants and issuances	(1,236,329)	—
Forfeitures	28,402	—
Shares available for issuance at December 31, 2005	**1,710,074**	**300,000**
Grants and issuances	(764,590)	—
Shares available for issuance at March 31, 2006	**945,484**	**300,000**

Note 4. Commitments and Contingencies

Costs associated with the Company's license agreements are expensed as the related research and development costs are incurred. Total future minimum obligations under the Company's various license agreements are $10,711,000 for milestone and license payments. The Company is also obligated to make additional milestone

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payments of up to $11,375,000 upon achieving certain product development events, as well as revenue-based royalty payments. Minimum license payments are subject to increase based on timing of various milestones and the extent to which the licensed technologies are used in various treatments. The Company's exclusive worldwide license agreement with ProCom One to develop and commercialize SILENOR™ (doxepin hydrochloride) includes a $500,000 payment upon the earlier of: (i) acceptance of our New Drug Application (NDA) by the Food and Drug Administration (FDA), or (ii) December 31, 2006. The license agreement is cancelable by Somaxon at any time if the Company believes the use of the product poses an unacceptable safety risk or if it fails to achieve a satisfactory level of efficacy. Consequently, the Company has not accrued this milestone payment as of March 31, 2006. In addition, the Company also has entered into contracts with a clinical research organization ("CRO") and other vendors to assist in clinical trial work. These contracts are cancelable at any time, but obligate the Company to reimburse the provider for any time or costs incurred through the date of termination.

In February 2006, the Company entered into a manufacturing supply agreement with Patheon Pharmaceuticals, Inc. to manufacture commercial quantities of SILENOR™ tablets. Under the terms of the contract, Somaxon is not obligated to purchase a minimum quantity; however, the Company is obligated to purchase specified percentages of the total annual commercial requirements of SILENOR™. The agreement has a five year term and renews for twelve-month periods thereafter. It is cancelable with written notice at least eighteen months prior to the end of the current term. Additionally, Somaxon may terminate the agreement with twelve months notice in connection with a partnering, collaboration, sublicensing, acquisition, or similar event provided that the termination does not occur within three years of the commencement of manufacturing services. The agreement is also subject to termination in the event of material breach of contract, bankruptcy, or government action inhibiting the use of the product candidate.

The Company leases its office facility under two lease agreements; one of which expires in January 2007, and the other of which expires in April 2006 and which the Company is currently in negotiations on an extension in term. Under the terms of the leases, monthly lease payments are about $19,000 per month. The Company paid deposits on these leases in the total amount of $58,682, of which $23,625 remains outstanding at March 31, 2006. The Company also is obligated under various operating leases for office equipment. Rent expense was $56,192 and $29,370 for the three month periods ended March 31, 2006 and 2005, respectively.

Note 5. Related Party Transactions

The Company licenses certain technologies from ProCom One which, as part of the license agreement, grants to ProCom One the right to designate one member of the Company's Board of Directors. The license agreement also provides a consulting arrangement for two ProCom affiliates under which the Company paid $63,750 and $50,000 during the three month periods ended March 31, 2006 and 2005, respectively.

The Company's outside counsel holds 13,896 shares of common stock as a result of purchases of preferred stock which were converted into common shares during the Company's initial public offering in December 2005. The Company paid $205,216 and $27,719 during the three month period ended March 31, 2006 and 2005, respectively for legal services rendered by the Company's outside counsel.

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

The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2005, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2005. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the caption "Risk Factors" in the Form 10-K for the year ended December 31, 2005 and the caption "Risk Factors" in this Form 10-Q for the three months ended March 31, 2006.

Overview

Background

We are a specialty pharmaceutical company focused on the in-licensing and development of proprietary product candidates for the treatment of diseases and disorders in the fields of psychiatry and neurology. To date, we have in-licensed three product candidates. Our lead product candidate, SILENOR™ (doxepin hydrochloride), is in Phase III clinical trials for the treatment of insomnia. Our product candidate nalmefene hydrochloride is in a Phase II/III clinical trial for the treatment of pathological gambling and a Phase II clinical trial for smoking cessation. We are also developing a new formulation of acamprosate calcium for the treatment of certain movement disorders. We intend to continue to build a portfolio of product candidates that are approved in the United States but with significant commercial potential for proprietary new uses, new dosages or alternative delivery systems, products that are currently commercialized outside the United States but not available in the United States, or product candidates that are in late stages of clinical development.

We were incorporated in August 2003 and are a development-stage company. During 2003, we focused on hiring our executive team and initial operating employees and on licensing our first product, SILENOR™. Substantial operations did not commence until 2004. During 2004, we initiated two Phase II clinical trials with SILENOR™ and entered into license agreements for nalmefene and acamprosate. During 2005, we initiated Phase III clinical trials on SILENOR™, commenced Phase II/III clinical trials on nalmefene, and began working on a new formulation for acamprosate. In April 2006, we received the results of our first Phase III clinical trial for SILENOR™ which demonstrated significant improvements in sleep maintenance and sleep onset compared to placebo. Incidences of adverse events were comparable to placebo.

We have incurred significant net losses since our inception. As of March 31, 2006, we had an accumulated deficit of approximately $67.1 million. We expect our operating losses to increase for the next several years as we pursue the clinical development and market launch of our product candidates and acquire or in-license products, technologies or businesses that are complementary to our own.

In December 2005, we completed our initial public offering which resulted in the issuance of 5,000,000 shares of common stock at a price of $11.00 per share for gross proceeds of $55.0 million. Issuance costs were $5.2 million, resulting in net proceeds from the offering of $49.8 million. In conjunction with the completion of our initial public offering, all outstanding shares of convertible preferred stock were converted into 12,241,382 shares of common stock.

Revenues

We have not generated any revenues to date, and we do not expect to generate any revenues from licensing, achievement of milestones or product sales until we execute a collaboration arrangement or are able to commercialize SILENOR™ ourselves.

License Fees

Our license fees consist of the costs incurred to license our product candidates. We charge all license fee and milestone payments for acquired development and commercialization rights to operations as incurred since the underlying technology associated with these expenditures relates to our research and development efforts and has no alternative future use.

Research and Development Expenses

Our research and development expenses consist primarily of salaries and related employee benefits, costs associated with clinical trials managed by our CROs and costs associated with non-clinical activities, such as regulatory expenses. Our most significant costs are for clinical trials. These expenses include payments to vendors such as CROs, investigators, clinical supplies and related consulting. Our historical research and development expenses relate predominately to the clinical trials for SILENOR™.

We have issued stock options to certain of our consultants. The fair value of these options is recorded as stock compensation expense within research and development expense. As described in more detail in our Notes to Financial Statements included elsewhere in this report, these stock options are periodically remeasured to their fair value.

We charge all research and development expenses to operations as incurred. We expect our research and development expenses to remain a significant component of our operating expenses in the future as we continue to develop our product candidates and if we are able to in-license additional product candidates.

We use our internal research and development resources across several projects and many resources are not attributable to specific projects. Accordingly, we do not account for our internal research and development costs on a project basis. We use external service providers to conduct our clinical trials and to manufacture our product candidates to be used in clinical trials. These external costs are tracked on a project basis and are expensed as incurred.

At this time, due to the risks inherent in the clinical trial process and given the early stage of our product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for potential commercialization. Clinical development timelines, the probability of success and development costs vary widely. While we are currently focused on advancing each of our product development programs, we anticipate that we will make determinations as to the scientific and clinical success of each product candidate, as well as ongoing assessments as to each product candidate’s commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates will be subject to future collaberations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. As a result, we cannot be certain when and to what extent we will receive cash inflows from the commercialization of our product candidates.

We expect our development expenses to be substantial and to increase over the next few years as we continue the advancement of our product development programs. We initiated our Phase III clinical trial program for SILENOR™ in June 2005 and our first nalmefene clinical trial in August 2005. We received the results from our first Phase III clinical trial for SILENOR™ in April 2006 which demonstrated significant improvements in sleep maintenance and sleep onset compared to placebo, and we have three additional Phase III clinical trials expected to complete later this year. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, would cause our research and development expense to increase and, in turn, have a material adverse effect on our results of operations.

Marketing, General and Administrative

Our marketing, general and administrative expenses consist primarily of compensation costs, benefits, and professional fees related to our administrative, finance, human resources, legal and internal systems support functions, as well as insurance and facility costs. We anticipate increases in marketing, general and administrative expenses as we add personnel, comply with the reporting obligations applicable to publicly-held companies, and continue to develop and prepare for the commercialization of our product candidates.

Interest and Other Income

Interest and other income consist primarily of interest earned on our cash, cash equivalents, and short-term investments.

Critical Accounting Policies and Estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principals generally accepted in the United States.

The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Clinical Trial Expenses

Expenditures relating to clinical trials are expensed as incurred and included within research and development expenses. Our clinical trial expenses are based on estimates of the services received and efforts expended to date pursuant to contracts with research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. Measurement of clinical trial expenses may require subjective judgments as we may not have been invoiced or otherwise notified of actual costs, making it necessary to make estimates of the efforts and related expense completed to date. The period over which services are performed, the level of services performed by a given date, and the cost of such services are often subjective determinations.

Our principal vendors operate within terms of contracts which establish program costs and estimated timelines. We assess the status of our programs through regular discussions between our program management team and the related vendors. Based on these assessments, we determine the status of our programs in relation to the scope of work outlined in the contracts, and recognize the related amount of expense accordingly. A significant portion of the estimated clinical trial cost normally relates to the cost to treat a patient during the trial. We recognize this cost over the estimated term of the trial beginning with patient enrollment. We adjust our estimates as actual costs become known to us. Changes in estimates could materially affect our results of operations.

License Fees

Costs related to patents and acquisition of intellectual property are expensed as incurred since the underlying technology associated with these expenditures is in connection with our development efforts and has no alternative future use.

Share-based Compensation

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, or SFAS No. 123(R), which requires the measurement and recognition of compensation expense in the Statement of Operations for all share-based payment awards made to employees and directors, including employee stock options, based on estimated fair values. Prior to adoption of SFAS No. 123(R), we accounted for share-based awards to employees and directors using the intrinsic value method in accordance with Accounting Principals Board Opinion No. 25 *Accounting for Stock Issued to Employees*, or APB 25, and provided pro-forma disclosure of net income (loss) as if a fair value method had been applied in measuring compensation expense. Under the intrinsic value method, deferred stock compensation was recognized to the extent that the price of the underlying common stock, as determined in the retrospective fair value analysis performed in conjunction with our initial public offering, exceeded the exercise price of the stock options at the date of grant.

Measurement and recognition of share-based compensation involves significant estimates and the use of an option valuation model, such as the Black-Scholes model which we use. Determining the fair value of share-based payment awards on the date of grant is affected by many complex and subjective assumptions, including estimates of our future volatility, employee exercise behavior, and the number of options expected to ultimately vest. Our expected future volatility is based on the volatility for comparable companies since the volatility of our own stock price has minimal observable history as a result of our recent initial public offering in December 2005. We applied the guidance in the Securities and Exchange Commission's Staff Accounting Bulletin No. 107 in estimating the expected service period for our options. Stock based compensation recorded in our Statement of Operations is based on awards expected to ultimately vest and has been reduced for estimated forfeitures. The actual amount of options which vest is ultimately recorded as amounts are known in future periods. See Note 3 in our Notes to Financial Statements included elsewhere in this report for additional information.

Net Operating Losses and Tax Credit Carryforwards

We have incurred significant net operating losses to date which have resulted in net operating loss carryforwards which begin to expire 20 years after being generated for federal purposes and 10 years after being generated for California tax

purposes. We also have research and development credits which begin to expire 20 years after being generated for federal purposes, and do not expire for California tax purposes. We have fully reserved our net operating loss carryforwards and research and development credits until such time as it is more likely than not that they will be realized.

Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of our net operating loss and credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. We determined that such an ownership change occurred as of June 30, 2005 as a result of various stock issuances used to finance our development activities. This ownership change resulted in limitations on the utilization of tax attributes, including net operating loss carryforwards and tax credits. We estimate that $0.3 million of our California net operating loss carryforwards were effectively eliminated, and $18.3 million of our federal and $17.3 million of our state net operating loss carryforwards were subject to limitation. An additional $0.9 million of our federal research and development credits were also subject to limitation. A portion of the limited net operating loss carryforwards becomes available for use each year and we estimate that approximately $2.8 million of the restricted net operating loss carryforwards become available each year between 2006 and 2010, decreasing to approximately $1.0 million thereafter. Net operating loss carryforwards and research and development credits generated subsequent to the ownership change are currently not subject to limitations, but could be subject to limitations in the future if additional ownership changes occur.

Results of Operations

Three months ended March 31, 2006, 2005 and 2004

License fees . License fees were $0.2 million, $0.1 million and zero for the three month periods ended March 31, 2006, 2005, and 2004, respectively. This is an increase of $40,000 for the three month period ended March 31, 2006 compared to March 31, 2005, and an increase of $0.1 million for the three month period ended March 31, 2005 compared to March 31, 2004. The following table summarizes the key components of our license fees.

	Three Months Ended March 31,			Dollar Change		Percent Change	
	2006	2005	2004	2006 vs. 2005	2005 vs. 2004	2006 vs. 2005	2005 vs. 2004
	(dollar amounts in thousands)						
SILENOR™	$ —	$ —	$ —	$ —	$ —	0%	0%
Nalmefene	4	39	—	(35)	39	-90%	100%
Acamprosate	150	75	—	75	75	100%	100%
Total license fees	$ 154	$ 114	$ —	$ 40	$ 114	35%	100%

License fees increased $40,000 for the three month period ended March 31, 2006 compared to March 31, 2005 primarily due to a $75,000 increase in quarterly license payments to Synchroneuron relating to our acamprosate drug. This is offset by a decrease in license payments relating to nalmefene as a result of a $35,000 upfront license payment made in January 2005 to the University of Miami upon entering a license agreement for the exclusive worldwide rights for a patent relating to the treatment of nicotine dependence.

License fees increased $0.1 million for March 31, 2005 compared to March 31, 2004 due to no license fees during the first quarter of 2004, which was the period prior to entering into agreements for nalmefene and acamprosate.

Research and Development Expenses . Research and development expenses were $12.3 million, $2.0 million and $0.2 million for the three month periods ended March 31, 2006, 2005, and 2004, respectively. This is an increase of $10.2 million for the three month period ended March 31, 2006 compared to March 31, 2005, and an increase of $1.8 million for the three month period ended March 31, 2005 compared to March 31, 2004. The following table summarizes the key components of our research and development expenses.

	Three Months Ended March 31,			Dollar Change		Percent Change	
	2006	2005	2004	2006 vs. 2005	2005 vs. 2004	2006 vs. 2005	2005 vs. 2004
	(dollar amounts in thousands)						
SILENOR™ clinical trials	$ 8,971	$ 1,040	$ 56	$ 7,931	$ 984	763%	1,757%
Nalmefene clinical trials	1,944	564	—	1,380	564	245%	100%
Personnel and other costs	1,163	431	148	732	283	170%	191%
Share-based compensation	216	11	—	205	11	1,864%	100%
Total research and development expense	$ 12,294	$ 2,046	$ 204	$ 10,248	$ 1,842	501%	903%

Expenses associated with SILENOR™ clinical trials increased $7.9 million for the three month period ended March 31, 2006 compared to March 31, 2005 primarily due to the Phase III clinical trial program underway during the first quarter of 2006. During the first quarter of 2005, our Phase 2 SILENOR™ clinical trial program was nearing completion. During the first quarter of 2004, minimal clinical trial activity had commenced as we were newly founded and organizing the clinical trial program during this period.

Expenses associated with Nalmefene clinical trials increased $1.4 million for the three month period ended March 31, 2006 compared to March 31, 2005 primarily due to the pathological gambling trial and the smoking cessation trial which were underway during the first quarter of 2006, but had not yet commenced during the first quarter of 2005. The nalmefene clinical trial costs incurred during the first quarter of 2005 relate primarily to drug manufacturing costs, while no costs were incurred during the first quarter of 2004 since the drug had not yet been licensed at that time.

Personnel and other costs experienced year-over-year increases as a result of increased headcount to conduct and manage the significant growth in clinical trial activities, as well as the adoption of a corporate bonus plan in the second half of 2005.

Share-based compensation increased $0.2 million for the three month period ended March 31, 2006 compared to March 31, 2005 primarily due to the adoption of SFAS No. 123(R) and the resulting recognition of share-based compensation expense.

Marketing, General and Administrative Expenses. Marketing, general and administrative expenses were $2.2 million, $0.9 million and $0.5 million for the three month periods ended March 31, 2006, 2005, and 2004, respectively. This is an increase of $1.3 million for the three month period ended March 31, 2006 compared to March 31, 2005, and an increase of $0.4 million for the three month period ended March 31, 2005 compared to March 31, 2004. The following table summarizes the key components of our marketing, general and administrative expenses.

	Three Months Ended March 31,			Dollar Change		Percent Change	
	2006	2005	2004	2006 vs. 2005	2005 vs. 2004	2006 vs. 2005	2005 vs. 2004
	(dollar amounts in thousands)						
Marketing expense	$ 215	$ 118	$ 11	$ 97	$ 107	82%	973%
Personnel and general costs	1,299	643	502	656	141	102%	28%
Share-based compensation	686	127	—	559	127	440%	100%
Total marketing, general and administrative expenses	$ 2,200	$ 888	$ 513	$ 1,312	$ 375	148%	73%

For the three month periods ended March 31, 2006 and 2005, marketing expenses experienced year-over-year increases as a result of an increase in market research and branding efforts. During these same periods, personnel and general costs increased primarily as a result of increases in headcount as our operations continue to grow. General and administrative expenses have also increased as a result of higher costs associated with complying with the regulations applicable to a public company. Share-based compensation increased $0.6 million for the three month period ended March 31, 2006 compared to March 31, 2005 primarily due to the adoption of SFAS No. 123(R) and the resulting recognition of share-based compensation expense. Share-based compensation recorded during the three month period ended March 31, 2005 is the result of stock options granted at a price under the fair value of our underlying stock as determined by our retrospective stock price analysis conducted in conjunction with our initial public offering.

Interest and Other Income. Interest and other income was $1.1 million, $0.1 million and negligible for the three month periods ended March 31, 2006, 2005, and 2004, respectively. This is an increase of $1.0 million for the three month period ended March 31, 2006 compared to March 31, 2005, and an increase of $0.1 million for the three month period ended March 31, 2005 compared to March 31, 2004. The increase in interest income is primarily due to higher average cash balance during the three month period ended March 31, 2006 as a result of raising $64.8 million in the Series C redeemable convertible preferred stock financing in June and September 2005, as well as $49.8 million of net proceeds from the completion of our initial public offering in December 2005. Additionally, interest rates earned on our cash balances were higher during the first quarter of 2006 compared to the first quarter of 2005.

Liquidity and Capital Resources

Since inception, our operations have been financed through the private placement of equity securities and our initial public offering. Through March 31, 2006, we have received net proceeds of approximately $139.8 million from the sale of shares of our preferred and common stock as follows:

- from August 2003 to January 2004, we issued and sold a total of 2,300,000 shares of Series A preferred stock for aggregate net proceeds of $2.3 million;
- from April 2004 to June 2004, we issued and sold 23,000,000 shares of Series B preferred stock for aggregate net proceeds of $22.9 million;
- in June 2005, we issued and sold a total of 40,741,048 shares of Series C preferred stock for aggregate net proceeds of $54.8 million;
- in September 2005, the Series C warrant was exercised and we issued 7,407,407 shares of Series C preferred stock for aggregate net proceeds of $10.0 million; and

- in December 2005, we issued and sold 5,000,000 shares of our common stock for aggregate net proceeds of $49.8 million in our initial public offering. In conjunction with our initial public offering, all of our outstanding shares of preferred stock were converted into 12,241,382 shares of common stock.

As of March 31, 2006, we had $83.1 million in cash and cash equivalents and $10.5 million in short-term investments. We have invested a substantial portion of our available cash funds in commercial paper and money market funds placed with reputable financial institutions for which credit loss is not anticipated. We have established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

For the three month period ended March 31, 2006, net cash used in operating activities was $10.3 million, compared to $4.5 million for the three month period ended March 31, 2005. The increase in net cash used in operating activities was due primarily to an increase in our net loss as a result of increased expenses related to the clinical development of SILENOR™ and nalmefene, and increased salaries and overhead of company personnel. We cannot be certain if, when or to what extent we will receive cash inflows from the commercialization of our product candidates. We expect our development expenses to be substantial and to increase over the next few years as we continue the advancement of our product development programs.

As a specialty pharmaceutical company focused on acquiring and developing proprietary pharmaceutical product candidates, we have entered into several license agreements to acquire the rights to develop and commercialize three product candidates. Pursuant to these agreements, we obtained exclusive licenses to the patent rights and know-how for certain indications and have the right to enter into sublicense agreements. We generally are required to make upfront payments as well as additional payments upon the achievement of specific development and regulatory approval milestones. We are also obligated to pay royalties under the agreements until the later of the expiration of the applicable patent or the applicable last date of market exclusivity following the first commercial sale.

The following table describes our commitments to settle contractual obligations in cash as of March 31, 2006:

	Payments Due by Period				
	Remainder of 2006	2007 through 2008	2009 through 2010	After 2010	Total
			(in thousands)		
Operating lease obligations	$ 99	$ 24	$ —	$ —	$ 123
Payments under license agreements	961	1,230	1,230	7,290	10,711
Total	$ 1,060	$ 1,254	$ 1,230	$ 7,290	$ 10,834

In addition, under our license agreements we are obligated to make additional milestone payments of up to $11.4 million upon the occurrence of certain product-development events as well as revenue-based royalty payments. License payments are subject to increase based on the timing of various milestones and the extent to which the licensed technologies are pursued for other indications. These milestone payments and royalty payments under our license agreements are not included in the table above because we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur.

We also enter into agreements with third parties to manufacture our product candidates, conduct our clinical trials, and perform data collection and analysis. Our payment obligations under these agreements depend upon the progress of our development programs. Therefore, we are unable to estimate with certainty the future costs we will incur under these agreements.

We do not have any off balance sheet arrangements.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include but are not limited to the following:

- the progress of our clinical trials;

- our ability to establish and maintain strategic collaborations, including licensing and other arrangements that we have or may establish, including milestone payments to ProCom One, BioTie Therapies and/or Synchroneuron;
- the costs involved in enforcing or defending patent claims or other intellectual property rights;
- the costs and timing of regulatory approvals;
- the costs of establishing manufacturing, sales or distribution capabilities;
- the success of the commercialization of our products; and
- the extent to which we acquire or invest in other products, technologies and businesses.

We believe that our existing cash and investments will be sufficient to meet our projected operating requirements through at least the next twelve months.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources generated from the proceeds of offerings of our equity securities. In addition, we may finance future cash needs through the sale of other equity securities, strategic collaboration agreements and debt financing. However, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements. In addition, we cannot be sure that our existing cash and investment resources will be adequate, or that additional financing will be available when needed, or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our development programs, relinquish some or even all rights to product candidates at an earlier stage of development, or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial rations that may restrict our ability to operate our business.

Caution on Forward-Looking Statements

Any statements in this report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as “believe,” “may,” “could,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “seek,” “plan,” “expect,” “should” or “would.” Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the potential for SILENOR™ to receive regulatory approval for one or more indications on a timely basis or at all; the results of pending clinical trials for SILENOR™ or our other product candidates; unexpected adverse side effects or inadequate therapeutic efficacy of SILENOR™ or our other products that could delay or prevent regulatory approval or commercialization, or that could result in recalls or product liability claims; other difficulties or delays in development, testing, manufacturing and marketing of and obtaining regulatory approval for SILENOR™ or our other product candidates; the scope and validity of patent protection for SILENOR™ and our other product candidates; the market potential for insomnia and other target markets, and our ability to compete; the potential to attract a strategic collaborator and terms of any related transaction; our ability to raise sufficient capital and other risks detailed in this report under Part II – Item 1A – Risk Factors below.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our cash and cash equivalents and investments as of March 31, 2006 consisted primarily of money market funds, commercial paper and U.S. government agency notes. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment will probably decline. To minimize this risk, we intend to continue to maintain our portfolio of cash equivalents and short-term investments in a variety of securities including commercial paper, money market funds and government and non-government debt securities, all with various maturities. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

Not applicable.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Our Annual Report on Form 10-K for the year ended December 31, 2005 includes a detailed discussion of our risk factors under the heading "Part I, Item 1A—Risk Factors." Set forth below are certain changes from the risk factors previously disclosed in our Annual Report on Form 10-K . You should carefully consider the risk factors discussed in our Annual Report on Form 10-K as well as the other information in this report, before deciding whether to invest in shares of our common stock. The occurrence of any of the risks discussed in the Annual Report on Form 10-K or this report could harm our business, financial condition, results of operations or growth prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

Our near-term success is dependent on the success of our lead product candidate, SILENOR ™ (doxepin hydrochloride), and we cannot be certain that it will receive regulatory approval or be successfully commercialized.

We have received the results of our initial Phase III clinical trial for SILENOR ™ and currently have three additional Phase III clinical trials underway to evaluate SILENOR™ for the treatment of insomnia. The completion of at least two well controlled clinical trials

is required before we are able to submit our new drug application, or NDA, to the Food and Drug Administration, or FDA. Like many companies, we also plan to submit the results of additional trials for the purpose of supporting the claims we plan to request in our label for SILENOR ™ . If our Phase III clinical trial program fails to demonstrate that SILENOR ™ is safe and effective, it will not receive regulatory approval. Even if clinical trials are completed as planned, their results may not support our assumptions or our intended product claims. We are seeking a strategic collaborator for SILENOR ™ . We may not be successful in our efforts to consummate a strategic collaboration. If a collaboration agreement becomes effective prior to the filing of the NDA, actions on the part of the collaborator could delay our NDA filing. Even if SILENOR ™ receives FDA approval, it may never be successfully commercialized. In addition, we may have inadequate financial or other resources to pursue this product candidate through the clinical trial process or through commercialization.

We do not have patent protection for SILENOR ™ in any jurisdiction outside the United States, which may limit our ability to commercialize SILENOR ™ . Furthermore, the patent protection in the United States for SILENOR ™ for the treatment of insomnia is limited to lower dosages ranging from a lower limit of 0.5 mg to various upper limits up to 20 mg of its active ingredient, doxepin. Doxepin is prescribed at dosages ranging from 75 mg to 300 mg daily for the treatment of depression and anxiety and is available in generic form in strengths as low as 10 mg in capsule form as well as a concentrated liquid form dispensed by a marked dropper and calibrated for 5 mg. As a result, we may face competition from the off-label use of these other dosage forms of generic doxepin. Off-label use occurs when a drug that is approved by the FDA for one indication is prescribed by physicians for a different, unapproved indication. If we are unable to obtain regulatory approval for, or are unable to successfully commercialize, SILENOR ™ , we may be unable to generate revenue, we may be unable to become profitable, and we may be unable to continue our operations.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of March 31, 2006, we had 29 full-time employees. We will need to continue to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue our development activities and commercialize our product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- manage our clinical trials effectively, including our Phase III clinical trials for SILENOR ™ and our Phase II/ III clinical trials for nalmefene, which are being conducted at numerous clinical trial sites;
- manage our internal development efforts effectively while carrying out our contractual obligations to collaborators and other third parties;
- continue to improve our operational, financial and management controls, reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California area. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. In particular, if we lose any members of our senior management team, we may not be able to find suitable replacements, and our business may be harmed as a result.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the product acquisition, development, regulatory and commercialization expertise of our senior management. If we lose one or more of the members of our senior management team or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel.

In addition, we have scientific and clinical advisors who assist us in formulating our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

Risks Related to Our Finances and Capital Requirements

We will require substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our development programs or commercialization efforts.

We are a development-stage company with no revenues, and our operations to date have generated substantial and increasing needs for cash. We expect our negative cash flows from operations to continue until we obtain regulatory approval for SILENOR ™ and are able to commercialize the product candidate ourselves or establish a collaboration with a pharmaceutical company to broaden the potential reach of sales and marketing efforts for SILENOR ™ . The development and approval of SILENOR ™ and our other product candidates and the acquisition and development of additional products or product candidates by us, as well as the development of our sales and marketing organizations, will require a commitment of substantial funds. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the rate of progress and cost of our clinical trials and other development activities;
- the scope, prioritization and number of clinical development programs we pursue;
- the costs and timing of regulatory approval;
- the costs of establishing or contracting for sales and marketing capabilities;
- the extent to which we acquire or in-license new products, technologies or businesses;
- the effect of competing technological and market developments; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We believe, based on our current operating plan, that our cash, cash equivalents and marketable securities as of March 31, 2006 will be sufficient to fund our operations for at least the next twelve months. We intend to seek additional funding through strategic alliances and may seek additional funding through public or private sales of our equity securities. In addition, we may obtain equipment leases and may pursue opportunities to obtain debt financing in the future. There can be no assurance, however, that additional equity or debt financing will be available on reasonable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our planned development, commercialization or expansion activities.

We have never generated revenues or been profitable, and we may not be able to generate revenues sufficient to achieve profitability.

We are a development-stage company and have not generated any revenues or been profitable since inception, and it is possible that we will not achieve profitability. We incurred net losses of approximately $13.5 million for the three month period ended March 31, 2006, $38.5 million for the year ended December 31, 2005 and $13.6 million for the year ended December 31, 2004. We expect to continue to incur significant operating and capital expenditures. As a result, we will need to generate significant revenues to achieve and maintain profitability. We cannot assure you that we will achieve significant revenues, if any, or that we will ever achieve profitability. Even if we do achieve profitability, we cannot assure you that we will be able to sustain or increase profitability on a quarterly or annual basis in the future. If revenues grow more slowly than we anticipate or if operating expenses exceed our expectations or cannot be adjusted accordingly, our business, results of operations and financial condition will be materially and adversely affected.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including:

- our addition or termination of development programs or funding support;
- variations in the level of expenses related to our existing three product candidates or future development programs;
- our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- any intellectual property infringement lawsuit in which we may become involved; and
- regulatory developments affecting our product candidates or those of our competitors.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Risks Relating to Intellectual Property

A recent reexamination at the U.S. Patent and Trademark Office has resulted in the narrowing of certain claims and the cancellation of other claims for one of our patents covering SILENOR ™ . In addition, we have initiated a reissue of that patent covering SILENOR™ which may result in the U.S. Patent and Trademark Office further narrowing certain claims and could result in the cancellation or rejection of certain or all of the claims of the patent.

Due to some recently identified prior art, we initiated a reexamination of one of the patents we have licensed covering SILENOR ™ , specifically U.S. Patent No. 5,502,047, *"Treatment For Insomnia,"* which claims the treatment of chronic insomnia using doxepin in a daily dosage of 0.5 mg to 20 mg and expires in March 2013. The reexamination proceedings have terminated and the U.S. Patent and Trademark Office has now issued a reexamination certificate narrowing certain claims, so that the broadest dosage ranges claimed by us are 0.5 mg to 20 mg for otherwise healthy patients, 0.5 mg to 20 mg for patients with insomnia resulting from depression, and 0.5 mg to 4 mg for all other chronic insomnia patients. We have also requested reissue of this same patent to add intermediate dosage ranges below 10 mg and to consider some additional prior art that is relevant primarily to claims for treating insomnia in depressed patients. During reissue, the U.S. Patent and Trademark Office could require narrowing or cancellation of certain claims or could reject all of the claims of this patent. Although we believe that our licensed patents will restrict the ability of competitors to market doxepin with identical drug labeling, we cannot be certain of the outcome of the U.S. Patent and Trademark Office's pending reissue.

Risks Relating to Securities Markets and Investment in Our Stock

There may not be a viable public market for our common stock, and market volatility may affect our stock price and the value of your investment.

Our common stock had not been publicly traded prior to our initial public offering, which was completed in December 2005, and an active trading market may not develop or be sustained. We have never declared or paid any cash dividends on our capital stock, and we currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our common stock for the foreseeable future. Therefore, investors will have to rely on appreciation in our stock price and a liquid trading market in order to achieve a gain on their investment. The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. For example, since our initial public offering through May 2, 2006, the trading prices for our common stock ranged from a high of $21.24 to a low of $9.69.

The market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

- changes in the regulatory status of SILENOR ™ or our other product candidates, including results of our clinical trials;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- events affecting our three existing in-license agreements and any future collaborations, commercial agreements and grants;
- variations in our quarterly operating results;
- changes in securities analysts' estimates of our financial performance;
- regulatory developments in the United States and foreign countries;
- fluctuations in stock market prices and trading volumes of similar companies;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- additions or departures of key personnel; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

The realization of any of the risks described in these "Risk Factors" could have a dramatic and material adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could hurt our business, operating results and financial condition.

If our executive officers, directors and largest stockholders choose to act together, they may be able to control our operations and act in a manner that advances their best interests and not necessarily those of other stockholders.

As of March 31, 2006, our executive officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 69.2% of our common stock. As a result, these stockholders, acting together, would be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

From January 1, 2006 to March 31, 2006 we had no unregistered sales of equity securities.

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-128871) that was declared effective by the Securities and Exchange Commission on December 14, 2005. On December 20, 2005, 5,000,000 shares of common stock were sold on our behalf at an initial public offering price of $11.00 per share, for an aggregate offering price of $55.0 million, managed by Morgan Stanley & Co. Incorporated, J.P. Morgan Securities Inc., Piper Jaffray & Co. and Thomas Weisel Partners LLC.

We paid to the underwriters underwriting discounts and commissions totaling approximately $3.9 million in connection with the offering. In addition, we incurred additional expenses of approximately $1.3 million in connection with

the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total expenses of approximately $5.2 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately $49.8 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of March 31, 2006, we had invested the $49.8 million in net proceeds from the offering in money market funds. Through March 31, 2006, we have not used the net proceeds from the offering. We intend to use the proceeds to fund clinical trials for our three development programs, for marketing, general and administrative expenses and for other research and development expenses.

Item 3. Defaults Upon Senior Securities

Not applicable.

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

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant
3.2(1)	Amended and Restated Bylaws of the Registrant
4.1(2)	Form of the Registrant's Common Stock Certificate
4.2(3)	Amended and Restated Investor Rights Agreement dated June 2, 2005
10.24†	Manufacturing Services Agreement between the Registrant and Patheon Pharmaceuticals Inc. dated February 1, 2006
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14 and Rule 15d-14 of the Securities Exchange Act, as amended
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14 and Rule 15d-14 of the Securities Exchange Act, as amended
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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† Confidential treatment has been requested for portions of this exhibit. These portions have been omitted and submitted separately to the Securities and Exchange Commission.

# Indicates management contract or compensatory plan.

(1) Filed with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 on November 30, 2005.

(2) Filed with Amendment No. 4 to the Registrant's Registration Statement on Form S-1 on December 13, 2005.

(3) Filed with the Registrant's Registration Statement on Form S-1 on October 7, 2005.

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Somaxon Pharmaceuticals, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

Dated: May 11, 2006

/s/ Meg M. McGilley
Meg M. McGilley
Vice President and Chief Financial Officer
(Duly Authorized Officer and
Principal Financial Officer)

Exhibit 10.24

EXECUTION DRAFT FEBRUARY 1, 2006

Manufacturing Services Agreement

Between

Patheon Pharmaceuticals Inc.

and

Somaxon Pharmaceuticals, Inc.

February 1, 2006

CERTAIN MATERIAL (INDICATED BY AN ASTERISK) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

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MANUFACTURING SERVICES AGREEMENT

THIS MANUFACTURING SERVICES AGREEMENT (the " Agreement ") made as of the 1st day of February 2006.

B E T W E E N:

PATHEON PHARMACEUTICALS INC. ,
a corporation existing under the laws of Delaware,

(hereinafter referred to as " **Patheon** "),

- and -

SOMAXON PHARMACEUTICALS, INC. ,
a corporation existing under the laws of Delaware,

(hereinafter referred to as the " **Client** ").

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1.
INTERPRETATION

1.1 Definitions . The following terms shall, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of such terms shall have corresponding meanings:

" **Act** " means the *Federal Food, Drug, and Cosmetic Act* , together with any regulation promulgated thereunder, including without limitation cGMPs, in each case as amended from time to time;

" **Active Materials** " means the materials listed on Schedule E hereto;

" **Active Materials Reimbursement Value** " means the value attributable to the Active Materials for certain purposes of this Agreement, as set forth in Schedule E hereto;

" **ANDA** " shall have the meaning ascribed thereto in Section 7.8(d);

“ **Adverse Experience** ” shall mean any side effect, injury, toxicity, sensitivity reaction, unexpected incidence, untoward medical occurrence or other adverse event or experience associated with the use of the Products, including, but not limited to, a “serious adverse event” within the meaning of 21 C.F.R. § 314.80(a), as amended from time to time;

“ **Affiliate** ” means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement;

(d) For the purposes of this definition, “control” means the ownership of shares carrying at least a majority of the votes in respect of the election of the directors of a corporation;

“ **Agreement** ” shall have the meaning ascribed thereto in the preamble;

“ **Applicable Laws** ” means all Laws to the extent applicable to the subject matter of, or the performance by the parties of their respective obligations under, this Agreement, including, but not limited to, (i) with respect to Patheon, the Act and any other Laws of all jurisdictions where the Products are manufactured, and (ii) with respect to Client, the Laws of all jurisdictions where the Products are manufactured, distributed and marketed;

“ **Annual Report”** means the annual report as described in 21 CFR, Section 314.81(b)(2);

“ **Annual Product Review Report** ” means the annual product review report as described in 21 CFR, Section 211.180(e);

“ **Authority** ” means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal, including, but not limited to, the FDA;

“ **Broader Intellectual Property Rights** ” shall have the meaning ascribed thereto in Section 13.1(c);

“ **Business Day** ” means a day other than a Saturday, Sunday or a day that is a statutory holiday in the State of Ohio or State of California;

“ **cGMPs** ” means current good manufacturing practices as described in Parts 210 and 211 of Title 21 of the United States’ Code of Federal Regulations, together with the latest FDA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time, including, but not limited to, the FDA’s Guidance for Industry, Manufacturing, Processing or Holding Active Pharmaceutical Ingredients **;**

“ **CMC** ” shall have the meaning ascribed thereto in Section 7.8(d);

“ **Certificate of Analysis** ” means (a) the certificate of analysis confirming the identity, strength, quality and purity of each batch of finished Product to which it pertains;

“ **Client** ” shall have the meaning ascribed thereto in the preamble;

“ **Commencement Date** ” means the first day upon which the Manufacturing Services shall commence;

“ **Components** ” means, collectively, all packaging components, raw materials and ingredients (including labels, product inserts and other labeling for the Products), required to be used in order to produce the Products in accordance with the Specifications, including the Active Materials;

“ **Confidential Information** ” shall have the meaning ascribed thereto in Section 11.1;

“ **Deficiency Notice** ” shall have the meaning ascribed thereto in Section 6.1(a);

“ **Disclosing Party** ” shall have the meaning ascribed thereto in Section 11.1;

“ **FCA** ” means free carrier, as that term is defined in INCOTERMS 2000 published by the International Chamber of Commerce;

“ **FDA** ” means the United States government agency known as the United States Food and Drug Administration, and any successor thereto;

“ **Firm Orders** ” has the meaning specified in Section 5.1(b);

“ **Force Majeure Event** ” shall have the meaning ascribed thereto in Section 13.8;

“ **Indemnitor** ” shall have the meaning ascribed thereto in Section 10.5(a);

“ **Indemnitee** ” shall have the meaning ascribed thereto in Section 10.5(a);

“ **Initial Term** ” shall have the meaning ascribed thereto in Section 8.1;

“ **Intellectual Property** ” includes, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, Inventions, copyright and industrial designs;

“ **Invention** ” means information relating to any invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

“ **Inventory** ” means all inventories of Components and work-in-process produced or held by Patheon or its Affiliates in connection with the manufacture of the Products, including, but not limited to, the Active Materials;

“ **Late Shipment** ” shall have the meaning ascribed thereto in Section 6.1(d);

“ **Laws** ” means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority, including, but not limited to, the Act and cGMPs;

“ **Manufacturing Services** ” means the manufacturing, quality control, quality assurance and stability testing, packaging and related activities of Patheon, as contemplated in this Agreement, required to produce Products from Active Materials and Components;

“ **Manufacturing Site** ” means the facility owned and operated by Patheon that is located at 2110 East Galbraith Road, Cincinnati, Ohio, USA 45237;

“ **Minimum Run Quantity** ” means the minimum number of batches, bottles or blisters of a Product to be produced during the same cycle of manufacturing as set forth in Schedule C hereto;

“ **NDA** ” shall have the meaning ascribed thereto in Section 7.8(d);

“ **Patheon** ” shall have the meaning ascribed thereto in the preamble;

“ **Patheon Manufacturing Responsibilities** ” means Patheon’s responsibilities and obligations with respect to the provision of Manufacturing Services as set forth in Section 2.2;

“ **Process Specifications** ” means clauses (a), (b), (c) and (d) of the definition of Specifications;

“ **Products** ” means the products listed on Schedule A hereto;

“ **Product Claims** ” shall have the meaning ascribed thereto in Section 10.2;

“ **Product Quality Complaint** ” is defined as any complaint that questions the purity, identity, potency or quality of the Product, its packaging, or labeling, or any complaint that concerns any incident that causes the Product or its labeling to be mistaken for, or applied to, another article or any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed Product, or any failure of one or more distributed batches of the Product to meet the Specifications therefor.

“ **Quality Agreement** ” means the agreement entered into between the parties hereto setting out the quality assurance standards to be applicable to the Manufacturing Services provided by Patheon, attached hereto as Schedule H;

“ **Recall** ” shall have the meaning ascribed thereto in Section 6.2(a);

“ **Receiving Party** ” shall have the meaning ascribed thereto in Section 11.1;

“ **Short Shipment** ” shall have the meaning ascribed thereto in Section 6.1(d);

“ **Specifications** ” means the file, for each Product, which is approved by the Client in accordance with the procedures listed in Schedule B hereto and which contains documents relating to such Product, including, without limitation:

(a) specifications for Active Materials and Components;

(b) manufacturing specifications, directions and processes;

(c) storage requirements;

(d) all environmental, health and safety information relating to the Product including material safety data sheets;

(e) the finished Product specifications, packaging specifications and shipping requirements for each Product, including, but not limited to, any requirements set forth in the applicable regulatory filings made with the FDA or other Authority (e.g., the NDA and/or ANDA) and provided by Client to Patheon;

all as updated, amended and revised from time to time by the Client in accordance with the terms of this Agreement;

" **Technical Dispute** " has the meaning specified in Section 12.2;

" **Territory** " shall mean (i) [***] and (ii) any additional country(ies) and/or commonwealths, territories and possessions which the Client may later designate in its sole discretion in an addendum to this Agreement; provided that the Client shall bear all incremental costs, including, but not limited to labeling costs, associated with the manufacture of the Product for such additional country(ies) and/or commonwealths, territories and possessions in amounts to be agreed by the parties;

" **Third Party Rights** " means the Intellectual Property of any third party;

" **Year** " means a calendar year, except that the first "Year" of this Agreement shall be deemed to be the period from the Commencement Date up to and including December 31, 2007 **;**

1.2 Currency. Unless otherwise indicated, all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.

1.3 Sections and Headings.

The division of this Agreement into Articles, Sections, subsections and Schedules and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section or Schedule refers to the specified Section or Schedule to this Agreement. In this Agreement, the terms " **this Agreement** ", " **hereof** ", " **herein** ", " **hereunder** " and similar expressions refer to this Agreement and not to any particular part, Section, Schedule or the provision hereof.

1.4 Singular Terms.

Except as otherwise expressly provided herein or unless the context otherwise requires, all references to the singular shall include the plural and vice versa.

1.5 Schedules.

The following Schedules are attached to, incorporated in and form part of this Agreement:

Schedule A - Products
Schedule B - Procedure for Shipment & Acceptance of Product Specifications

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Schedule C	-	Minimum Run Quantity, Annual Volume & Fees
Schedule D	-	Stability Testing
Schedule E	-	Active Materials & Active Materials Reimbursement Value
Schedule F	-	Batch Numbering & Expiration Dates
Schedule G	-	Technical Dispute Resolution
Schedule H	-	Quality Agreement
Schedule I	-	Product Bill of Materials

ARTICLE 2.
PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

During the term of this Agreement, Patheon shall manufacture and supply, in accordance with the provisions of this Agreement, all quantities of the Products ordered by the Client consistent with Article 5, and shall provide such Manufacturing Services for the Territory for the fees specified in Schedules C and D. The Client shall purchase at least (i) [***]% of its requirement of Products of between [***] tablets per Year; and (ii) [***]% of its requirement of Products of greater than [***] tablets per Year for sale in the Territory from Patheon pursuant to the terms of this Agreement; provided, however, that such purchase requirements shall be prorated for the first Year to the extent the first Year is less than a complete calendar year. In providing the Manufacturing Services, the Client and Patheon agree that:

(a) Conversion of Active Materials and Components . Patheon shall convert Active Materials and Components into Products.

(b) Quality Control and Quality Assurance . Patheon shall perform the quality control and quality assurance testing specified in the Quality Agreement. Each time Patheon ships Products to the Client, it shall provide the Client with a Certificate of Analysis that sets out the test results for each batch of Products, and that certifies that such batch has been evaluated by Patheon's Quality Control/Quality Assurance department and that the Products comply with the Specifications.

(c) Components . Patheon shall purchase and test all Components (with the exception of those that are supplied by the Client) at Patheon's expense and as specified by the Specifications.

(d) Active Materials . [***] shall purchase the Active Materials in sufficient quantities and at such times as may be necessary to provide the Manufacturing Services by Patheon hereunder. [***] shall bear the risk of loss of the Active Materials while in transit from the supplier and thereafter until incorporated into Products and deemed shipped to the Client

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under Section 5.4. Patheon shall test the Active Materials at [***] expense and as specified by the Specifications.

(e) Stability Testing . Patheon shall conduct stability testing on the Products in accordance with the protocols set out in the Specifications for the separate fees specified in Schedule D. Patheon shall not make any changes to these testing protocols without prior written approval from the Client. In the event that any batch of Products fails stability testing, (i) Patheon shall investigate and confirm that all analytical methods have been properly applied and, if applicable, corrected, and (ii) Patheon and the Client shall jointly determine the proceedings and methods to be undertaken to investigate the causes of such failure, including which party shall bear the cost of such investigation, provided that, subject to Section 10.2, Patheon shall be liable for such costs if the failure is attributable to Patheon's failure to provide the Manufacturing Services in accordance with the Specifications or cGMPs. Patheon will provide any and all data and results relating to the stability testing upon request by the Client.

(f) Packaging . Patheon shall package the Products with labels, product inserts and other packaging as set out in the Specifications. The Client shall be responsible for the cost of artwork development. In addition, Patheon shall make arrangements for and implement the imprinting of batch numbers and expiration dates for each Product shipped. Such batch numbers and expiration dates shall be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. The system used by Patheon for batch numbering and expiration dates is detailed in Schedule F hereto. The Client may, in its sole discretion, make changes to labels, product inserts and other packaging for the Products, which changes shall be submitted by the Client to all applicable Agencies and other third parties responsible for the approval of the Products. The Client shall be responsible for the cost of labeling obsolescence when changes occur. Patheon's name shall not appear on the label or anywhere else on the Products unless: (i) required by any Laws; or (ii) Patheon and the Client expressly consent to such use of Patheon's name in writing.

(g) Storage . Until finished Products are shipped, Patheon shall store all such Products identifiably distinct from any other raw material and finished or filled product stocks and shall comply with all storage requirements set forth in the Specifications and all Applicable Laws, including, but not limited to, cGMPs. Patheon shall assume responsibility for any loss or damage to such finished Product while stored by Patheon.

(h) Facility . Patheon will manufacture, test, perform quality control and package the Product at the Manufacturing Site. Patheon shall not manufacture, test, perform quality control or package any Product in any other facility without first obtaining the Client's prior written consent.

(i) Product Rejection for Process Failure . The parties acknowledge that at the time of execution of this Agreement the Product is in development. Prior to packaging any bulk

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finished Product, Patheon shall test each batch of bulk finished Product for compliance with the finished Product Specifications (excluding packaging-related specifications). In the event any nonconforming Product is observed in connection with such testing procedures, Patheon shall promptly suspend the packaging of the applicable batch, notify Client in writing, and consult with Client with respect to available alternatives.

If Patheon manufactures Products in accordance with the Process Specifications and a batch or portion of a batch does not meet a finished Product Specification, [***] shall [***] for its [***], any [***], and any [***].

2.2 Standard of Performance.

Patheon shall provide the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws.

ARTICLE 3.
CLIENT'S OBLIGATIONS

3.1 Payment.

Pursuant to the terms of this Agreement, the Client shall pay Patheon for the provision of the Manufacturing Services according to the fees specified in Schedules C and D hereto (such fees being subject to adjustment in accordance with the terms hereof).

ARTICLE 4.
CONVERSION FEES AND COMPONENT COSTS

4.1 [***] Pricing.

The fees for the Manufacturing Services (including Component costs) for the [***] are listed in Schedules C and D and the fees for the Manufacturing Services ([***]) are intended by the parties to be [***] for the [***] of this Agreement, subject to the adjustments set forth in Section 4.3.

4.2 Price Adjustments — Subsequent Years' Pricing.

The fees for the Manufacturing Services provided pursuant to the terms of this Agreement for any Year beginning after the [***] Year under this Agreement shall be determined in accordance with the following:

(a) Manufacturing and Component Costs . At the [***] and [***] of this Agreement, Patheon shall be entitled to request an adjustment to the fees (i) for Manufacturing Services in respect of the Products to reflect inflation, which adjustment shall not exceed [***],

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unless the parties otherwise agree in writing; and (ii) for Component costs to [***] any increase or decrease in such costs; provided, however, that in the event any proposed increase in the cost of a Component exceeds [***]% of the cost for that Component upon which the most recent fee quote was based, Patheon shall use its commercially reasonable efforts to locate an equivalent alternative lower cost supplier for the applicable Component. Notwithstanding the foregoing, to the extent costs for Components decrease in the [***] or any [***] of this Agreement, Patheon shall pass on to the Client [***] of any decrease in such costs.

(b) Pricing Basis . The Client acknowledges that the fee for Manufacturing Services in respect of a Product in any Year is quoted based upon the Minimum Run Quantity per Product specified in Schedule C and is subject to change if the specified Minimum Run Quantity is revised. For greater certainty, if Patheon and the Client agree that the Minimum Run Quantity in respect of a Product shall be increased or decreased and, as a result of such increase or decrease, Patheon's fees for services relating to such Product decrease or increase on a per unit basis, then if such revised Minimum Run Quantity is not otherwise contemplated in Schedule C, Patheon shall be entitled to a decrease or increase in the fee for Manufacturing Services in respect of such Product by an amount sufficient to pass on to the Client the cost savings or to absorb, but not exceed, such increased costs, as the case may be. When the volume reaches the upper tiers contemplated in Schedule C, the Client will need to select which option Patheon is to follow, i.e. small batch size and two (2) batches per campaign or one (1) large batch per campaign. Batch sizes will not be varied on an order by order basis.

4.3 Mid-Year Pricing

During any Year of this Agreement, Patheon shall be entitled to request an adjustment to the fees for Component costs (i) to pass on the actual amount of any increase or decrease in such costs; and (ii) if at any time market conditions result in Patheon's cost of Components being materially greater than normal forecasted increases, then Patheon shall be entitled to request an adjustment to the fee for Manufacturing Services in respect of any affected Product to compensate it for such increased Component costs; provided, however, that in the event any proposed increase in the cost of a Component exceeds [***]% of the cost for that Component upon which the most recent fee quote was based, Patheon shall use its commercially reasonable efforts to locate an equivalent alternative lower cost supplier for the applicable Component. For the purposes of this Section 4.3, changes materially greater than normal forecasted increases shall be considered to have occurred if: (i) the cost of a Component increases by [***]% of the cost for that Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases by [***]% of the total Component costs for such Product upon which the most recent fee quote was based. To the extent that Component costs have been previously adjusted pursuant to clause (a) of Section 4.2 or this Section 4.3 to reflect an increase in the cost of one or more Components, the adjustments provided for in (i) and (ii) above shall operate based on the costs

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attributed to such Component (or Components) at the time the last of such adjustments were made.

4.4 Fee Adjustment Procedure

In connection with all fee adjustment requests pursuant to this Article 4, Patheon shall deliver to the Client by not later than November 1st of each Year a revised Schedule C in draft form and such budgetary pricing information or other documentation (including the [***] in the case of any adjustment request pertaining to fees for Manufacturing Services and, the adjusted Component costs) reasonably sufficient to demonstrate that a fee adjustment is justified. Upon delivery of such a request, each of the Client and Patheon shall forthwith use all reasonable efforts to agree on a revised fee for the Manufacturing Services in respect of each affected Product and Schedule C shall be amended accordingly. Such revised fee shall be effective with respect to any Product delivered after the end of the then current Year.

4.5 Adjustments Due to Technical Changes.

Amendments to the Specifications or the Quality Agreement requested by the Client will only be implemented following a technical and cost review by Patheon and are subject to the Client and Patheon reaching agreement as to revisions, if any, to the fees specified in Schedules C or D necessitated by any such amendment. If the Client accepts a proposed fee change, the proposed change in the Specifications shall be implemented, and the fee change shall become effective only with respect to those orders of Products that are manufactured in accordance with the revised Specifications. In addition, the Client agrees to purchase, at Patheon's cost therefor (including all costs incurred by Patheon in connection with the purchase and handling of such Inventory), all Inventory utilized under the "old" Specifications and purchased or maintained by Patheon in order to fill Firm Orders or in accordance with Section 5.2, to the extent that such Inventory can no longer be utilized under the revised Specifications. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or in accordance with Section 5.2 shall be cancelled where possible, and where such orders are not subject to cancellation without penalty, shall be assigned to and satisfied by the Client.

4.6 Multi-Country Packaging Requirements.

If and when the Client decides that it wishes to have Patheon manufacture the Product for countries in the Territory in addition to [***], then the Client shall inform Patheon of the packaging requirements for each new country and Patheon shall prepare a quotation for consideration by the Client of the additional Component costs, if any, and the change over fees for the Product destined for such new country. The agreed additional packaging requirements and related packaging costs and change over fees shall be set out in a written amendment to this Agreement.

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ARTICLE 5.
ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Rolling Forecasts . Concurrent with the execution of this Agreement, the Client shall provide Patheon with a written non-binding 12 month forecast of the volume of each Product that the Client then anticipates will be required to be produced and delivered to the Client during each month of the 12 month period thereafter. Such forecast will be updated by the Client monthly on or before the 10 th day of the month on a rolling 12 month basis and updated promptly after such time as the Client determines that the volumes contemplated in the most recent of such forecasts has changed by more than [***]%. The most recent 12 month forecast shall supersede all previous forecasts.

(b) Firm Orders . On or before the 20th day of each calendar month, the Client shall issue firm written orders (" **Firm Orders** ") for the Products to be produced and delivered to the Client on a date not less than 90 days from the first day of the calendar month immediately following the date that the Firm Order is submitted. Such Firm Orders submitted to Patheon shall specify the Client's purchase order number, quantities by Product type, monthly delivery schedule and any other elements necessary to ensure the timely production and shipment of the Products. The quantities of Products ordered in such Firm Orders shall be firm and binding on the Client and shall not be subject to reduction by the Client. Firm Orders submitted by the Client pursuant to this Section 5.1 must be accepted by Patheon and shall be automatically firm and binding on Patheon if they are not more than [***]% of the amount most recently forecast for the delivery period specified in the Firm Order. Patheon will use commercially reasonable efforts to manufacture Product in excess of [***]% of the amount most recently forecast for the delivery period specified in the Firm Order. Firm Orders not rejected by Patheon within three Business Days of receipt by Patheon shall be deemed to have been accepted by Patheon.

(c) Three Year Forecast . On or before the 1 st day of November of each Year commencing not later than six months prior to the anticipated Commencement Date (as estimated in the Client's reasonable judgment based on clinical development timelines and regulatory activities), the Client shall provide Patheon with a written non-binding three-year forecast (broken down by quarters for the second and third years of the forecast) of the volume of each Product the Client then anticipates will be required to be produced and delivered to the Client during the three-year period, and updated on or before the 1 st day of May in each Year.

5.2 Reliance by Patheon.

The Client understands and acknowledges that Patheon will rely on the first [***] months contemplated in the most recent forecast provided by the Client pursuant to Section 5.1(a) and the Firm Orders submitted pursuant to Section 5.1(b) in ordering the Components

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required to meet such Firm Orders. In addition, the Client understands that to ensure an orderly supply of such Components, it may be desirable for Patheon to purchase such Components in sufficient volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to by Patheon and the Client. Accordingly, the Client authorizes Patheon to purchase Components in order to satisfy the production requirements for Products for the first [***] months contemplated in the most recent forecast provided by the Client pursuant to Section 5.1(a) and agrees that Patheon may make such other purchases of Components to meet production requirements during such longer periods as may be agreed to in writing from time to time by the Client at the request of Patheon or the Client. The Client shall provide Patheon with its written authorization to order Components in respect of any launch quantities of Product requested by the Client, which upon acceptance by Patheon shall constitute a Firm Order. If Components ordered by Patheon pursuant to Firm Orders or in order to satisfy the production requirements for Products for the first [***] months contemplated in the most recent forecast provided by the Client pursuant to Section 5.1(a) are not included in finished Products purchased by the Client within [***] months after the forecasted month in respect of which such purchases have been made (or such longer period as the parties may agree), then Patheon shall promptly notify Client and the Client shall pay to Patheon [***]; provided, however, that (i) the Client shall have the option but not the obligation to take title to and possession of all or any portion of such Components by written notice to Patheon, in which case Patheon shall cooperate with the Client in the surrender, delivery and transfer of such Components as promptly as is commercially reasonable, with any shipping and related expenses to be borne by the Client, or (ii) in the event such Components are incorporated into Products subsequently purchased by the Client or into third party products manufactured by Patheon and subsequently purchased by a third party, the Client will receive credit for any costs of such Components previously paid to Patheon by the Client. Patheon shall not be obligated to provide information regarding any Component which is subject to confidentiality obligations between Patheon and its supplier.

5.3 Minimum Orders.

The Client may only order Products in multiples of the Minimum Run Quantities set out in Schedule C.

5.4 Shipments.

Shipments of Products shall be made FCA the Manufacturing Site unless otherwise mutually agreed in writing and Patheon shall make every reasonable effort to ship finished goods within [***] months of the start of manufacture of the Products unless otherwise agreed upon in writing by both parties. Failure to ship within [***] months is not a cause for refusal of Product. Notwithstanding the foregoing, if FDA approves the Products for [***] months of shelf life, the Products must carry at least [***] months of shelf life when shipped.

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Risk of loss or of damage to Products shall remain with Patheon until Products are loaded onto the carrier's vehicle by Patheon for shipment at the shipping point at which time risk of loss or damage shall transfer to the Client. Patheon shall, in accordance with the Client's instructions and as agent for the Client, (i) arrange for shipping, including preparing and executing a packing list, so that the Product will be delivered to the delivery address on the delivery date set forth in the applicable Firm Order, with such shipping to be paid by the Client and (ii) at the Client's risk and expense, obtain any export license or other official authorization necessary to export the Products, including all customs formalities. The Client shall arrange for insurance and shall select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Patheon shall notify Client in writing at the time of shipment as to the quantity of Product shipped, the anticipated delivery date and confirmation of the carrier. If any order is delayed and is not likely to be delivered to the carrier on time, Patheon shall immediately notify Client and Client may reasonably direct Patheon to ship such order by expedited means of transportation as designated by Client, at [***] expense. If the delay of any order results in substantial back orders to the Client and Patheon caused the delay, [***] shall pay the reasonable additional cost for the expedited transport. In all cases, Products shall be transported in accordance with the Specifications and Applicable Laws, including, but not limited to, cGMPs.

5.5 Invoices and Payment.

(a) Invoices . Invoices for Products that are shipped to Client shall be sent by fax or email to such fax number or email address as may be provided by the Client in writing from time to time, but not earlier than the date of shipment of the corresponding Products. Patheon shall also submit to the Client, with each shipment of Products, a duplicate copy of the invoice covering such shipment. Patheon shall also provide the Client with an invoice covering any Inventory or Components which are to be purchased by Patheon pursuant to Section 5.2 hereof. Each such invoice shall, to the extent applicable, identify the Client purchase order number, Product numbers, names and quantities, unit price, freight charges and the total amount to be remitted by the Client.

(b) Payment . The Client shall pay undisputed amounts of all invoices within [***] days of the date of postmark or confirmed facsimile or email transmission of the invoice.

(c) Disputed Amounts . In the event that the Client disputes any amounts under any invoice for Products, such dispute shall be resolved in accordance with Section 6.1 (with respect to non-conformance of Products) or otherwise under Article 12. Pending resolution of such dispute, the Client shall be obligated to pay any amounts under such invoice that are not in dispute. Upon resolution of any such dispute in favor of Patheon, the Client shall pay all remaining amounts owing under such invoice within the later of (i) [***] Business days after such resolution or (ii) [***] days after the date of such invoice.

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ARTICLE 6.
PRODUCT CLAIMS; RECALLS; ADVERSE EVENTS

6.1 Product Claims.

(a) Product Claims . The Client has the right to reject and return, at the expense of Patheon, all or any portion of any shipment of Products that deviates from the Specifications or cGMPs, without invalidating any remainder of such shipment. The Client or its designated agent shall inspect the Products manufactured by Patheon upon receipt of such Products and related Certificate(s) of Analysis and shall give Patheon written notice (a " **Deficiency Notice** ") of all claims for Products that deviate from the Specifications or cGMPs within 30 days after the Client's receipt of such Products and related Certificate(s) of Analysis (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within 30 days after discovery thereof by the Client, but in no event after the expiration date of the Product). Should the Client fail to provide Patheon with the Deficiency Notice within the applicable 30-day period, then the delivery shall be deemed to have been accepted by the Client on the 30 th day after delivery or discovery, as applicable. Except as set out in Section 6.2, Patheon shall have no liability for any deviations for which Client has failed to provide notice within the applicable 30-day period.

(b) Determination of Deficiency . Upon receipt of a Deficiency Notice, Patheon shall have 10 days to advise the Client by notice in writing that it disagrees with the contents of such Deficiency Notice. If the Client and Patheon fail to agree within 10 days after Patheon's notice to the Client as to whether any Products identified in the Deficiency Notice deviate from the Specifications or cGMPs, then the parties shall mutually select an independent laboratory within five days from the parties' failure to agree, which independent laboratory shall evaluate if the Products deviate from the Specifications or cGMPs. The parties shall cause the independent laboratory to conduct its evaluation as promptly as practicable, and in any event within 30 days from the date of selection of the laboratory. Such evaluation shall be binding on the parties, and if such evaluation certifies that any Products deviate from the Specifications or cGMPs, the Client may reject those Products in the manner contemplated in this Section 6.1. If such evaluation does not so certify in respect of any such Products, then the Client shall be deemed to have accepted delivery of such Products on the date the evaluation is delivered by the independent laboratory to the parties. The expenses of such testing shall be borne by Patheon if the non-conformity with the Specifications or cGMPs is confirmed by the independent laboratory, and otherwise by the Client.

(c) Patheon Responsibility . In the event the Client rejects Products in accordance with this Section 6.1 and the deviation is determined to arise from Patheon's failure to provide the Manufacturing Services in accordance with the Specifications or cGMPs, Patheon will, at the Client's election, either: (i) credit the Client's account for Patheon's invoice price to

the Client for such defective Products or (ii) use its commercially reasonable efforts to replace such Products with conforming Products within [***] days' of the Client's rejection of the non-conforming Products; provided, however, that Patheon shall [***]. If the Client shall have previously paid for such defective Products, Patheon shall, at the Client's election, either: (i) refund the invoice price for such defective Products within [***] days' of the Client's rejection of the non-conforming Products; (ii) offset such amount against other amounts due to Patheon hereunder; or (iii) use its commercially reasonable efforts to replace such Products with conforming Products within [***] days' of the Client's rejection of the non-conforming Products without the Client being liable for payment therefor under Section 3.1. In connection with the production of any replacement Products under this Section 6.1(c), Patheon's cost for the procurement of any additional [***] required for the manufacture of such replacement Products shall be limited to the [***]. Nothing in this Section 6.1 shall be construed to limit the rights and remedies available to the Client at law or in equity.

(d) Shortages . Claims for shortages in the amount of Products shipped by Patheon shall be dealt with as may reasonably be agreed to by the parties. If a shipment of Products, however, contains less than [***] % of the minimum yield performance (as defined in the final Specifications and mutually agreed to by the parties) of the quantity specified in the corresponding Firm Order (the "Shortage Amount"), the Client shall notify Patheon promptly upon such discovery and, in any event, not later than 10 days after receipt of the shipment. Upon receipt of Client's written request, Patheon shall use commercially reasonable efforts, subject to the availability of Active Materials and Components, to manufacture and ship the Shortage Amount within [***] days provided, however, that Patheon shall [***]. In the event that the Shortage Amount is less than a validated batch size as set forth in Schedule C, then Patheon shall manufacture the next highest validated batch size of the Product ("Shortage Batch") and package the Shortage Batch, including the Shortage Amount, in accord with the Client's written instructions. Nothing in this Section 6.1 shall be construed to limit the rights and remedies available to the Client at law or in equity.

6.2 Product Recalls and Returns.

(a) Records and Notice . Patheon and the Client shall each maintain such records as may be necessary to permit a Recall of any Products delivered to the Client or customers of the Client. Each party shall promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Products and/or which might result in the Recall or seizure of the Products. Upon receiving any such notice or upon any such discovery, each party shall cease and desist from further shipments of such Products in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, shall be made and implemented by the Client. " **Recall** " shall mean any action (i) by the Client to recover title to or possession of

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quantities of the Products sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any regulatory authorities to detain or destroy any of the Products. Recall shall also include any action by either party to refrain from selling or shipping quantities of the Products to third parties which would have been subject to a Recall if sold or shipped.

(b) Recalls . In the event (i) any Authority issues a directive, order or, following the issuance of a safety warning or alert with respect to a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders such a Recall, or (iii) the Client determines that any Product should be Recalled or that a "dear doctor" letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably requested by the Client, having regard to all Applicable Laws.

(c) Product Returns . The Client shall have the responsibility for handling customer returns of the Products. Patheon shall provide the Client with such assistance as the Client may reasonably request to handle such returns.

(d) Patheon's Responsibility . To the extent that a Recall or return results from, or arises out of, a failure by Patheon to provide the Manufacturing Services in accordance with the Specifications or cGMPs, Patheon shall be responsible for the documented out-of-pocket expenses of such Recall or return and shall promptly, at the Client's election, either: (i) refund the invoice price for such Recalled or returned Products; (ii) offset such amount against other amounts due to Patheon hereunder; or (iii) use its commercially reasonable efforts to replace such Recalled or returned Products with conforming Products within [***] days' of the Client's election under this clause (d) without the Client being liable for payment therefor under Section 3.1; provided, however, that Patheon shall [***]. In all other circumstances, Recalls, returns or other corrective actions shall be made at the Client's direction and cost and expense. In connection with the production of any replacement Products under this clause (d), Patheon's cost for the procurement of any additional [***] required for the manufacture of such replacement Products shall be limited to the [***].

6.3 Disposition of Defective or Recalled Products.

The Client shall not dispose of any damaged, defective, returned or Recalled Products in relation to which it intends to assert a claim against Patheon unless it has given Patheon 60 days' notice of its intention to do so, and Patheon has not, in turn, instructed the Client to return such Products to Patheon. Patheon shall bear the cost of shipping, storage and disposition with respect to any damaged, defective, returned or Recalled Products in relation to which it bears responsibility under Section 6.1 or 6.2 hereof, and shall promptly reimburse Client for any such costs which may be incurred directly by the Client. In all other circumstances, the Client shall bear the cost of disposition with respect to any damaged, defective, returned or

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Recalled Products. Notwithstanding the foregoing, the Client shall have the right at all times to retain a reasonable sample of such Products for its own archival purposes.

6.4 Customer Questions and Complaints.

The Client shall have the sole responsibility for responding to Product Quality Complaints, subject to Patheon's obligation of cooperation and expense reimbursement set forth below. Product Quality Complaints received by Patheon from the Client's customers shall be referred to the Client within two Business Days from the receipt thereof by Patheon.

6.5 Adverse Event Reporting .

Patheon shall notify the Client promptly and not later than 24 hours after it becomes aware of any Adverse Experience associated with the use of the Products, whether or not determined to be attributable to the Products, and whether or not deemed to be serious or non-serious. Such information shall be sent to the Client as set forth in the Quality Agreement.

If the cause of any Adverse Experience results from a failure by Patheon to provide the Manufacturing Services in accordance with the Specifications or cGMPs, Patheon shall bear all costs incurred in respect of this Section 6.5. In all other circumstances, such costs shall be borne by the Client.

ARTICLE 7.
CO-OPERATION

7.1 Quarterly Review.

Each party shall forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers shall meet not less than quarterly to review the current status of the business relationship and manage any issues that have arisen.

7.2 Communication with Governmental Agencies.

The Client shall be primarily responsible for communicating with any Authority regarding such Products, including, but not limited to, the FDA and any other Authority responsible for granting regulatory approval for the Products; provided, however, that if in the opinion of Patheon's counsel, Patheon must communicate with an Authority to comply with the terms of this Agreement or the requirements of any Applicable Laws, it may do so. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, each party shall permit the other party to accompany and take part in any communications with any Authority, and to receive copies of all such communications from any Authority.

7.3 Records and Accounting by Patheon.

Patheon shall keep records of the manufacture, testing and shipping of the Products, Active Materials and Components and retain samples of such Products, Active Materials and Components as are necessary to comply with all Applicable Laws, including, but not limited to, cGMPs and other manufacturing regulatory requirements applicable to Patheon, the Manufacturing Site, the Products, the Active Materials and/or the Components, as well as to assist with resolving Product complaints and other similar investigations. Copies of such records and samples shall be retained for a period of one year following the date of Product expiry, or longer if required by Applicable Laws after which Patheon may destroy such records or samples; provided that Patheon has first given the Client 60 days notice of its intention to do so and the Client has not, in turn, instructed Patheon to ship such records or samples to the Client at the Client's expense.

7.4 Client's Inspection of Reports and Records.

The Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, provided a Patheon representative is present during any such inspection.

7.5 Client's Access to Manufacturing Site.

Patheon shall provide the Client with reasonable access at mutually agreeable times to its Manufacturing Site or any other facilities in which the Products are manufactured, stored, handled or shipped in order to permit the Client's verification of Patheon's compliance with the Patheon Manufacturing Responsibilities and with all Applicable Laws. For greater certainty, the right of access provided in this Section 7.5 shall not include a right to access or inspect Patheon's financial records.

7.6 Government Inspection .

Patheon shall make its internal practices, books and records relating to the manufacture of the Products available and allow access to all facilities used for manufacturing the Products to the FDA and any other Authority having jurisdiction over the manufacture of the Products for the purposes of determining Patheon's compliance with Applicable Laws, including, but not limited to, cGMPs. Patheon shall advise the Client by telephone and facsimile within one Business Day of any proposed or announced visit, audit or inspection, and as soon as possible (but in any case within two Business Days) after any unannounced visit, audit or inspection, by the FDA or any other Authority relating to the Products. Patheon shall provide the Client with a reasonable description in writing of each such visit or inspection promptly (but in no event later than five calendar days) thereafter, and with copies of any Authority-issued inspection observation reports (including, without limitation, FDA Form 483s and equivalent

forms from other regulatory bodies) and Authority correspondence, purged only of confidential information that is unrelated to the Products. Patheon and the Client will cooperate in resolving any concerns with any Authority, and the Client may review Patheon's responses to any such reports and communications, and Patheon shall in its reasonable discretion incorporate into such responses any comments received from the Client. Patheon will also inform the Client of any action taken by any Authority against Patheon or any of its officers or employees which may be reasonably expected to adversely affect the Products or Patheon's ability to supply the Products hereunder within two Business Days after the action is taken.

7.7 Reports.

Patheon will supply on an annual basis all Product data in its control, including release test results, complaint test results and all investigations (in manufacturing, testing and storage), that the Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that the Client is required to file with the FDA. At the Client's request Patheon shall provide a copy of the Annual Product Review Report to the Client [***]. Any additional report requested by Client beyond the scope of cGMPs and customary FDA requirements shall [***].

7.8 Validation and FDA Filings

(a) Validation . Patheon will validate all applicable processes, methods, equipment, utilities, facilities and computers used in the manufacture, packaging, storage, testing and release of Products in conformance with all Applicable Laws, including, but not limited to, cGMPs. Upon request, Patheon shall provide to Client a copy of the results of Product specific validation when such results are available.

(b) FDA Filings . The Client shall have the sole responsibility for filing all documents with the FDA and taking any other actions that may be required for the receipt of FDA Approval for the commercial manufacture of all of the Products. Patheon shall assist the Client, to the extent consistent with Patheon's obligations under this Agreement, including, but not limited to, the obligations under clause (a) of this Section 7.8 above, to obtain FDA Approval for the commercial manufacture of all Products as quickly as reasonably possible. Copies of all relevant CMC (as hereinafter defined) submissions and any related FDA correspondence are to be provided to Patheon by the Client.

(c) Verification of Data . At least 14 days prior to filing any documents with the FDA that incorporate data generated by Patheon, the Client shall provide Patheon with a copy of the documents incorporating such data so as to give Patheon the opportunity to verify the accuracy and regulatory validity of such documents as they relate to the Patheon generated data.

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(d) Verification of CMC . At least 14 days prior to filing with the FDA the Chemistry and Manufacturing Controls (" **CMC** ") of the New Drug Application (" **NDA** ") or the Abbreviated New Drug Application (" **ANDA** ") filing, as the case may be, the Client shall provide Patheon with a copy of the CMC portion as well as any supporting documents which have been relied upon to prepare the CMC portion so as to permit Patheon to verify that the CMC portion accurately describes the work that Patheon has performed and the manufacturing processes that Patheon will perform pursuant to this Agreement. Notwithstanding the foregoing, the Client may omit from the materials provided to Patheon any CMC portion and supporting documents which have been previously provided by Patheon to the Client and which have not been modified or edited by the Client.

(e) Pre-Approval Inspection . If Client does not provide Patheon with the documentation requested under paragraphs (c) and (d) above within the time stipulated in these paragraphs and if Patheon reasonably believes that Patheon's standing with the FDA may be jeopardized, [***].

(f) Comments . Within 10 days of Patheon's receipt from the Client of any documents under paragraphs (c) and (d) above, Patheon shall provide any comments it may have on such documents in writing to the Client, including any alleged inaccuracies or deficiencies, and representatives of the parties shall cooperate in good faith with one another over the following four-day period to address the comments and revise the materials accordingly.

(g) Deficiencies . In the event the representatives of the parties fail to agree upon the resolution of any alleged inaccuracies or deficiencies within such four-day period, the program directors or equivalent executives of each of Patheon and the Client shall meet as promptly as possible to discuss and attempt to resolve the dispute. If the program directors or equivalent executive are unable to resolve the dispute (or otherwise fail to meet) within the following 10-day period, then the parties will submit the dispute to an independent scientific mediator mutually selected by the parties. None of such mediator candidates may have been previously employed or otherwise received compensation from either the Client or Patheon except pursuant to any earlier dispute between Client and Patheon. The selected mediator shall hold any proceedings deemed necessary and make his or her findings within 30 days of his or her selection. The findings of the mediator shall be conclusive and binding upon the parties for purposes of any subsequent submissions to the Regulatory Authority and the parties shall thereafter cooperate with one another in connection with any pre-approval inspection by the FDA that may follow. All out-of-pocket costs relating to the dispute resolution process, including the mediator's fees and expenses, shall be borne solely by the unsuccessful party or as otherwise determined by the mediator.

(h) Client Responsibility . For clarity, the parties agree that in reviewing the documents referred to in paragraphs (c) and (d) above, Patheon's role will be limited to verifying

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the accuracy of the description and documentation of the work undertaken or to be undertaken by Patheon. As such, Patheon shall not assume any responsibility for the accuracy of the NDA or the ANDA, as the case may be. The sole responsibility of the preparation and filing of the NDA shall be borne by the Client.

ARTICLE 8.
TERM AND TERMINATION

8.1 Initial Term.

This Agreement shall become effective as of the date of execution hereof by both parties and shall continue until the date that is five Years from the Commencement Date (the " **Initial Term** "), unless terminated earlier by one of the parties in accordance herewith. This Agreement shall automatically continue after the Initial Term for successive terms of 12 months each unless either party gives written notice to the other party of its intention to terminate this Agreement at least 18 months prior to the end of the then current term.

8.2 Termination for Cause.

(a) Either party at its sole option may terminate this Agreement upon written notice in circumstances where the other party has failed to remedy a material breach of any of its representations, warranties or other obligations under this Agreement within 60 days following receipt of a written notice of said breach that expressly states that it is a notice under this Section 8.2(a).

(b) Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party in the event that: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other party; or (iii) this Agreement is assigned by such other party for the benefit of creditors.

(c) The Client may terminate this Agreement as to any Product upon 30 days' prior written notice in the event that any Authority takes any action, or raises any objection, that prevents the Client from importing, exporting, purchasing or selling such Product.

8.3 Product Partnering.

The Client may, at its sole option, terminate this Agreement upon 12 months' prior written notice to Patheon in connection with the Client's partnering, collaboration, licensing, sublicensing, co-promotion, sale or divestiture of rights to any Product; provided, however, that no such termination shall be effective prior to the 36 th month anniversary of the Commencement Date of this Agreement.

8.4 Product Discontinuation.

The Client shall provide at least [***] months' advance notice if it intends to no longer order a Product due to that Product's discontinuance in the market.

8.5 Obligations on Termination.

If this Agreement expires or is terminated in whole or in part for any reason, then (in addition to any other remedies either party may have in the event of default by the other party):

(a) Patheon shall cease the manufacture of Products and shall terminate any unfilled orders with third parties that Patheon may have previously submitted with respect to Active Materials and Components to the extent such orders may be terminated or revoked;

(b) the Client shall take delivery of and pay for all undelivered Products that are manufactured and/or packaged pursuant to a Firm Order, at the price in effect at the time the Firm Order was placed; provided that no such payment shall be due from the Client if this Agreement is terminated by Client pursuant to Section 8.2(a), including, but not limited to, termination for Patheon's failure to provide Manufacturing Services in respect of such undelivered Products in accordance with the Specifications and cGMPs;

(c) the Client shall purchase, at Patheon's [***] costs ([***] in connection with the purchase and handling of such Inventory), the Inventory applicable to the Products which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2 prior to notice of termination being given; provided that no such payment shall be due from the Client if this Agreement is terminated by Client pursuant to Section 8.2(a), including, but not limited to, termination for Patheon's failure to provide Manufacturing Services in accordance with the Specifications and cGMPs;

(d) the Client shall satisfy the purchase price payable pursuant to Patheon's orders with suppliers of Components, provided such orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2; provided that no such payment shall be due from the Client if this Agreement is terminated by Client pursuant to Section 8.2(a), including, but not limited to, termination for Patheon's failure to provide Manufacturing Services in accordance with the Specifications and cGMPs;

(e) if this Agreement is terminated by Client pursuant to Section 8.2(a), including, but not limited to, termination for Patheon's failure to provide Manufacturing Services in accordance with the Specifications and cGMPs, the Client shall have the option but not the obligation to take title to, possession of, all of any (i) undelivered Products and (ii) Inventory, including, but not limited to Active Materials and/or Components, in each case only after the

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Client has made any payment(s) which may be required under this Section 8.5 above, and Patheon shall cooperate with the Client in the surrender, delivery and transfer of such items as promptly as is commercially reasonable, with any shipping and related expenses to be borne by [***];

(f) if this Agreement is terminated for any reason other than pursuant to Section 8.2(a), the Client shall have the obligation to take title to, possession of, all of any (i) undelivered Products and (ii) Inventory, including, but not limited to Active Materials and/or Components, in each case only after the Client has made any payment(s) which may be required under this Section 8.5 above, and Patheon shall cooperate with the Client in the surrender, delivery and transfer of such items as promptly as is commercially reasonable, with any shipping and related expenses to be borne by [***];

(g) upon the request of the Client, and at the Client's expense, Patheon shall provide such assistance as is reasonably necessary to assist the Client in transferring the manufacture of the Product to another facility; provided, however, no competitor of Patheon shall be permitted to have access to the Manufacturing Site; and

(h) upon the request of the Client, Patheon shall cooperate in the technology transfer of the manufacture of the Products to a third-party supplier/manufacturer selected by the Client in its sole discretion. In furtherance of the technology transfer, Patheon shall make its employees and other internal resources reasonably available to the Client and the designated third-party supplier/manufacturer and provide copies of all technology, documents, data and other information constituting manufacturing know-how or otherwise necessary for regulatory qualification of the successor manufacturing process. Any such third-party supplier/ manufacturer that the Client may designate to manufacture the Products shall be required to sign a customary and appropriate confidentiality agreement with Patheon with respect to the nondisclosure and use of any such manufacturing know-how or other confidential information transferred. With respect to all documents, data and other information provided in connection with the technology transfer, (i) Patheon shall be responsible for the cost of providing a single copy only; and (ii) in addition to paper and other tangible copies, Patheon shall, upon the Client's request, also provide to the Client and/or the third-party supplier/manufacturer electronic copies of such documents, data and other information, provided, that, Patheon or its affiliates have electronic copies thereof, and provided, further, that Patheon shall have no obligation to reformat or otherwise alter or modify any such electronic materials. Notwithstanding the foregoing, no competitor of Patheon shall be permitted to have access to the Manufacturing Site without Patheon's written consent. In order to facilitate the technology transfer contemplated hereby, Patheon shall provide to the Client the services of at least the equivalent of [***] full-time equivalent (" **FTE** ") [***]. In addition to the foregoing FTE, the Client shall reimburse Patheon for its costs associated with the transfer of technology contemplated by this subsection (h) unless the transfer is in connection with the termination of this Agreement by the Client pursuant to

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Section 8.2(a), including, but not limited to, termination for Patheon's failure to provide Manufacturing Services in accordance with the Specifications and cGMPs.

Any termination or expiration of this Agreement shall not affect any outstanding obligations or payments due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the parties may have under this Agreement. For greater certainty, termination of this Agreement for any reason shall not affect the obligations and responsibilities of the parties pursuant to Sections 6.2, 6.3, 6.4, 6.5, 7.2, 7.3, 7.4, 7.6, 7.7, 8.5, Articles 10, 11 and 12 and Sections 13.1, 13.2, 13.3, 13.4, 13.5, 13.6, 13.7, 13.11 and 13.16, all of which survive any termination.

ARTICLE 9.
REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Each Party.

Each party covenants, represents and warrants that:

(a) it has the full right and authority to enter into this Agreement, and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder;

(b) this Agreement has been duly executed and delivered by, and is a legal and valid obligation binding upon such party, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity; and

(c) the entry into, the execution and delivery of, and the carrying out and other performance of its obligations under this Agreement by such party (i) does not conflict with, or contravene or constitute any default under, any agreement, instrument or understanding, oral or written, to which it is a party, including, but not limited to, its certificate of incorporation or by-laws, and (b) does not violate Applicable Laws or any judgment, injunction, order or decree of any Authority having jurisdiction over it.

9.2 Client Warranties.

The Client covenants, represents and warrants that:

(a) the Specifications for each of the Products are its or its Affiliate's property and that the Client may lawfully disclose the Specifications to Patheon;

(b) any Intellectual Property included in the Specifications or otherwise provided to Patheon by the Client to be utilized by Patheon and in connection with the provision of the Manufacturing Services, other than Patheon Intellectual Property, (i) is the Client's or its Affiliate's unencumbered property, (ii) may be lawfully used as directed by the Client, and (iii) such use does not infringe and will not infringe any Third Party Rights;

(c) to the knowledge of the Client, the provision of the Manufacturing Services by Patheon in respect of any Product pursuant to this Agreement or use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement does not and will not infringe any Third Party Rights;

(d) the Client is not aware of any pending or threatened claims against the Client, the subject of which is the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Components, or the sale, use or other disposition of any Product made in accordance with the Specifications;

(e) following approval by the applicable Authority, the Specifications for all Products will conform to all Applicable Laws, including, without limitation, cGMPs; and

(f) the Products, if labeled and manufactured in accordance with the Specifications and in compliance with Applicable Laws, including, without limitation cGMPs, (i) may be lawfully sold and distributed in every jurisdiction in which the Client markets such Products, (ii) will be fit for the purpose intended, and (iii) will be safe for human consumption.

9.3 Patheon Warranties.

Patheon covenants, represents and warrants that:

(a) it shall perform the Manufacturing Services in accordance with the Specifications and cGMPs;

(b) it has and will maintain throughout the term of this Agreement, the expertise, with respect to personnel and equipment, to fulfill the obligations established hereunder, and has obtained all requisite material licenses, authorizations and approvals required by all Authorities to manufacture the Products;

(c) the Manufacturing Site, all other facilities, all equipment and all personnel to be employed by Patheon in rendering the Manufacturing Services are currently, and will be at the time each batch of Products is produced, qualified in accordance with all Applicable Laws, including, but not limited to, cGMPs;

(d) there are no pending or uncorrected citations or adverse conditions noted in any inspection of the Manufacturing Site or any other facilities to be employed by Patheon in rendering the Manufacturing Services which would cause the Products to be misbranded or adulterated within the meaning of the Act, including, but not limited to, all cGMPs;

(e) to the knowledge of Patheon, the Manufacturing Services and the contributions of Patheon to the manufacture of the finished Product in accordance with this Agreement do not and will not infringe any Third Party Rights provided, however, that Patheon does not warrant against infringement attributable to the finished Product which, when used together with Patheon's manufacturing processes, results in a claim for infringement;

(f) Patheon is not aware of any pending or threatened claims against Patheon asserting that any of the activities of Patheon relating to the manufacture, import, use, or sale of pharmaceutical products, or the conduct of the activities contemplated herein by the Client, infringe, misappropriate, or violate the rights of any Third Party Rights; and

(g) all employees, consultants, subcontractors and agents performing services for Patheon hereunder have assigned, or will assign, in writing to Patheon all of their right, title and interest in, to and under any and all Inventions directly relating to the Product.

(h) all Product manufactured and supplied to the Client under this Agreement shall not be adulterated or misbranded within the meaning of the Act or other Applicable Laws as of the time that the finished Product is transferred to the carrier at Patheon's shipping point.

(i) all Product manufactured and supplied to the Client under this Agreement shall have the minimum shelf life specified for such Product in the Specifications and, in any event, shall be shipped to the Client promptly (and in any event not more than three (3) months) after the date of its manufacture.

9.4 Debarred Persons.

Patheon covenants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the Act.

9.5 Permits.

(a) The Client shall be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals in respect of the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

(b) Patheon shall be solely responsible for obtaining and maintaining all permits, site licenses or other regulatory approvals for the manufacture of Products. In carrying out its obligations under this Agreement, Patheon shall comply with all applicable environmental and health and safety Laws (current or as amended or added), and shall be solely responsible for determining how to comply with same in carrying out these obligations. Notwithstanding the foregoing, nothing provided to Patheon by the Client, by way of materials, specifications, processing information or otherwise, is meant to diminish Patheon's responsibility for such compliance. Patheon shall promptly notify the Client of any circumstances, including the receipt of any notice, warning, citation, finding, report or service of process or the occurrence of any release, spill, upset, or discharge of hazardous substances (as may be defined under Applicable Laws) relating to Patheon's compliance with this Section 9.5 (b) and which relates to the manufacture of the Products.

9.6 Compliance with Laws.

Each party, in connection with its performance under this Agreement, shall comply with all Applicable Laws.

9.7 No Other Warranty.

NEITHER PARTY MAKES ANY WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY WITH RESPECT TO THE PRODUCTS.

ARTICLE 10.
REMEDIES AND INDEMNITIES

10.1 Consequential Damages.

Under no circumstances whatsoever shall either party be liable to the other in contract, tort, negligence, breach of statutory duty or otherwise for any (direct or indirect) loss of profits, of production, of anticipated savings, of business or goodwill or for any liability, damage, costs or expense of any kind incurred by the other party of an indirect or consequential nature.

10.2 Limitation of Liability.

(a) Active Materials . Under no circumstances whatsoever shall [***] be responsible for any loss or damage to the Active Materials unless the Active Materials are lost or

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damaged through the negligence or willful misconduct of [***]. [***] for such Active Materials shall be limited to the [***].

(b) Products . Except to the extent that Patheon has failed to provide the Manufacturing Services in accordance with the Specifications, cGMPs, Applicable Laws or Section 9.3 of this Agreement, Patheon shall not be liable nor have any responsibility for any deficiencies in, or other liabilities associated with, any Product manufactured by it, including, without limitation, the costs and expenses of any Recall (collectively, " **Product Claims** "). For greater certainty, Patheon shall have no obligation for any Product Claims to the extent such Product Claim (i) is caused by deficiencies with respect to the Specifications, the safety, efficacy or marketability of the Products or any distribution thereof, (ii) results from a defect in the Active Materials or Components that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iii) is caused by actions of third parties occurring after such Product is shipped by Patheon pursuant to Section 5.4, (iv) is due to packaging or labeling defects or omissions for which Patheon has no responsibility, or (d) is due to any other breach by the Client of its obligations under this Agreement.

(c) Maximum Liability . Except as set forth in Sections 10.2(a) and 10.3, and excluding Patheon's liability for replacement Product under Article 6, Patheon's maximum liability under this Agreement for any reason whatsoever, shall not exceed in a Year, in the aggregate, the greater of $[***] or [***]% of the purchase price for Product arising from Firm Orders submitted in such Year up to a cap of $[***].

10.3 Patheon.

Subject to Sections 10.1 and 10.2, Patheon agrees to defend, indemnify and hold the Client, its officers, employees and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favor of third parties (other than Affiliates) resulting from, or relating to any claim of personal injury or property damage to the extent that such injury or damage is the result of (a) a failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, or (b) any other breach of this Agreement by Patheon, including, without limitation, any representation, warranty or covenant contained herein, except to the extent that any such losses, damages, costs, claims, demands, judgments and liability are due to the negligence or wrongful act(s) of the Client, its officers, employees or agents or Affiliates. Patheon's obligations under this Section 10.3 shall not be subject to the maximum liability limitation set forth in Section 10.2(c).

In the event of a claim, the Client shall: (i) promptly notify Patheon of any such claim; (ii) use commercially reasonable efforts to mitigate the effects of such claim; (iii) reasonably cooperate with Patheon in the defense of such claim; (iv) permit Patheon to control the defense and settlement of such claim, all at Patheon's cost and expense.

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10.4 Client.

Subject to Sections 10.1 and 10.2, the Client agrees to defend, indemnify and hold Patheon, its officers, employees and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favor of third parties (other than Affiliates) resulting from, or relating to (a) any claim of infringement or alleged infringement of any Third Party Rights in respect of the Products, or (b) any claim of personal injury or property damage to the extent that such injury or damage is the result of a breach of this Agreement by the Client, including, without limitation, any representation or warranty contained herein, except to the extent that any such losses, damages, costs, claims, demands, judgments and liability are due to the negligence or wrongful act(s) of Patheon, its officers, employees or agents or Affiliates.

In the event of a claim, Patheon shall: (i) promptly notify the Client of any such claims; (ii) use commercially reasonable efforts to mitigate the effects of such claim; (iii) reasonably cooperate with the Client in the defense of such claim; (iv) permit the Client to control the defense and settlement of such claim, all at the Client's cost and expense.

10.5 Indemnification Procedure.

(a) Each indemnified party (the " **Indemnitee** ") agrees to give the indemnifying party (the " **Indemnitor** ") prompt written notice of any Claims or discovery of fact upon which the Indemnitee intends to base a request for indemnification. Notwithstanding the foregoing, the failure to give timely notice to the Indemnitor shall not release the Indemnitor from any liability to the Indemnitee to the extent the Indemnitor is not materially prejudiced thereby.

(b) The Indemnitee shall furnish promptly to the Indemnitor copies of all papers and official documents in the Indemnitee's possession or control which relate to any Claims; provided, however, that if the Indemnitee defends or participates in the defense of any Claims, then the Indemnitor shall also provide such papers and documents to the Indemnitee. The Indemnitee shall reasonably cooperate with the Indemnitor in defending against any Claims.

(c) The Indemnitor shall have the right, by prompt written notice to the Indemnitee, to assume direction and control of the defense of any Claim, with counsel reasonably satisfactory to the Indemnitee and at the sole cost of the Indemnitor, so long as (i) the Indemnitor shall promptly notify the Indemnitee in writing (but in no event more than thirty (30) days after the Indemnitor's receipt of notice of the Claim) that the Indemnitor intends to indemnify the Indemnitee pursuant to this Article absent the development of facts that give the Indemnitor the right to claim indemnification from the Indemnitee, and (ii) the Indemnitor diligently pursues the defense of the Claim.

(d) If the Indemnitor assumes the defense of the Claim as provided in this Section 10.5, the Indemnitee may participate in such defense with the Indemnitee's own counsel who shall be retained, at the Indemnitee's sole cost and expense; provided, however, that neither the Indemnitee nor the Indemnitor shall consent to the entry of any judgment or enter into any settlement with respect to the Claim without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed. If the Indemnitee withholds consent in respect of a judgment or settlement involving only the payment of money by the Indemnitor and which would not involve any stipulation or admission of liability or result in the Indemnitee becoming subject to injunctive relief or other relief, the Indemnitor shall have the right, upon written notice to the Indemnitee within five days after receipt of the Indemnitee's written denial of consent, to pay to the Indemnitee, or to a trust for its or the applicable third party's benefit, such amount established by such judgment or settlement in addition to all interest, costs or other charges relating thereto, together with all attorneys' fees and expenses incurred to such date for which the Indemnitor is obligated under this Agreement, if any, at which time the Indemnitor's rights and obligations with respect to such Claim shall cease.

(e) The Indemnitor shall not be liable for any settlement or other disposition of a Claim by the Indemnitee which is reached without the written consent of the Indemnitor.

ARTICLE 11.
CONFIDENTIALITY

11.1 Confidentiality.

The parties agree that, for the term of this Agreement and for seven years thereafter (other than for trade secrets, for which the confidentiality obligations set forth herein shall last as long as trade secret law shall allow), all non-public, proprietary or "confidential" disclosures, know-how, data, and technical, financial and other information of any nature whatsoever (collectively, "Confidential Information"), disclosed or submitted, either orally or in writing (including, without limitation, by electronic means) or through observation, by one party (the "Disclosing Party") to the other party (the "Receiving Party") hereunder, including, without limitation, the terms of this Agreement, shall be received and maintained by the Receiving Party in strict confidence, shall not be used for any purpose other than the purposes expressly contemplated by this Agreement, and shall not be disclosed to any third party (including, without limitation, in connection with any publications, presentations or other disclosures). Notwithstanding the foregoing, (a) either party may disclose on a need-to-know basis the existence of this Agreement and the terms hereof to any bona fide potential acquirers, corporate partners, investors or financial advisors; (b) the Client may disclose that Patheon is a supplier to the Client with respect to the Product; (c) Patheon may disclose the fact that the Client is a client of Patheon but shall not disclose any other information relating to any product for which Patheon provides services to the Client. The Receiving Party will promptly notify the Disclosing Party

upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information. Confidential Information belongs to and shall remain the property of the Disclosing Party.

11.2 Exceptions.

The provisions of Section 11.1 shall not apply to any information of the Disclosing Party which can be shown by competent evidence by the Receiving Party:

(a) to have been known to or in the possession of the Receiving Party prior to the date of its actual receipt from the Disclosing Party as evidenced by the Receiving Party's written records;

(b) to be or to have become readily available to the public other than through any act or omission of any party in breach of any confidentiality obligations owed to the Disclosing Party;

(c) to have been disclosed to the Receiving Party, other than under an obligation of confidentiality, by a third party which had no obligation to the Disclosing Party not to disclose such information to others; or

(d) to have been subsequently independently developed by the Receiving Party without use of or reference or access to the Disclosing Party's Confidential Information as evidenced by the Receiving Party's written records.

11.3 Authorized Disclosure.

The Receiving Party may disclose the Disclosing Party's Confidential Information hereunder solely to the extent (a) approved by the Disclosing Party; or (b) the Receiving Party is legally required to disclose such Confidential Information; provided, however, that prior to any such required disclosure, the Receiving Party will, except where impracticable, give reasonable advance written notice to the Disclosing Party of such disclosure (so that the Disclosing Party may seek a protective order and or other appropriate remedy or waive compliance with the confidentiality provisions of this Article 11) and will use good faith efforts to secure confidential treatment of such Confidential Information required to be disclosed. In the event that a party makes a disclosure of Confidential Information deemed necessary under applicable federal or state securities laws or any rule or regulation of a nationally recognized securities exchange, the party shall use good faith efforts to obtain confidential treatment for the disclosure to the extent available. The party making such a disclosure shall provide the other party with reasonable advance written notice of its intent to make such a disclosure and shall provide the other party the opportunity to comment on any confidential treatment requested prior to the submission.

11.4 Return of Confidential Information.

The Receiving Party shall keep the Disclosing Party's Confidential Information in appropriately secure locations. Upon the expiration or termination of this Agreement or at any time upon the Disclosing Party's request, the Receiving Party shall destroy or return to the Disclosing Party, at the Disclosing Party's written request, all Confidential Information belonging to the Disclosing Party possessed by the Receiving Party, or its officers, directors, employees, agents and consultants; provided, however, that a Receiving Party may retain one (1) copy of the Disclosing Party's Confidential Information in an appropriately secure location, which by Applicable Laws it must retain, for so long as such Applicable Laws require such retention but thereafter shall dispose of such retained Confidential Information in accordance with Applicable Laws or this Section 11.4.

11.5 Equitable Relief.

The Receiving Party agrees that, due to the unique nature of the Confidential Information, the unauthorized disclosure or use of the Confidential Information of the Disclosing Party may cause irreparable harm and significant injury to the Disclosing Party, the extent of which may be difficult to ascertain and for which there may be no adequate remedy at law. Accordingly, the Receiving Party agrees that the Disclosing Party, in addition to any other available remedies, shall have the right to seek an immediate injunction and other equitable relief enjoining any breach or threatened breach of this Agreement. The Receiving Party shall notify the Disclosing Party in writing immediately upon the Receiving Party's becoming aware of any such breach or threatened breach.

ARTICLE 12.
DISPUTE RESOLUTION

12.1 Commercial Disputes.

In the event of any dispute arising out of or in connection with this Agreement (other than a dispute determined in accordance with Section 6.1(b) or a Technical Dispute), the parties shall first try to solve it amicably. In this regard, any party may send a notice of dispute to the other, and each party shall appoint, within 10 Business Days from receipt of such notice of dispute, a single representative having full power and authority to solve the dispute. The representatives so designated shall meet as necessary in order to solve such dispute. If these representatives fail to solve the matter within one month from their appointment, or if a party fails to appoint a representative within the 10 Business Day period set forth above, such dispute shall immediately be referred to the Chief Operating Officer or Executive Vice President, Operations (or such other officer of comparable or greater authority as they may designate) of each party who will meet and discuss as necessary in order to try to solve the dispute amicably.

Should the parties fail to reach a resolution under this Section 12.1, their dispute will be referred to a court of competent jurisdiction in accordance with Section 13.16.

12.2 Technical Dispute Resolution.

In the event of a dispute (other than disputes in relation to the matters set out in Sections 6.1(b) and 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labeling, quality control testing, handling, storage or other activities under this Agreement (a " **Technical Dispute** "), the parties shall make all reasonable efforts to resolve the dispute by amicable negotiations. In this regard, senior representatives of each party shall, as soon as practicable and in any event no later than 10 Business Days after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite such meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within 30 Business Days of such written request, the Technical Dispute shall, at the request of either party, be referred for determination to an expert in accordance with the provisions of Schedule G. In the event that the parties cannot agree whether a dispute is a Technical Dispute, Section 12.1 shall prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution pursuant to the applicable marketing approval for such Products shall not by itself indicate compliance by Patheon with its obligations in respect of the Manufacturing Services and further that nothing in this Agreement (including Schedule G) shall remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

ARTICLE 13.
MISCELLANEOUS

13.1 Inventions.

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, royalty-free, non-transferable, non-sublicensable license of Client's Intellectual Property that relates to the Product solely to perform the Manufacturing Services.

(b) All Inventions and other Intellectual Property generated or derived by Patheon in the course of performing the Manufacturing Services, to the extent it is specific to the development, manufacture, use and sale of the Client's Products that is the subject of the Manufacturing Services (including, but not limited to, any new use, new formulation or any change in the method of producing, testing or storing any Product), shall be the exclusive property of Client. Patheon shall execute such instruments as shall be required to evidence or effectuate the Client's ownership of any such Inventions or other Intellectual Property, and shall cooperate upon reasonable request in the prosecution of patents and other Intellectual Property rights related thereto.

(c) All Intellectual Property generated or derived by Patheon in the course of performing the Manufacturing Services which are not specific, or dependent upon, Client's Product and which have general application to manufacturing processes or formulation development of drug products or drug delivery systems shall be the exclusive property of Patheon (the " **Broader Intellectual Property Rights** "). Patheon hereby grants to Client, a worldwide, perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable and sublicensable license of Patheon's Broader Intellectual Property Rights to manufacture and have manufactured the Products and to use, import, export, offer to sell, and sell the same, with full right to sublicense to any third party in connection with the manufacture, sale or distribution of the Product.

(d) Each party shall be solely responsible for the costs of filing, prosecution and maintenance of patents and patent applications on its own Inventions.

(e) Either party shall give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Products or the processes for developing or manufacturing the Products owned or otherwise controlled by such party in respect of the Products.

13.2 Intellectual Property.

Subject to Section 13.1, all Intellectual Property of the Client shall be owned by the Client and all Intellectual Property of Patheon shall be owned by Patheon. The Client and Patheon hereby acknowledge that neither party has, nor shall it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Each party agrees not to use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13.3 Insurance.

Each party shall maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of three years thereafter, which insurance, at the time of FDA approval for the Product, shall afford limits of not less than (i) $[***] for each occurrence for personal injury or property damage liability; and (ii) $[***] in the aggregate per annum with respect to product and completed operations liability. If requested each party will provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. The insurance certificate shall further provide for a minimum of 30 days' written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault on the part of such party, then such party shall forthwith notify the other party in writing

*** Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

and the parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors.

The parties are independent contractors and this Agreement shall not be construed to create between Patheon and the Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners or any similar relationship, the existence of which is expressly denied by the parties hereto, and nothing in this Agreement shall be construed to give either party the power or authority to act for, bind, or commit the other party.

13.5 Trademarks.

The Client and Patheon hereby acknowledge that neither party has, nor shall it acquire, any interest in any of the other party's trademarks or trade names unless otherwise expressly agreed to in writing. Each party agrees not to use any trademark or trade name of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13.6 No Waiver.

Either party's failure to require the other party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement. No waiver shall be effective unless made in writing and signed by the waiving party.

13.7 Assignment.

(a) Patheon may not assign this Agreement or any of its rights or obligations hereunder except with the written consent of the Client, such consent not to be unreasonably withheld; provided, however, that Patheon may arrange for subcontractors to perform specific testing services arising under this Agreement without the consent of the Client; provided, further, that Patheon shall provide advance notice of the name and function of any such subcontractor and shall ensure such subcontractor's adherence to the terms of this Agreement, including, but not limited to, the obligations of confidentiality set forth in Article 11.

(b) The Client may assign this Agreement or any of its rights or obligations hereunder[***] without approval from Patheon; provided, however, that the Client shall give prior written notice of any assignment to Patheon, any assignee shall covenant in writing with Patheon to be bound by the terms of this Agreement and the Client shall remain liable hereunder. [***].

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(c) Notwithstanding the foregoing provisions of this Section 13.7, either party may assign this Agreement to any of its Affiliates or to a successor to, purchaser or licensee of all or substantially all of its business, provided that such assignee agrees in writing to be bound hereunder. For purposes of the foregoing, the phrase "all or substantially all of its business" shall mean, with respect to the Client, the business of the Client relating to the Product and not necessarily any other products to which the Client may have rights.

13.8 Force Majeure.

Neither party shall be liable for the failure to perform its obligations under this Agreement if such failure is occasioned by a cause or contingency beyond such party's reasonable control, including, but not limited to, the following if such cause or contingency beyond such party's reasonable control: strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any Authority acting within color of right (a " **Force Majeure Event** "). A party claiming a right to excused performance under this Section 13.8 shall immediately notify the other party in writing of the extent of its inability to perform, which notice shall specify the occurrence beyond its reasonable control that prevents such performance. Notwithstanding the foregoing, if a Force Majeure Event prevents a party's performance under this Agreement for an aggregate of 120 days, the other party may terminate this Agreement upon written notice to the non-performing party.

13.9 Additional Product.

Additional products may be added to this Agreement and such additional products shall be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by an addendum signed by each of the parties hereto.

13.10 Notices.

Any notice, approval, instruction or other written communication required or permitted hereunder shall be sufficient if made or given to the other party by personal delivery, by telecopier or facsimile communication or by sending the same by first class mail, postage prepaid to the mailing address, or telecopier or facsimile number set forth below:

If to the Client:

Somaxon Pharmaceuticals, Inc.
12750 High Bluff Drive, Suite 310

San Diego, CA 92130
Attention: President and Chief Executive Officer
Telecopier No.: 858-509-1589

with a copy to:

Latham & Watkins LLP
12636 High Bluff Drive, Suite 400
San Diego, CA 92130
Attention: Scott N. Wolfe / Cheston J. Larson
Telecopier No.: 858-523-5450

If to Patheon:

Patheon Inc.
7070 Mississauga Road, Suite 350
Mississauga, Ontario L5N 7J8
Canada
Attention: President, Patheon USA
Telecopier No.: 905.812.6705

with a copy to:

Patheon Pharmaceuticals Inc.
2110 East Galbraith Road
Cincinnati, Ohio 45237

Attention: Director of Legal Services
Telecopier No.: 513-948-6927

or to such other addresses or telecopier or facsimile numbers provided to the other party in accordance with the terms of this Section 13.10. Notices or written communications made or given by personal delivery or by telecopier or facsimile shall be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States or Canadian mail, postage prepaid or upon receipt, whichever is sooner.

13.11 Severability.

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable in any respect, such determination shall not impair or affect the validity, legality or enforceability of the remaining provisions hereof, and each provision is hereby declared to be separate, severable and distinct.

13.12 Entire Agreement.

This Agreement, together with the Quality Agreement constitutes the full, complete, final and integrated agreement between the parties hereto relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions or understandings with respect to the subject matter hereof. Any modification, amendment or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents shall be this Agreement and the Quality Agreement.

13.13 Other Terms.

The parties agree that no terms, provisions or conditions of any purchase order or other business form or written authorization used by the Client or Patheon will have any effect on the rights, duties or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of the Client or Patheon to object to such terms, provisions, or conditions unless such document specifically refers to this Agreement and is signed by both parties.

13.14 No Third Party Benefit or Right.

For greater certainty, nothing in this Agreement shall confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement.

13.15 Execution in Counterparts.

This Agreement may be executed in two counterparts, by original or facsimile signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

13.16 Governing Law.

This Agreement shall be construed and enforced under the laws of the State of New York, without regard to the United Nations Convention on Contracts for the International Sale of Goods and without giving effect to any choice of laws rule that would cause the application of the laws of any jurisdiction other than the internal laws of the State of New York, to the rights and duties of the parties.

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IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the date first written above.

PATHEON PHARMACEUTICALS INC.

by /s/ Bradley J. Mitchell

- Treasurer

by Bradley J. Mitchell

SOMAXON PHARMACEUTICALS, INC.

by /s/ Kenneth M. Cohen

- President & CEO

by Kenneth M. Cohen

-

SCHEDULE A

PRODUCTS

Doxepin 1, 3, and 6 mg tablets supplied in [***] as shown in Schedule C.

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SCHEDULE B

PROCEDURE FOR SHIPMENT AND ACCEPTANCE OF PRODUCT SPECIFICATIONS

Prior to the commencement of commercial manufacturing of Product under this Agreement the Client shall provide Patheon with originally executed copies of the FDA approved Specifications. If the Specifications provided are subsequently amended, then the Client shall provide Patheon with revised and originally executed copies of such revised Specifications. Upon acceptance of the revised Specifications, Patheon shall provide the Client with a signed and dated receipt evidencing such acceptance of the revised Specifications by Patheon.

SCHEDULE C

MINIMUM RUN QUANTITY, ANNUAL VOLUME AND FEES

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[***]

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SCHEDULE D

STABILITY TESTING

Patheon shall conduct stability studies on the finished Products according to the Specifications therefor, as required by the FDA or foreign Agencies as advised by the Client or as requested by the Client, and in any case on:

- at least the first [***] of finished Product from the Manufacturing Site after the Commencement Date;
- at least [***] of finished Product [***] per calendar Year thereafter; or
- The cost of such stability studies shall be as follows or as may otherwise be agreed to between the parties in writing:

  $[***] per stability time point (multiple samples may tested if they are due at the same time)

Patheon shall provide to the Client a report of all results and data obtained from such stability studies periodically as may be specified in the stability protocol for the Product and/or the Quality Agreement.

Patheon and the Client shall agree in writing on any further stability testing to be performed by Patheon in connection with the Products. Such agreement shall specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by the Client in connection with such additional testing.

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SCHEDULE E

ACTIVE MATERIALS & ACTIVE MATERIALS REIMBURSEMENT VALUE

Active Material	Supplier	Active Materials Reimbursement Value
Doxepin HCI	[***] ●	$[***] per kg. up to a maximum amount of $[***] per annum

*** Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE F

BATCH NUMBERING AND EXPIRATION DATES

Each batch of Product manufactured by Patheon will bear a unique packaging lot number using the Patheon batch numbering system. This number will appear on the Product label and on the batch documentation.

Patheon will calculate the expiration date for each batch of Product by adding the expiration period, supplied by the Client to the date of manufacture of each batch. The expiration date will appear on the Product label.

SCHEDULE G

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 shall be resolved in the following matter:

1. **Appointment of Expert** . Within 10 Business Days after a party requests pursuant to Section 12.2 that an expert be appointed to resolve a Technical Dispute, the parties shall jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the parties are unable to so agree within such 10 Business Day period, or in the event of disclosure of a conflict by an expert pursuant to paragraph 2 hereof which results in the parties not confirming the appointment of such expert, then an expert (willing to act in that capacity hereunder) shall be appointed by an experienced arbitrator on the roster of the [American Arbitration Association].

2. **Conflicts of Interest** . Any person appointed as an expert shall be entitled to act and continue to act as such notwithstanding that at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment provided that before accepting such appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses any such interest or duty and the parties shall after such disclosure have confirmed his appointment.

3. **Procedure** . Where an expert is appointed:

(a) Timing . The expert shall be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and that he issues such authorizations to the parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within 15 Business Days (or such other date as the parties and the expert may agree) after receipt of all information requested by him pursuant to paragraph 3(b) hereof.

(b) Disclosure of Evidence . The parties undertake one to the other to provide to any expert all such evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they shall disclose promptly and in any event within five Business Days of a written request from the relevant expert to do so.

(c) Advisors . Each party may appoint such counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the parties shall co-operate and seek to narrow and limit the issues to be determined.

(d) Appointment of New Expert . If within the time specified in paragraph 3(a) above the expert shall not have rendered a decision in accordance with his appointment, a new expert may (at the request of either party) be appointed and the appointment of the existing expert shall thereupon cease for the purposes of determining the matter at issue between the

parties save that if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then such a decision shall have effect and the proposed appointment of the new expert shall be withdrawn.

(e) Final and Binding . The determination of the expert shall, save in the event of fraud or manifest error, be final and binding upon the parties.

(f) Costs . Each party shall bear its own costs in connection with any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert shall be borne by the losing party.

For greater certainty, the parties agree that the release of the Products for sale or distribution pursuant to the applicable marketing approval for such Products shall not by itself indicate compliance by Patheon with its obligations in respect of the Manufacturing Services and further that nothing in this Agreement (including this Schedule G) shall remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

SCHEDULE H

QUALITY AGREEMENT

THIS AGREEMENT made as of the 1st day of February 2006

BETWEEN:

SOMAXON PHARMACEUTICALS, INC.
a corporation existing under the laws of the State of Delaware,

(the **"Client")**

- and-

PATHEON PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware,

Specific sites covered by this Agreement:
Patheon Pharmaceuticals Inc., 2110 East Galbraith Drive, Cincinnati, OH 45237-1625

("Patheon")

BACKGROUND: Patheon and the Client entered into a manufacturing services agreement dated February 1, 2006 (the " **MSA** ") under which Patheon agreed to provide pharmaceutical manufacturing services involving the Products described in Schedule A hereto. Under the MSA Client must provide certain information to Patheon for Patheon to perform the services (the **"Specifications")** and Patheon must operate within the Specifications. The parties want to allocate responsibility for procedures and specifications that impact the identity, strength, quality, and purity of the Products.

AGREEMENT: In consideration of the rights conferred and the obligations assumed under the MSA and herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), the parties agree to be legally bound as follows:

ARTICLE 1

RESPONSIBILITIES

1.1 Patheon is responsible for all the operations that are marked with "X" in the column titled "Patheon" and the Client is responsible for all the operations that are marked with "X" in the column titled "Client". If marked with "(X)", the designated party will cooperate.

(a) General

		Client	Patheon
1.	Provide Specifications.	X	(X)
2.	Manufacture and package Product(s) according to the Specifications.		X
3.	Permit GMP audits of all relevant premises, procedures and documentation by Client, and permit inspection by regulatory authorities.		X
4.	Will not subcontract any of the work to a third party without prior written consent of Client.		X
5.	Provide copies of Annual Product Review reports when requested by Client.		X
6.	Provide copies of information and correspondence necessary to support the Annual Report when requested by Client.		X
7.	Notify and obtain written approval from the Client before initiating any proposed changes to the process, materials, testing, equipment or premises that may affect the Product(s). Client approval will not be unreasonably withheld.	(X)	X
8.	Notify the Client within one business day of receipt of any FDA Form 483's, warning letters or the like from regulatory agencies relating to: (i) the Product(s); (ii) the supply of Product(s) or (iii) the facilities used to produce, test or package the Product(s). Client will review and approve in writing responses that relate directly to the Product(s) before submitting to the regulatory agency. Patheon	(X)	X

		Client	Patheon
	reserves the right to respond to such regulatory agencies without approval, if, in the reasonable opinion of Patheon's counsel, it is required to do so.		
9.	Notify the Client within one business day of any regulatory authority requests for samples, batch documentation, or other information related to the Product(s).		X
10.	Conduct operations in compliance with applicable federal, state and local environmental, occupational health and safety laws, and cGMP regulations.		X
11.	Investigate all medical and non-medical product complaints related to the manufacturing of the Product(s).	X	(X)
12.	Investigate all manufacturing Product complaints provided by Client.	(X)	X
13.	Notify other party within one business day of receipt of information meeting NDA Field Alert criteria as defined in 21 CFR 314.81(b)(l).	X	X
14.	Initiate NDA Field Alert reports.	X	
15.	Initiate and manage Product recalls.	X	(X)
16.	Timely liaise with Regulatory Authorities for approval, maintenance and updating of marketing approval.	X	

(b) Validation and Process Testing Activities

		Client	Patheon
1.	Establish applicable master validation plans and maintain a validation program for the Product(s).	X	X
2.	Qualify (IQ/OQ) facilities, utilities, laboratory equipment and process equipment.		X

		Client	Patheon
3.	Calibrate instrumentation and qualify computer systems used in the manufacture and testing of the Product(s).		X
4.	Prepare all validation protocols and reports, for manufacturing, and packaging operations.	(X)	X
5.	Review and approve master validation plan, and validation protocols and reports for manufacturing and packaging of the Product(s).	X	X
6.	Maintain appropriate equipment cleaning procedures and cleaning validation program.		X
7.	Provide toxicological information to be used in the development of a cleaning program.	X	
8.	Validate analytical test methods for finished Product(s).		X

(c) Raw Materials

		Client	Patheon
1.	Provide the master formula including Bill of Materials.	X	(X)
2.	Provide approved supplier list. Client to audit and approve API suppliers and ensure cGMP compliance where Client stipulates the supplier. Client stipulated suppliers will be included on Client's approved supplier list (attached hereto as Schedule D).	X	
3.	Client to qualify and approve product specific excipient suppliers and ensure cGMP compliance. Client stipulated suppliers will be included on Client's approved supplier list (attached hereto as Schedule D).	X	
4.	Patheon to qualify and approve excipient suppliers and ensure cGMP compliance where Patheon stipulates the suppliers. Patheon stipulated suppliers will be included on the Patheon approved supplier list (Schedule C).		X
5.	Provide API specifications.	X	

		Client	Patheon
6.	Procure API (including Certificates of Analysis).		X
7.	Validate non-Compendial testing methods for API.	(X)	X
8.	Analyze and release API.		X
9.	Retain reference sample of API for one year past the expiration date of the last batch of Product(s) manufactured with that material in the Product(s) or such longer period required by law.		X
10.	Procure inactive ingredients (including Certificates of Analysis).		X
11.	Provide test methods and method validation for inactive ingredients (if non-Compendial).	X	(X)
12.	Analyze and release inactive ingredients.		X
13.	Retain reference samples of inactive ingredients for 3 years or such longer period as required by law.		X
14.	Maintain records and evidence on the testing of raw materials for five years after the materials were last used in the manufacture of the Product(s).		X
15.	At Client's request, confirm that all bovine, caprine, or ovine derived raw materials purchased by Patheon for the manufacture of Product(s) have a BSE/TSE certificate of compliance from the raw material vendor.		X

(d) Bulk Manufacture

		Client	Patheon
1.	Create, control, issue and execute master batch record.		X
2.	Approve master batch record.	X	X
3.	Document, investigate and resolve deviations from approved manufacturing instructions or specifications.	(X)	X

(e) Packaging

		Client	Patheon
1.	Provide specifications for packaging components.	X	(X)
2.	Review and approve labelling proofs.	X	
3.	Provide artwork and labelling text (blister, carton, leaflet, label etc.) specifications.	X	(X)
4.	Create, control, issue and execute master packaging record.		X
5.	Approve master packaging record.	X	X
6.	Qualify and approve packaging component suppliers. Client to qualify and approve packaging component suppliers and ensure cGMP compliance where Client stipulates the supplier. Client stipulated suppliers will be included on its approved supplier list (attached hereto as Schedule D).	X	(X)
7.	Patheon to qualify and approve packaging component suppliers and ensure cGMP compliance where Patheon stipulates the supplier. Patheon stipulated suppliers will be included on its approved supplier list (Schedule C).		X
8.	Provide test methods for packaging components.	(X)	X
9.	Procure packaging components.		X
10.	Analyze and release packaging components.		X
11.	Maintain records and evidence on the testing of packaging/labelling materials for five years after the materials were last used in the packaging/labelling of the Product(s).		X
12.	Document, investigate and resolve any deviation from approved packaging instructions or specifications.		X

(f) Testing & Release of Finished Product

		Client	Patheon
1.	Provide finished product specifications.	X	
2.	Supply / develop analytical test methods for finished product.	X	(X)
3.	Test finished product.		X
4.	Maintain all batch records for a minimum of one year past Product(s) expiry date and supply copies of all such records to the Client upon request.		X
5.	Notify Client QA of Out-Of-Specification results within one business day of confirmation.		X
6.	Retain reference samples of finished product for one year past expiration date.		X
7.	Retain reserve sample of finished product as required by 21 CFR 211.170(b)(1).		X
8.	Release finished product to Client and provide C of A.		X

(g) Stability Testing (if required)

		Client	Patheon
1.	Provide stability testing protocol for finished Product(s).	(X)	X
2.	Store stability samples.		X
3.	Develop and validate stability indicating assay.		X
4.	Perform stability testing.		X
5.	Notify the Client of any confirmed stability failure for Product(s) supplied to the Client within one business day.		X

ARTICLE 2

COMPLIANCE BETWEEN PRODUCT REGISTRATION AND THE MANUFACTURING PROCESS

2.1 Technical Changes

(a) In accordance with Patheon Standard Operating Procedures, Patheon will communicate all proposed process changes to the Client for prior review and written approval; the Client's approval will not be unreasonably withheld. The Client will determine whether to initiate registration variation procedures and will maintain adequate control over the quality commitments of the marketing authorization for Product(s).

(b) After validation of a process change and at Client's request, Patheon will deliver a copy of the validation report and the associated stability data, if applicable, to the Client.

2.2 Labelling / Packaging Material Changes

The Client may initiate changes and will review and approve any changes proposed by Patheon to labelling or primary packaging, including a change in the supplier of any labelling or primary packaging materials, before any such change occurs.

2.3 Other Changes

Patheon will communicate any proposed changes in storage or shipping to the Client for prior review and written approval; the Client's approval will not be unreasonably withheld. Patheon will also inform the Client of any planned changes in facilities or equipment directly related to the Product(s).

2.4 Regulatory Approvals

The Client will obtain and/or maintain all regulatory approvals for the Products and the Specifications, including, without limitation, all marketing and post-marketing approvals.

2.5 Field Alerts and Recalls

The Client will notify Patheon before filing any NDA Field Alert or initiating a Recall related to the Product(s). Patheon and the Client will work together to assure the accuracy of any NDA Field Alert or Recall related to the Product(s). The Client will have final authority to initiate a Product Recall or an NDA Field Alert.

ARTICLE 3

BATCH RELEASE

3.1 Batch review and release to the Client will be the responsibility of Patheon who shall act in accordance with Patheon's standard operating procedures. The Client will have sole responsibility for release of the Product(s) to the market.

3.2 For each batch released by Patheon for shipment to the Client, Patheon will deliver to the Client a certificate of analysis (C of A)/certificate of compliance (C of C), which will include a statement that the batch has been manufactured in accordance with cGMPs and the Specifications.

3.3 Patheon will notify the Client in the event of (i) any major deviation during manufacture which affects the quality or efficacy of the Product(s) or (ii) a confirmed out of specification (OOS) result. Patheon will provide a copy of the deviation investigation and/or OOS investigation report upon request.

ARTICLE 4

BATCH DOCUMENTATION

4.1 Patheon will retain originals of all batch documentation for one year past the expiry date of the Product(s), or longer if required by law, after which Patheon shall provide written notice to the Client and offer the Client the opportunity to take possession of such documents. If the Client does not elect to take possession within 45 days of Patheon's notice, Patheon may destroy such documents.

4.2 At the request of the Client, Patheon will provide a copy of any of the executed batch documents relating to Product(s) to the Client within two Business Days.

ARTICLE 5

STABILITY

5.1 Patheon will perform such stability testing as described in a stability protocol developed by Patheon and agreed to in writing by the Client.

5.2 If a confirmed result indicates that a Product(s) failed to remain within stability specifications, Patheon will notify the Client within one Business Day.

5.3 Patheon will provide stability data to the Client on an ongoing basis as agreed to by both parties.

5.4 If the MSA is terminated, Patheon will continue to provide the Client with stability data supporting the acceptability of the Product(s) until the Product(s) distributed by the Client reaches the end of its shelf life or such other date as may be required by applicable law.

ARTICLE 6

VALIDATION

6.1 With assistance from Patheon, Client will ensure that analytical methods and manufacturing and packaging procedures for the Product(s) are validated.

6.2 Patheon is responsible for executing the approved validation protocols.

ARTICLE 7

GENERAL

7.1 Any communications required under this Agreement will be directed to the person(s) identified in Schedule B.

7.2 Capitalized terms not otherwise defined herein will have the meaning specified in the MSA.

7.3 If any the terms of this Quality Agreement and the terms of the MSA conflict, the terms of the MSA will govern.

7.4 Any modification, amendment or supplement to this Quality Agreement must be in writing and signed by authorized representatives of Patheon and the Client.

SOMAXON PHARMACEUTICALS, INC.		**PATHEON PHARMACEUTICALS INC.**	
Name:	Doranne Frano	Name:	Jack Domet
Signature :	/s/ Doranne Frano	Signature:	/s/ Jack Domet
Title:	Sr. Director, Regulatory & Quality Assurance	Title:	Director, Quality Operations
Date:	Feb 1, 2006	Date:	2/2/2006

SCHEDULE A

PRODUCT(S)

Product(s)	Dosage Form	Dosage (Strength)
Doxepin	**[***]**	**[***] mg**
Doxepin	**[***]**	**[***] mg**
Doxepin	**[***]**	**[***] mg**

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SCHEDULE B

QUALITY CONTACTS

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SCHEDULE C

PATHEON APPROVED SUPPLIER LIST

Excipient		Supplier
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
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SCHEDULE D

CLIENT APPROVED SUPPLIER LIST

Doxepin HC1 **[***]**

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Abbreviations and Definitions

API	*Active Pharmaceutical Ingredient*
BSE	*Bovine Spongiform Encephalopathy*
C of A	*Certificate of Analysis*
C of C	*Certificate of Compliance*
CFR	*Code of Federal Regulations*
CGMP/GMP	*Current Good Manufacturing Practice as described in 21 CFR 210 and 211.*
FDA	*Food & Drug Administration*
IQ	*Installation Qualification*
MSA	*Manufacturing Services Agreement*
NDA	*New Drug Application*
OOS	*Out of Specification*
OQ	*Operational Qualification*
Primary Packaging Materials	*A component that is or maybe in direct contact with the dosage form*
TSE	*Transmissible Spongiform Encephalopathy*

SCHEDULE I

PRODUCT BILL OF MATERIALS

Product Name: DOXEPIN [***] **MG TABLETS —** [***]
Product Code: [***]

Theoretical Batch Size: [***]

Formula:

[***]	**[***]**
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Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kenneth M. Cohen, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Somaxon Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including any consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2006

/s/ Kenneth M. Cohen
Kenneth M. Cohen
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Meg M. McGilley, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Somaxon Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including any consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2006

/s/ Meg M. McGilley
Meg M. McGilley
Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Somaxon Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2006, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kenneth M. Cohen, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 11, 2006

/s/ Kenneth M. Cohen
Kenneth M. Cohen
President and Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Certification of Chief Financial Officer

In connection with the Quarterly Report of Somaxon Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2006, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Meg M. McGilley, Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 11, 2006

/s/ Meg M. McGilley
Meg M. McGilley
Vice President and Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.