Somaxon 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.

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Somaxon™ Pharmaceuticals Inc

Annual Report **2005**

Business Strategy

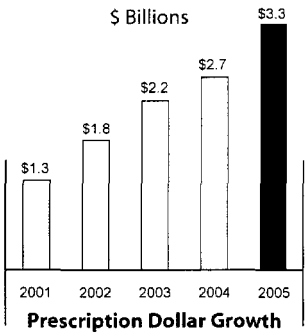
We are a specialty pharmaceutical company focused on the development and in-licensing of product candidates in the fields of psychiatry and neurology. Our near-term strategy is to focus on advancing the clinical development of our existing product candidates. Longer-term, we plan to build a portfolio by in-licensing and developing products for the U.S. market that are currently commercialized outside the United States; products approved in the United States with significant commercial potential for proprietary new uses, new dosages or alternative delivery systems; or products in late stages of clinical development.

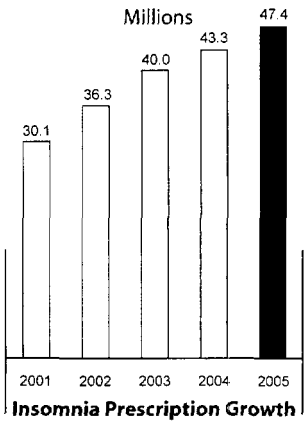
To date, we have in-licensed three product candidates. SILENOR™ (doxepin HCl), our lead product candidate, is currently being investigated in Phase 3 clinical trials for the treatment of insomnia. We are also evaluating nalmefene in a Phase 2/3 clinical trial for the treatment of pathological gambling and in a pilot Phase 2 clinical trial for smoking cessation. Finally, we are developing a new formulation of acamprosate calcium for the treatment of certain movement disorders.

We intend to build a U.S. commercial operation directed at promoting our products to psychiatrists and neurologists. By targeting these medical professionals, we can focus our commercial operations and leverage our infrastructure across products. We believe this infrastructure also will allow us to more easily acquire or in-license additional products, or to co-promote products to these physician specialists.

We will consider opportunities to partner our products with larger pharmaceutical companies where marketing and expanded reach to primary care physicians could enhance the commercial opportunity. We believe that SILENOR™, in particular, is an excellent candidate for partnering with a company that has the resources and capabilities to be competitive in the rapidly expanding insomnia market.

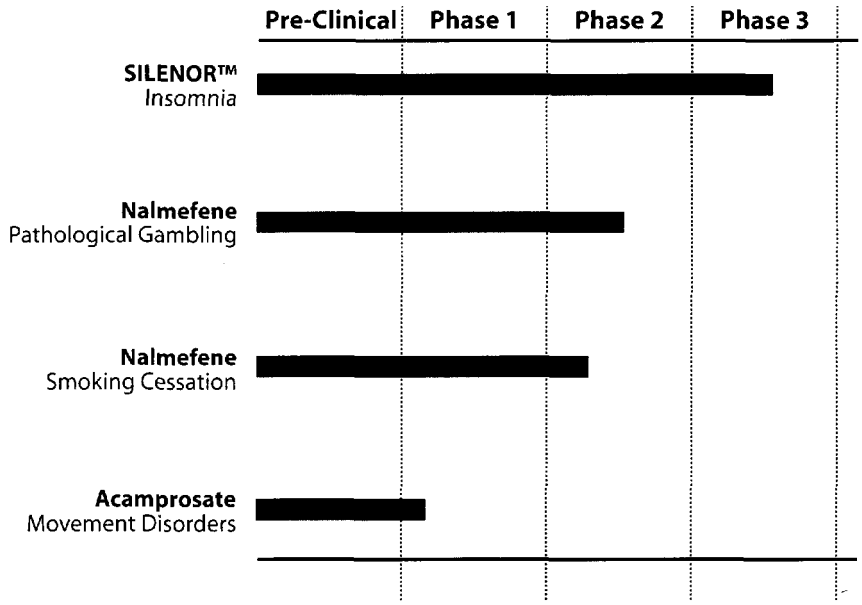
Insomnia Market 2005





Source: Wolters Kluwer Health

Product Candidate Pipeline



To Our Shareholders

It has been an exciting and rewarding year at Somaxon. Somaxon stands at an extraordinary point in our development as a company. We initiated a Phase 3 clinical program for our lead product candidate, SILENOR™ for the treatment of insomnia, a Phase 2 clinical trial for nalmefene which is being investigated for pathological gambling and a pilot study in smoking cessation, and formulation development for acamprosate, a potential treatment for movement disorders. We raised $65 million in gross proceeds from a Series C financing and completed an initial public offering in December, raising an additional $55 million in gross proceeds.

Somaxon is focused on in-licensing and developing proprietary pharmaceutical products for large target markets in psychiatry and neurology. We are especially interested in providing investors with an attractive risk-reward profile by developing product candidates that are in later stages of clinical development and that offer significant potential for proprietary new usages or novel dosage forms. Since we formed our company in 2003, we've met this objective by in-licensing three product candidates.

We are presently conducting Phase 3 clinical trials that are designed to evaluate SILENOR™ for the treatment of patients with insomnia. Positive results from our first Phase 3 clinical trial were announced in April 2006. This important clinical milestone demonstrated that SILENOR™ helped adults with chronic insomnia fall asleep faster (sleep onset) and stay asleep longer (sleep maintenance) than placebo in a statistically significant and clinically relevant manner. SILENOR™ demonstrated these robust effects without evidence of next-day residual sedation or other worrisome side effects. We expect results from our three remaining Phase 3 clinical trials later in 2006. Upon the successful completion of these clinical trials, we expect to file an NDA in the first quarter of 2007.

If we obtain approval for SILENOR™ from the Food and Drug Administration, we believe this product has the potential to capture a significant share of the rapidly growing insomnia market by successfully addressing the needs of patients and overcoming the limitations of currently available therapies. By demonstrating improvement in the key parameters of sleep; including sleep onset, sleep maintenance, and sleep duration, even into the last hour of the night, without next day residual effects or fear of dependency, SILENOR™ has the potential to become a first line choice for people with insomnia.

Add to this product profile a strong patent position which extends well into the next decade, SILENOR™ offers an opportunity to create substantial value for our company and our investors.

Finally, with the positive results we now have in hand, we will begin discussions with larger pharmaceutical companies to help us commercialize SILENOR™ if it is approved by the FDA. Our goal is to find a partner who is willing to make the necessary commitment to the long-term success of SILENOR™ and help provide Somaxon with attractive financial returns.

As our three product candidates move forward in development, Somaxon moves closer to achieving the goals that we believe will enhance shareholder value. Thanks to a successful IPO in December, we finished 2005 with over $100 million in cash. We have the financial resources to execute our clinical development plan beyond the filing of an NDA for SILENOR™. Positive Phase 3 clinical data leading to the filing of an NDA and to an attractive strategic relationship that will maximize the commercial potential of SILENOR™ are our highest priorities.

We look forward to reporting on further progress as we advance our programs and build our company.

Kenneth M. Cohen
President and Chief Executive Officer

David F. Hale
Chairman of the Board

Insomnia

Sleep is essential for human performance, general health and well being. Yet a growing number of American adults are affected by and are being diagnosed with insomnia, which can be characterized by difficulty falling asleep, waking frequently during the night, waking too early, or waking up not feeling refreshed.

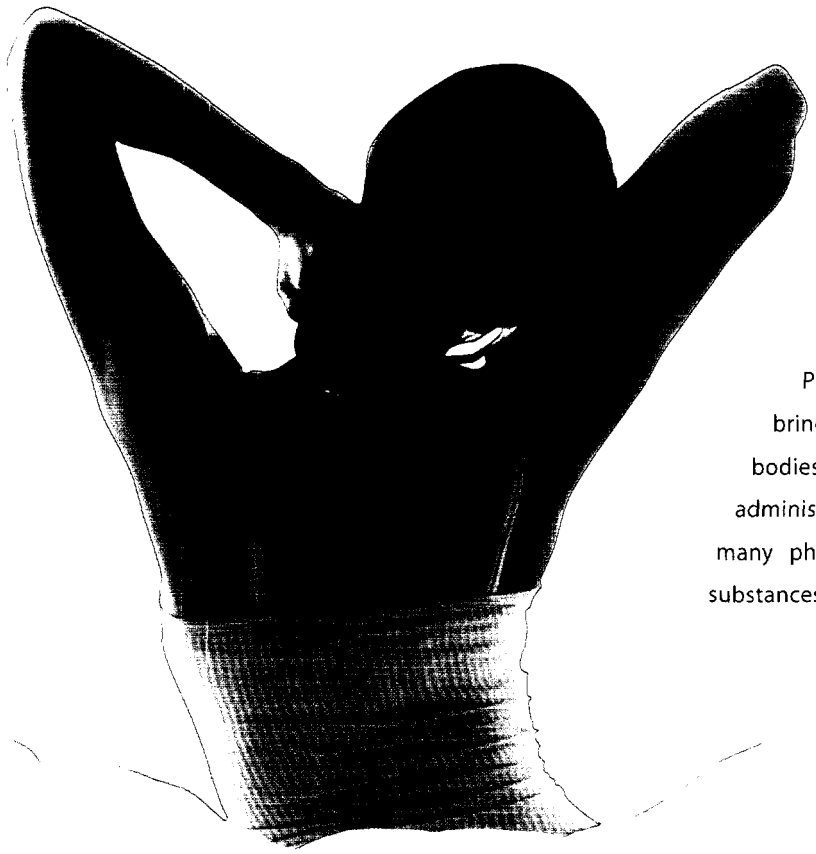
The individual and societal implications of untreated chronic insomnia can be severe leading to a host of problems, including mood disturbances, difficulties with concentration and memory, cardiovascular, pulmonary and gastrointestinal disorders. Even in otherwise healthy young people, sleep deprivation has been associated with early signs of aging, carbohydrate intolerance and insulin resistance.

Results from a 2005 National Sleep Foundation survey of Americans suggest that:

- 54% experience insomnia symptoms a few nights a week
- 41% have difficulty falling asleep (sleep onset)
- 32% awake often during the night (sleep maintenance)
- 41% wake up too early and can not get back to sleep (sleep maintenance and duration)

Despite the growing prevalence and awareness of insomnia, it remains significantly under-treated. Of the 70 million insomniacs in this country, only about 10 million currently take a prescription medication.

Increased awareness and new product options are beginning to change this trend. The U.S. market for prescription insomnia products is growing rapidly and exceeded $3 billion in 2005. This growth is expected to continue as clinicians and consumers alike become more aware of the correlation between a full night's sleep and good health.



Today, the most widely-prescribed products to treat insomnia are classified as Schedule IV controlled substances. This means the United States Drug Enforcement Administration (DEA) has determined that these medications, such as benzodiazepines and GABA-receptor agonists, are associated with the potential for abuse and dependence. Prescriptions for Schedule IV controlled substances bring scrutiny from the DEA and other regulatory bodies, and often require burdensome registration and administrative controls in physicians' offices. As a result, many physicians are reluctant to prescribe controlled substances, especially when treating a patient with a history

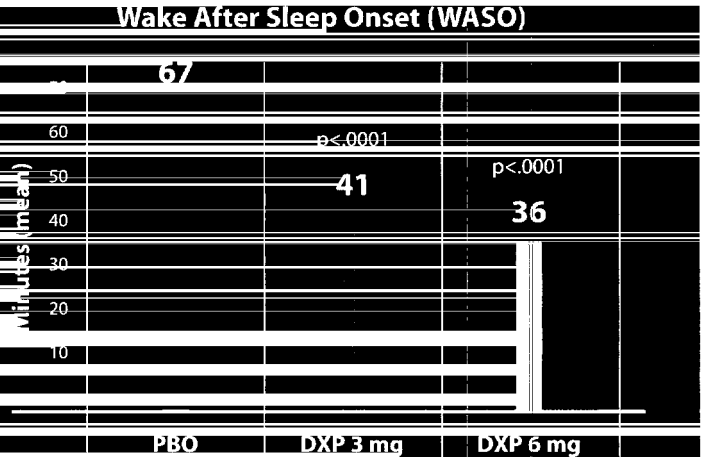
of addiction or if other effective, "non-scheduled" treatment options are available. To underscore this point, a recent survey of physicians conducted by Morgan Stanley Equity Research (February 2006) found that 83 percent of respondents said they would consider prescribing an effective non-scheduled medication for their patients with insomnia prior to using scheduled alternatives.

We believe that the prescription insomnia market remains underserved. Through our Phase 3 clinical trials, we are investigating the potential of SILENOR™ to be the first non-scheduled insomnia medication that addresses all three of the major components of insomnia (sleep onset, sleep maintenance and early awakenings) without the undesired side effects and safety concerns of other therapies.

We are developing SILENOR™ for the treatment of patients with insomnia. We believe that SILENOR™ has several appealing features that may offer benefits in the treatment of insomnia.

SILENOR™ is a low-dose (1 mg, 3 mg, 6 mg) oral tablet formulation of doxepin hydrochloride that is patent protected for its use in insomnia. Doxepin has been prescribed for more than 40 years for the treatment of depression and anxiety at dosages 50 to 100 times greater than those we are evaluating for insomnia. Although established as an effective antidepressant at high doses, doxepin is known to have a range of undesirable side effects including daytime sedation and drowsiness, dry mouth, dry eyes and other anticholinergic effects. In controlled clinical trials conducted by Somaxon the side effects observed were comparable to placebo.

To date we have completed two Phase 2 clinical trials and one of our planned Phase 3 clinical trials in patients with insomnia. We are encouraged by the results. The first of our Phase 3 clinical trials to report results (April 2006) demonstrated that SILENOR™ was a safe and effective treatment in adults who have been diagnosed with chronic insomnia. The trial's primary endpoint was Wake After Sleep Onset (WASO) an objective measurement of sleep maintenance. This and other endpoints were evaluated in a sleep laboratory setting over a 35-day period. In this study of 229 patients, SILENOR™ demonstrated a statistically significant benefit versus placebo on measures of sleep onset, sleep maintenance, total sleep time and sleep efficiency at the tested doses. Specifically, in this clinical trial with the tested doses of 3 mg and 6 mg, SILENOR™ demonstrated statistically significant results in adults with chronic insomnia. The primary endpoint for this study, 8 hour WASO, was significant for both doses. SILENOR™ demonstrated improvement in mean WASO of 26 minutes for 3 mg ($p<0.0001$) and 31 minutes for 6 mg ($p<0.0001$) versus placebo for the primary analysis. Statistical significance versus placebo was maintained at both doses for all time points.



Significant improvements were also demonstrated in key secondary endpoints including latency to persistent sleep, a sleep onset measure, total sleep time and sleep efficiency.

Both doses of SILENOR™ were well tolerated. Side effects in the SILENOR™ groups were comparable to placebo and there were no statistically significant differences versus placebo in next day residual measures. There was no evidence of tolerance to SILENOR™ over the treatment period and sleep architecture was preserved. Rebound insomnia, withdrawal effects, memory impairment, weight gain and anticholinergic effects were not observed.

Unlike most approved insomnia medications, SILENOR™ does not act via a set of brain receptors known as the benzodiazepine, or GABA receptors. Drugs that act on these receptors have been associated with amnesia, hallucinations, dependency and addiction. The DEA classifies these products as Schedule IV controlled substances and carefully monitors and controls their prescribing and use. Although the mechanism of action for the sleep-promoting effects of SILENOR™ is not definitively known, it differs from the currently available sleep-promoting agents in that the effects are mediated through the histaminergic system and not GABA. Histamine blocking has been demonstrated to reduce wakefulness and is thought to promote the initiation and maintenance of sleep.

We expect to complete all our additional Phase 3 clinical trials in 2006 and file an NDA in the first quarter of 2007.

Impulse Control Disorders

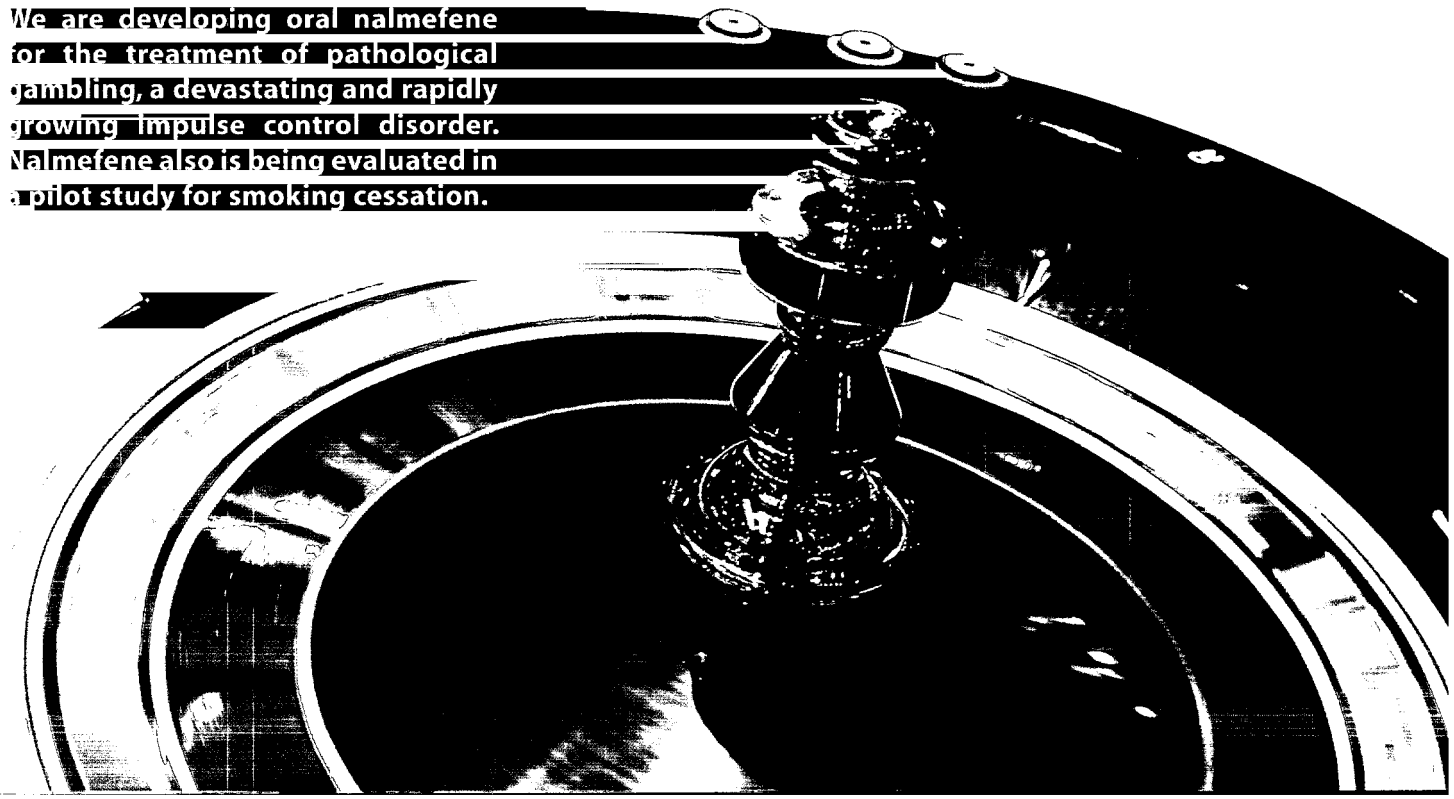
Nalmefene HCl is a specific and selective opioid receptor antagonist (blocker). Opioid receptors have been associated with urges and cravings, common manifestations of people who suffer from impulse control disorders. A Phase 2 clinical trial suggests that nalmefene may help to reduce the urges, cravings and behavior of pathological gamblers.

The impulse control disorder category includes a number of serious conditions, including pathological gambling, kleptomania, pyromania, intermittent explosive disorder and compulsive buying. Problems with gambling are a significant and growing issue. In fact, a recent study estimated that in the United States alone, there are approximately 2.5 million pathological gamblers, 3 million problem gamblers and an additional 15 million people who are at-risk gamblers. Today, there are no approved treatments for this problem.

In a multi-center Phase 2 clinical trial conducted by our licensor, nalmefene was shown to be statistically superior to placebo in limiting gambling behavior and reducing the frequency and intensity of gambling thoughts/urges. In addition, 59% of patients who received 25mg per day of nalmefene were rated as "much improved" or "very much improved" as compared with 34% of those who received placebo. Transient side effects which appeared to be more common and dose related in patients on nalmefene included nausea, insomnia and dizziness.

Based on positive findings from this and other trials of nalmefene, we initiated a confirmatory Phase 2/3 clinical trial for pathological gambling in July, 2005. Additionally, a pilot Phase 2 clinical trial investigating nalmefene for smoking cessation is underway. The company expects results from the smoking cessation trial to be available in mid 2006 and the pathological gambling trial in early 2007.

We are developing oral nalmefene for the treatment of pathological gambling, a devastating and rapidly growing impulse control disorder. Nalmefene also is being evaluated in a pilot study for smoking cessation.



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

Form 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2005

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
None	None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.0001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 ☑

As of March 9, 2006, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $327.5 million, based on the closing price of the registrant's common stock on the Nasdaq National Market of $18.15 per share. The registrant has elected to use March 9, 2006 as the calculation date, as on June 30, 2005 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately-held concern.

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of March 9, 2006 was 18,045,366.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission on or before April 30, 2006 are incorporated by reference into Part III of this report.

SOMAXON PHARMACEUTICALS, INC.

FORM 10-K — ANNUAL REPORT
For the Fiscal Year Ended December 31, 2005

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PART I

Forward-Looking Statements

Any statements in this report and the information incorporated herein by reference about our expectations, beliefs, plans, objectives, assumptions or future events or performance that are not historical facts 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, statements about the progress and timing of clinical trials, the safety and efficacy of our product candidates, the goals of our development activities, estimates of the potential markets for our product candidates, estimates of the capacity of manufacturing and other facilities to support our products, our expected future revenues, operations and expenditures and projected cash needs; and other risks detailed below in Item 1A "Risk Factors."

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.

Corporate Information

We were incorporated in Delaware in August 2003. Our principal executive offices are located at 12750 High Bluff Drive, Suite 310, San Diego, California 92130, and our telephone number is (858) 509-3670. Our website address is www.somaxon.com. Unless the context requires otherwise, in this report the terms "Somaxon," "we," "us" and "our" refer to Somaxon Pharmaceuticals, Inc., a Delaware corporation.

We have received a Notice of Allowance from the U.S. Patent and Trademark Office for the intent-to-use trademark application for our corporate name, Somaxon Pharmaceuticals™, for use in connection with pharmaceutical preparations for the treatment of neurological, psychiatric and rheumatological disorders. We have obtained foreign trademark registrations for the trademark SOMAXON PHARMACEUTICALS in Europe, Japan and Australia and have pending foreign trademark applications for the same mark in Canada. We have also applied for U.S. Trademark registration for SILENOR™ and are developing commercial names for our nalmefene and acamprosate product candidates. All other trademarks, service marks or trade names appearing in this report, including but not limited to Ambien®, Ambien CR™, Campral®, Dalmane®, Desyrel®, Lunesta™, Luvox®, Paxil®, Prozac®, Requip®, Restoril®, Revex®, Rozerem™, Sinequan®, Sonata®, TOPAMAX® and Zyban®, are the property of their respective owners. Use or display by us of other parties' trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

Item 1. *Business*

Overview

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. Since inception, we have in-licensed three product candidates. Our lead product candidate, SILENOR™ (doxepin hydrochloride), is in Phase III clinical trials for the treatment of patients with insomnia. Our product candidate nalmefene hydrochloride is in a Phase II/III clinical trial for the treatment of patients affected by 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 patients with certain movement disorders. We intend 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 or alternative delivery systems, or in late stages of clinical development.

Our current portfolio consists of the following three product candidates:

- *SILENOR ™ for Insomnia.* According to the American Psychiatric Association, approximately one-third of adult Americans (approximately 73 million people) are affected by insomnia. One study has found that fewer than 15% of those who suffer from insomnia are treated with prescription medications. We are developing SILENOR™ for the treatment of patients with insomnia and believe that SILENOR™ will offer significant benefits over currently available therapies in the insomnia market. We in-licensed the patents and the development and commercial rights to SILENOR™and intend to develop the product for the U.S. market. SILENOR™ is an oral formulation of doxepin at strengths of 1 mg, 3 mg, and 6 mg. Doxepin has been marketed and used for over 35 years at dosages from 75 mg to 300 mg per day for the treatment of patients with depression and anxiety. Doxepin has a well-established safety profile and we expect that our targeted dosages will be well tolerated and provide a wide margin of safety. SILENOR™ binds to H1 receptors in the brain and blocks histamine which is believed to play an important role in the regulation of sleep. The leading approved insomnia medications, Ambien, Sonata and Lunesta, work by binding and activating a different set of brain receptors known as GABA receptors. Currently approved GABA receptor-activating drugs are deemed to have the potential for abuse and are therefore designated by the Drug Enforcement Administration, or DEA, as Schedule IV controlled substances, which require additional registration and administrative controls. We have completed two placebo-controlled Phase II clinical trials, one in adults and one in elderly patients with chronic primary sleep maintenance insomnia, and we are currently conducting four Phase III clinical trials in patients with insomnia. Based on our analysis of the results of our prior clinical trials, we believe that SILENOR™ will induce and maintain sleep throughout the night, without next-day residual effects, in both adult and elderly patients. We expect data from our first Phase III clinical trial to be available in the second quarter of 2006 and currently anticipate filing the related New Drug Application, or NDA, in the first quarter of 2007.

- *Nalmefene for Impulse Control and Substance Abuse Disorders.* We are developing nalmefene for the treatment of pathological gambling, an impulse control disorder. We are also evaluating nalmefene for smoking cessation. Nalmefene, an opioid antagonist, is approved and has been used for over 10 years in the United States in an intravenous form for the reversal of opioid drug effects. We in-licensed the North American development and commercial rights to an oral form of nalmefene and patents for its use in the treatment of impulse control disorders, nicotine dependence and other conditions. The impulse control disorder category includes a number of serious conditions, including pathological gambling, kleptomania, pyromania, intermittent explosive disorder and compulsive buying. There are no approved therapies for any of these disorders. The University of Chicago's 1999 Gambling Impact and Behavior Study estimates that in the United States alone, there are approximately 2.5 million pathological gamblers, 3 million problem gamblers and an additional 15 million people who are at-risk gamblers. In a multi-center Phase II clinical trial conducted by our licensor, nalmefene was shown to be statistically superior to placebo in limiting gambling behavior and reducing the frequency and intensity of gambling thoughts/urges. Based on these results, we have initiated a confirmatory Phase II/III clinical trial for pathological gambling. We expect results from the pathological gambling trial to be available in early 2007. We have also initiated a pilot Phase II clinical trial investigating nalmefene for smoking cessation. We expect results from the smoking cessation trial to be available in mid-2006.

- *Acamprosate for Movement Disorders.* We are developing acamprosate for the treatment of patients with tardive dyskinesia, a movement disorder which limits a person's ability to perform activities of daily living and impairs quality of life. In many cases, this disorder is induced by the long-term use of certain drugs prescribed to treat schizophrenia or Parkinson's disease. There are currently no approved therapies to treat this disorder. We in-licensed the worldwide development and commercial rights for the use of acamprosate in the treatment of movement disorders and other conditions. Our acamprosate program is currently focused on the development of a new patent-protected formulation of the drug, designed to reduce daily dosing requirements and improve tolerability. If we are successful in

reformulating the product, we plan to conduct Phase I clinical trials in 2006 prior to initiating a dose-finding Phase II clinical trial in patients with movement disorders.

On December 20, 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 per share for gross proceeds of $55.0 million. Issuance costs related to the offering were $5.2 million resulting in net proceeds from the offering of $49.8 million. In conjunction with the completion of the IPO, all outstanding shares of our convertible preferred stock were converted into 12,241,382 shares of common stock at a conversion rate of one share of common stock for every six shares of preferred stock.

Our Strategy

Our goal is to be a leading specialty pharmaceutical company focused on the in-licensing and development of proprietary product candidates in the fields of psychiatry and neurology. Our near-term strategy is to focus on the regulatory approval of our existing product candidates, and our long-term strategy is to build a portfolio of product candidates that are currently commercialized outside the United States, approved in the United States but with significant commercial potential for proprietary new uses, new dosages or alternative delivery systems, or in late stages of development. Specifically, we intend to:

- *Maximize the value of our lead product candidate, SILENOR™.* We are applying the expertise of our clinical development team to conduct and successfully complete four Phase III clinical trials for SILENOR™ in the treatment of insomnia. We have designed our Phase III clinical program to facilitate regulatory approval and optimize marketing claims for this product candidate. We believe that SILENOR™ will benefit from a strategic alliance to gain competitive access to primary care physicians who write more than 60% of the prescriptions for insomnia. We plan to establish a strategic partnership for the commercialization of SILENOR™ after our Phase III data are available.

- *Build a focused sales and marketing organization to target relevant specialists.* We intend to build a commercial operation tightly focused on promoting our products to psychiatrists and neurologists. Importantly, in these markets a relatively small number of specialists account for a substantial portion of the prescription activity in each category. We will actively pursue strategic collaborations to draw on the development, regulatory and commercial expertise of larger pharmaceutical companies in those instances where we believe our products would benefit from such expertise.

- *Pursue the clinical development of our other product candidates.* In August 2005, we initiated a Phase II/III multi-center, placebo-controlled clinical trial evaluating the safety and efficacy of oral nalmefene in pathological gamblers. In addition, in September 2005, we initiated a Phase II clinical trial for smoking cessation. We estimate that data from these trials will be available in the second half of 2006. We are currently developing new formulations of acamprosate and are planning to conduct a Phase I clinical trial in 2006.

- *Acquire or in-license late-stage development products with substantial human clinical experience.* We will seek additional opportunities to acquire or in-license products to more fully exploit our clinical and regulatory capabilities. We believe the psychiatry and neurology markets are an excellent focal point for a specialty pharmaceutical company, as drugs in these classes represent significant market opportunities. To reduce the risks, costs and time-to-market of clinical development, we will focus on products that are currently commercialized outside the United States, approved in the United States but with significant commercial potential for proprietary new uses, including patent-protected, marketable indications, new dosage forms or alternative delivery systems, or in late states of development.

Our Product Development Programs

Our current product development programs are focused on candidates in the fields of psychiatry and neurology. Our portfolio consists of the following three product candidates:

Product	Indication	Patent Rights	Marketing Rights	Phase of Development
SILENOR™	Insomnia	United States	Worldwide	Phase III • Adult 35 day trial (enrollment complete) • Elderly 3 month trial (enrolling) • Elderly 1 month outpatient trial (enrolling) • Transient insomnia trial (enrolling)
Nalmefene	Pathological gambling and other impulse control disorders	United States	North America	Phase II/III (enrolling)
	Smoking cessation/ nicotine dependence	United States	Worldwide	Phase II (enrollment complete)
Acamprosate	Movement disorders and other conditions	Worldwide	Worldwide	Formulation development

Additionally, all of our product candidates require additional Phase I clinical evaluation prior to submission of an NDA. For example, with regard to SILENOR™ we are undertaking several Phase I clinical trials which evaluate the effect of food on absorption of the product candidate and the effect of SILENOR™ when co-administered with other drugs. With regard to nalmefene, we plan to initiate a clinical trial evaluating the product candidate's cardiac effect when measured by an electrocardiogram. With regard to acamprosate, various preclinical and Phase I clinical trials are planned to facilitate the selection and evaluation of a new formulation for the product candidate to be tested in subsequent trials.

SILENOR™ (doxepin hydrochloride) for Insomnia

Disease Background and Market Opportunity

Sleep is essential for human performance, general health and well-being. Insomnia, the most common sleep complaint across all stages of adulthood, is a condition characterized by difficulty falling asleep, waking frequently during the night or too early, or waking up feeling unrefreshed. According to the American Psychiatric Association, approximately one-third of adult Americans (approximately 73 million people) are affected by insomnia. One study has found that fewer than 15% of those who suffer from insomnia are treated with prescription medications. Chronic insomnia, insomnia lasting more than four weeks, is often associated with a wide range of adverse conditions, including mood disturbances, difficulties with concentration and memory, and certain cardiovascular, pulmonary and gastrointestinal disorders. Even in otherwise healthy young people, sleep deprivation has been associated with early signs of aging, carbohydrate intolerance and insulin resistance. It is estimated that health care services and medications used for the treatment of insomnia cost almost $14 billion in 1999, a number that is likely to increase with the aging of the U.S. population.

The U.S. market for prescription products to treat insomnia exceeded $3.3 billion in 2005, according to Wolters Kluwer (formerly known as NDC Health), a growth rate of 25% for the year. Ambien is the current market leader in the insomnia segment. According to Wolters Kluwer, Ambien accounted for approximately $2.3 billion in retail sales in 2005. Other sedative hypnotics, including: Sonata, newly introduced Lunesta and Rozerem, several hypnotic benzodiazepines such as temazapam (Restoril) and flurazepam (Dalmane), and sedative antidepressants such as trazodone (Desyrel), which are usually available in generic forms, account for the remaining prescriptions.

We believe that sedative antidepressants account for a large percentage of the total prescriptions written for insomnia because they are not Schedule IV controlled substances. The National Disease and Therapeutic Index estimates that more than 66% of trazodone prescriptions may be prescribed off-label for insomnia, even

though trazodone is not indicated for that use. Despite limited data to support the safety and efficacy of trazodone for insomnia, trazodone is often prescribed off-label because it is a non-scheduled agent, unlike the benzodiazepines and GABA-receptor agonists.

Increased awareness and diagnosis of insomnia as well as the limitations of current treatments have led to the development of several new drugs to treat the condition. Lunesta was launched in April 2005, and Rozerem and Ambien CR were launched in September 2005.

Other compounds are currently in development or undergoing regulatory review.

We believe that the increased awareness at both the patient and physician level, the limitations of current therapy and the commercialization and promotion of new products will substantially increase the size of the insomnia market.

Limitations of Current Therapies

According to the 2005 Sleep in America Poll, 54% of respondents reported experiencing insomnia symptoms a few nights a week, 21% of respondents had difficulty falling asleep (sleep onset), 32% awoke often during the night (sleep maintenance) and 21% woke up too early and could not get back to sleep (sleep maintenance and duration). Historically, insomnia therapies have addressed sleep onset rather than sleep maintenance and duration. Only recently have therapies been approved with indications for sleep maintenance.

While there are a number of products currently available for the treatment of insomnia, we believe that the market is still underserved due to the limitations of current therapies. The primary limitations of current therapies relate to the abuse potential of Schedule IV controlled substances, tolerability or undesirable side effects, and the limited ability to address all three major components of insomnia: sleep onset, maintenance and duration.

All drugs approved for the treatment of insomnia that act via the GABA receptors are Schedule IV controlled substances. These drugs, benzodiazepines and other GABA-receptor agonists, are deemed by the U.S. Food and Drug Administration, or FDA, and the DEA to have a potential for addiction and abuse and are classified by the DEA as Schedule IV controlled substances. As a result, many physicians are reluctant to prescribe, and patients are reluctant to take, scheduled drugs for chronic use in treating insomnia. The prescribing of a Schedule IV controlled substance brings scrutiny from the DEA and other regulatory bodies, and requires unique and burdensome registration and administrative controls. We believe that many physicians are uncomfortable prescribing controlled substances, especially when treating a patient with a history of addiction or when other effective non-scheduled treatment options are available.

Drugs currently prescribed for insomnia, including antidepressants, benzodiazepines or other drugs that work via the GABA receptors, are associated with many unwanted side effects, such as dry mouth, unpleasant taste, blurred vision, residual next-day effects, memory loss, hormonal changes and gastrointestinal effects. We believe that drugs with improved tolerability would be well received by both physicians and patients.

SILENOR™ and Its Advantages

Based on our analysis of the results of the SILENOR™ Phase II clinical trials which demonstrated a statistically significant improvement in sleep onset and sleep maintenance and duration in adults and elderly and the design of the Phase III clinical program for SILENOR™, we believe that there is an opportunity to obtain FDA approval of SILENOR™ for the treatment of insomnia that will offer a number of significant competitive advantages over other insomnia therapies:

- *Non-scheduled.* Doxepin, at higher dosages, is not a scheduled drug. Additionally, the doxepin package insert states that doxepin has not been demonstrated to produce the physical tolerance or psychological dependence associated with addictive compounds. Because doxepin is the sole active ingredient in SILENOR™, we believe that SILENOR™ will likewise be a non-scheduled drug.

- *Safety and tolerability.* SILENOR™ will benefit from doxepin's well-established safety profile, having been prescribed for over 35 years at up to 50 times our proposed maximum insomnia dosage. Clinical results to date have demonstrated no significant unwanted side effects or next-day residual effects relative to placebo.

- *Efficacy.* We believe that SILENOR™ may be the first non-scheduled drug to improve all three key sleep parameters: sleep onset, maintenance and duration.

- *Population.* We anticipate that SILENOR™ will be suitable for the treatment of chronic and transient insomnia in adults and the elderly, demonstrating benefits to a broad segment of insomnia patients.

- *Long-term use.* SILENOR™ may have the potential for long-term use. Doxepin is currently indicated and prescribed for long-term use in patients with depression and anxiety. Doxepin at dosages of 25 mg to 50 mg had also been evaluated by Hajak et al for the treatment of insomnia for up to four weeks in a randomized, controlled clinical study which demonstrated that the efficacy that was observed on night one was sustained at night twenty-eight. Additionally, in a 20-patient, 12-week, double-blind, placebo-controlled proof-of-principle trial, doxepin at a strength of 6 mg demonstrated improvements on numerous measures related to sleep maintenance and duration at several time points. The effects were sustained over the 12-week evaluation period.

SILENOR™ is an oral formulation of doxepin at strengths of 1 mg to 6 mg. Doxepin belongs to a class of psychotherapeutic agents known as dibenzoxepin tricyclic compounds. Doxepin was first approved by the FDA in 1969 and was originally marketed by Pfizer Inc. under the brand name Sinequan. Doxepin is currently marketed in oral capsule and solution form for depression and anxiety. Therapeutic dosages of doxepin for its indicated uses range from 75 mg to 300 mg daily, and at these dosages, doxepin exhibits potent sedative properties. However, the available strengths of doxepin are seldom used in the treatment of insomnia as they leave many patients reporting next-day residual effects and other undesirable side effects. It has been hypothesized that doxepin's sedative effects on sleep derive from strong H1 histamine-blocking properties. It is believed that the drug does not work via any of the GABA receptors and, according to its current FDA-approved labeling, does not appear to have any potential for dependency, addiction or abuse.

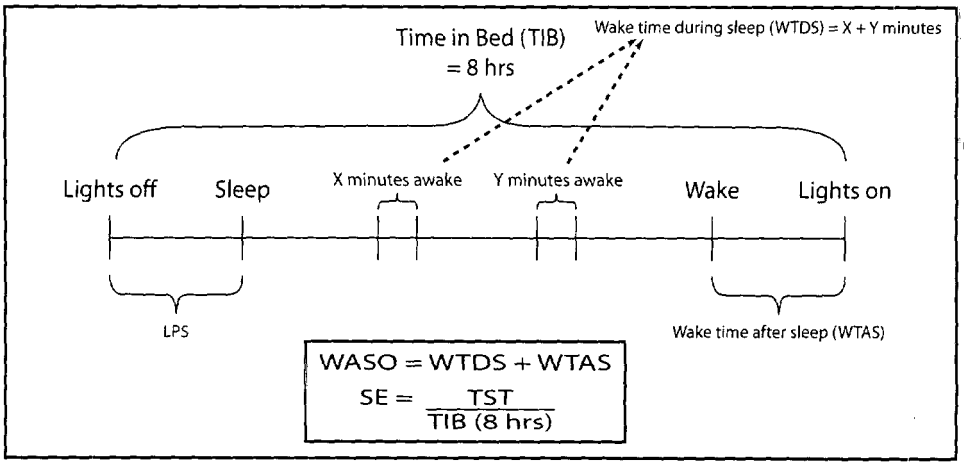
We completed two Phase II randomized, multi-center, double-blind, placebo-controlled, dose-response clinical trials in a sleep laboratory setting in patients with primary sleep maintenance insomnia. One clinical trial evaluated SILENOR™ in adults and the other in the elderly. The goal of these trials was to evaluate a range of sleep efficacy parameters, and to evaluate the safety and tolerability profile of various strengths of doxepin (1 mg, 3 mg and 6 mg). Each trial was conducted at 11 sites throughout the United States. All patients participated in four double-blind treatment periods (three dosages of low-dose doxepin as well as placebo) using a crossover design. Each patient received, in a random fashion, all trial doses including placebo in a sleep laboratory setting, and the trial included a five- or 12-day drug-free period between each dose designed to assure drug clearance.

The objective sleep efficacy parameters that we evaluated included Wake After Sleep Onset, or WASO, which is defined as the number of minutes a patient is awake from the time the patient initially falls asleep until the end of the evaluation period. WASO is the FDA's preferred endpoint for the purpose of demonstrating sleep maintenance in sleep laboratory studies. We also evaluated Total Sleep Time, or TST, which is the total minutes of sleep recorded; Sleep Efficiency, or SE, which is the total minutes of sleep divided by the total minutes in bed (8 hours); and Latency to Persistent Sleep, or LPS, which is the number of minutes it takes to achieve persistent sleep. We also evaluated a number of patient-reported sleep outcomes including subjective TST, which is the patient's estimate of the total minutes of sleep, and Latency to Sleep Onset, or LSO, which is the patient's estimate of how long it took to fall asleep.

In each patient, the drug effects were measured against the placebo using a statistical methodology of p values. A p value is a measurement of statistical significance that represents the risk that the observed difference is caused by chance alone. A p value of < 0.05 indicates that the probability of concluding that the

two groups are different, when they are actually not different, is less than five percent, and is usually the threshold for which one can declare confidence that the observed difference is meaningful.

The objective sleep efficacy parameters are illustrated in the following diagram:



The above diagram assumes two awakenings: one of "X" minutes duration and one of "Y" minutes duration. The actual number and length of awakenings during the night will vary by patient.

Results of the clinical trials can be summarized as follows:

Adult Phase II Clinical Trial (67 patients)

Wake After Sleep Onset. WASO at all tested dosages of SILENOR™ (1 mg, 3 mg and 6 mg) showed statistically significant improvements as compared to placebo (1 mg, $p = 0.009$; 3 mg and 6 mg, $p < 0.0001$). The mean number of minutes of WASO for placebo was 61.1 minutes, improving to 46.7 minutes at 1 mg, 38.9 minutes at 3 mg and 38.1 minutes at 6 mg dosages of SILENOR™.

Total Sleep Time. TST improved significantly at all SILENOR™ dosages (1 mg, $p = 0.0005$; 3 mg and 6 mg, $p < 0.0001$) as compared to placebo. The mean number of minutes of TST for placebo was 389.6 minutes, improving to 407.5 minutes at 1 mg, 415.4 minutes at 3 mg and 418.4 minutes at 6 mg dosages of SILENOR™.

Sleep Efficiency. SE was measured for the entire night, and analyzed for the initial, middle and final thirds of the night. This approach is useful in assessing the drug's ability to maintain sleep throughout the night. All dosage levels of SILENOR™ showed a significant improvement in SE for the entire night (1 mg, $p = 0.0005$; 3 mg and 6 mg, $p < 0.0001$). As measured in percentages, the mean SE for placebo was 81.2%, improving to 84.9% at 1 mg, 86.5% at 3 mg and 87.2% at 6 mg dosages of SILENOR™. SILENOR™ showed a positive effect on SE in the first and middle thirds of the night. Even in the last third of the night, when many insomnia patients tend to wake up and are unable to fall back asleep, SILENOR™ at all dosages significantly improved SE ($p < 0.0001$) as compared to placebo. In the final third of the night, the mean SE for placebo was 79.6%, improving to 86.8% at 1 mg, 88.2% at 3 mg and 89.3% at 6 mg dosages of SILENOR™. We believe that this observation demonstrates the persistent nature of the sleep maintenance effect.

Sleep Onset. The primary goal of the Phase II clinical trials was to demonstrate the effect of SILENOR™ on sleep maintenance and, therefore, the trials were not specifically designed to study effects on sleep onset. Despite this, LPS improved numerically (up to 19%) over placebo, but did not reach statistical significance. Patients' subjective assessment of LSO was superior to placebo at all dosages, reaching statistical significance at 6 mg ($p < 0.03$). The mean number of minutes for LSO improved from 49.6 minutes at placebo to 46.5 minutes at 1 mg, 45.3 minutes at 3 mg and 43.0 minutes at 6 mg dosages of SILENOR™.

Other Parameters. Other objective and subjective parameters, such as Wake Time During Sleep, or WTDS, and subjective TST were generally consistent with the above-described results.

SILENOR™ was well tolerated at all dosages evaluated. The number of patients reporting adverse events, as well as the incidence and nature of adverse events, was similar across all dosages of SILENOR™ and placebo. There were no reports of memory impairment and no serious adverse events. There were no clinically relevant changes noted in laboratory parameters, electrocardiograms, or ECGs, vital signs, physical examinations or neurological assessments. Tests specifically administered to assess hangover/ residual effects exhibited no significant differences versus placebo.

Elderly Phase II Clinical Trial (76 patients)

Wake After Sleep Onset. WASO at all tested dosages of SILENOR™ (1 mg, 3 mg and 6 mg) produced statistically significant improvements as compared to placebo ($p < 0.0001$). The mean number of minutes of WASO for placebo was 98.0 minutes, improving to 80.1 minutes at 1 mg, 70.8 minutes at 3 mg and 64.3 minutes at 6 mg dosages of SILENOR™.

Total Sleep Time. TST improved significantly at all SILENOR™ dosages ($p < 0.0001$) as compared to placebo. The mean number of minutes of TST for placebo was 360.7 minutes, improving to 377.4 minutes at 1 mg, 390.6 minutes at 3 mg and 398.4 minutes at 6 mg dosages of SILENOR™.

Sleep Efficiency. SE for the entire night was significantly improved for all dosages ($p < 0.0001$) versus placebo. As measured in percentages, the mean SE for placebo was 75.1%, improving to 78.6% at 1 mg, 81.4% at 3 mg and 83.0% at 6 mg dosages of SILENOR™. SILENOR™ showed a positive effect on SE in the first and middle thirds of the night. In the final third of the night, 3 mg and 6 mg dosages significantly improved SE versus placebo ($p < 0.0001$). In the final third of the night, the mean SE for placebo was 69.2%, improving to 73.0% at 1 mg, 78.9% at 3 mg and 80.8% at 6 mg dosages of SILENOR™. We believe that this observation demonstrates the persistent nature of the sleep maintenance effect.

Sleep Onset. As in the adult trial, the selection criteria for entry into the trial targeted patients with sleep maintenance, not sleep induction difficulties. Despite this approach, SILENOR™ improved LPS numerically as compared to placebo. Subsets analyses of patients with greater difficulty falling asleep at baseline suggest a more pronounced effect of SILENOR™ versus placebo. LSO demonstrated a statistically significant improvement ($p < 0.02$) at the 6 mg dosage as compared to placebo. The mean number of minutes for LSO improved from 45.5 minutes at placebo to 33.8 minutes at the 6 mg dosage of SILENOR™.

SILENOR™ was well tolerated at all dosages. The number of patients reporting adverse events, as well as the incidence and nature of adverse events, was similar across all dosages of SILENOR™ and placebo. There were no reports of memory impairment, and no drug-related serious adverse events. There were no clinically relevant changes noted in laboratory parameters, vital signs, physical examinations, neurological assessments or ECGs. Results of tests specifically administered to assess hangover/residual effects exhibited no significant differences versus placebo.

Clinical Development Plan

After an End of Phase II meeting with the FDA, we initiated a Phase III clinical trial program for SILENOR™. By early 2006, we had commenced four Phase III clinical trials for the treatment of insomnia. These trials are designed to demonstrate the safety and efficacy of SILENOR™ in adult and elderly patients with primary chronic insomnia characterized by sleep maintenance difficulties and in adults with induced transient insomnia. The four Phase III trials will collectively enroll approximately 1,200 patients.

Enrollment in the first Phase III clinical trial began in the second quarter of 2005. This trial is a randomized, placebo-controlled, double-blind, multi-center 35-day study that objectively measures sleep endpoints in a sleep laboratory setting. The trial also assesses subjective patient-reported outcomes. This trial assesses the safety and efficacy of SILENOR™ in approximately 240 adults with primary sleep maintenance insomnia. The primary endpoint of the trial is WASO, the sleep maintenance endpoint recommended by the

FDA. We will evaluate several additional secondary endpoints, measured both objectively and as subjective patient-reported outcomes. Data from this trial are anticipated to be available in the second quarter of 2006.

We initiated a second Phase III clinical trial in September 2005. This trial is a three-month evaluation of SILENOR™ in approximately 250 elderly patients diagnosed with primary sleep maintenance insomnia. The primary endpoint is WASO. Multiple secondary endpoints, measured both objectively and as patient-reported outcomes, will be evaluated. We have initiated two additional Phase III clinical trials with SILENOR™. One provides a second evaluation of the product in approximately 240 elderly patients in an outpatient setting for four weeks. Subjective TST is the intended primary endpoint of this trial. The other Phase III clinical trial, which began in early 2006, is designed to evaluate the safety and efficacy of SILENOR™ in approximately 500 adults with induced transient insomnia. The primary endpoint for this trial will be LPS.

Based upon discussions with the FDA, we anticipate that this clinical development program will support the submission of an NDA. The FDA has indicated that we may submit the NDA for SILENOR™ using an application under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, an approach to seek regulatory approval for, among other things, new indications of drugs which have previously been approved by the FDA. The process allows a company to rely on published literature reports or the FDA's findings of safety and efficacy for a previously-approved drug for which the company does not have a right of reference. This may mean that we would not be required to duplicate some previously conducted research, accordingly saving the company time and money. In addition, we may qualify for a period of three-year marketing exclusivity for a new condition of approval. We currently anticipate filing the NDA in the first quarter of 2007.

Nalmefene for Impulse Control and Substance Abuse Disorders

Disease Background and Market Opportunity

Impulse control disorders affect millions of Americans and have been recognized by the Diagnostic and Statistical Manual of Mental Disorders as a clinical diagnosis since 1980. The Diagnostic and Statistical Manual of Mental Disorders — Fourth Edition, or DSM-IV, published by the American Psychiatric Association, is the standard reference manual used to classify and diagnose mental disorders. The impulse control disorder category includes pathological gambling, kleptomania, pyromania, intermittent explosive disorder and compulsive buying. The University of Chicago's 1999 Gambling Impact and Behavior Study estimates that in the United States alone, there are approximately 2.5 million pathological gamblers, 3 million problem gamblers and an additional 15 million people who are at-risk for pathological gambling. There is also growing evidence of problematic adolescent gambling. The Gambling Impact and Behavior Study of 1999 found that approximately 3.5% of 16 to 17 year-olds could be considered at-risk, problem or pathological gamblers. In particular, the pervasiveness of internet gambling is a potential facilitating factor in youth gambling. Other disorders such as intermittent explosive disorder and compulsive buying are also significant problems. According to Datamonitor, potentially 6.4 million persons in the United States suffer from intermittent explosive disorder. Although estimates of the market for compulsive buying vary widely, based on a report in the 2004 *Annals of Clinical Psychiatry*, we believe the prevalence of this disorder ranges from 1.1% to 5.9% of American adults, or 2.4 to 13.0 million American adults.

We are evaluating nalmefene in a Phase II/ III clinical trial for the treatment of pathological gambling, which represents a significant unmet medical need. Currently, there is no approved drug therapy to treat pathological gambling. Pathological gambling is characterized by persistent and recurrent patterns of gambling behavior. Accordingly, pathological gambling often results in impaired functioning and reduced quality of life. Pathological gamblers may experience difficulties at work, become demoralized and depressed, abuse alcohol or drugs and develop other psychiatric co-morbidities. There is a high co-morbidity between pathological gambling and substance abuse disorders, particularly alcohol abuse and dependence. In 2005, Petry et al. reported in the *Journal of Clinical Psychiatry* that almost three-quarters of pathological gamblers had alcohol use disorder and approximately 38% had drug use disorder. We believe that pathological gambling remains largely a neglected public health problem due to a low rate of diagnosis and lack of approved treatments.

Impulse control disorders share features with substance abuse disorders, including drug, alcohol and tobacco addiction, which potentially have similar neurobiological mechanisms. Substance abuse disorders,

including nicotine dependence, are major public health problems in the United States. In 2005, the U.S. Centers for Disease Control and Prevention, or CDC, estimated that approximately 45 million, or 22%, of adults in the United States are smokers. The impact of nicotine dependence in terms of morbidity, mortality and economic costs to society is enormous. According to the Surgeon General, tobacco usage kills more than 440,000 people in the United States annually. Smoking is linked to an estimated $75 billion in medical expenditures in the United States per year. When indirect costs such as lost productivity due to smoking are considered, the costs increase significantly to approximately $158 billion per year.

Limitations of Current Therapies

There are no approved drugs for the treatment of pathological gambling or other impulse control disorders. Another opioid antagonist, naltrexone, has been investigated in the treatment of pathological gambling. Various studies of naltrexone, including a double-blind, placebo-controlled trial, suggest that an opioid antagonist may be effective for the pharmacological treatment of this disorder. Efficacy appears to require dosing at levels significantly higher than approved in the product's current label, which carries a "black box" warning related to liver toxicity.

Currently, the standard of care for pathological gambling is behavioral and cognitive therapy. Most states have a gambling hot-line that refers patients to specialists or to Gamblers Anonymous. Although approximately 1,000 chapters exist in North America, there is little evidence to suggest the long-term efficacy of Gamblers Anonymous. Specific psychotherapies that focus on changing inappropriate thoughts and behaviors, such as cognitive and behavioral therapies, have shown promise. However, access to this form of treatment is often limited by insurance barriers, cost factors and an inadequate number of trained therapists.

Various pharmacological interventions have shown inconsistent results in efficacy studies of the treatment of pathological gambling. Selective serotonin reuptake inhibitors, or SSRIs, such as GlaxoSmithKline plc's Paxil and Solvay Pharmaceuticals, Inc.'s Luvox, which have been demonstrated to have anti-compulsive and anti-impulsive effects, were theorized to have a potential in treating impulse control disorders. To date, however, SSRIs have demonstrated mixed results in the treatment of pathological gambling and other impulse control disorders in controlled clinical trials.

There are a number of approved approaches to the treatment of nicotine dependence, including nicotine replacement therapy and the use of antidepressants, but they are not effective for a majority of patients. According to a 2001 National Institute on Drug Abuse Research Report, nearly 35 million smokers make a serious attempt to quit each year, but most relapse within a few days of attempting to quit and less than 7% achieve more than one year of abstinence. Behavioral therapies have also been used with some success. There remains an enormous need for improved therapies to treat this critical public health problem.

Nalmefene and its Advantages

Nalmefene is a specific and selective opioid receptor antagonist characterized by its affinity to multiple opioid receptor sites. Nalmefene works similarly to other opioid receptor antagonists such as naltrexone and naloxone, but has an alternate metabolism pathway and has been shown in animal studies to be more potent and more bioavailable. BioTie Therapies Corp., our licensor, has sponsored eight clinical trials (Phase I to Phase III) with oral nalmefene for alcohol use disorders. BioTie Therapies has also conducted one Phase II clinical trial in pathological gambling. In these nine trials, over 800 subjects were exposed to nalmefene at daily dosages of 5 mg to 100 mg for various periods, and at dosages up to 40 mg for a period of 52 weeks. The safety profile of nalmefene in those clinical trials was acceptable. While previous alcoholism and pathological gambling studies conducted by our licensor did not demonstrate an effect on liver function tests, a recent review of unpublished data indicates elevations of enzymes in liver function tests in a small number of patients. As with all clinical studies, we continue to closely monitor for any such effects in our ongoing clinical trials, and will provide additional data when these studies are completed.

In a double-blind, multi-center Phase II clinical trial, nalmefene was effective and well-tolerated in the acute treatment of pathological gambling. The trial, conducted by BioTie Therapies, was a 16-week randomized, placebo-controlled, dose-response trial conducted at fifteen academic centers across the

United States to compare the efficacy of nalmefene with placebo in the treatment of adults with pathological gambling. Two hundred seven subjects meeting the DSM-IV criteria for pathological gambling were randomized to one of three fixed daily dosages of nalmefene (25 mg, 50 mg or 100 mg) or placebo. The primary endpoint consisted of mean change from baseline on the Yale Brown Obsessive Compulsive Scale modified for Pathological Gambling, or PG-YBOCS, a clinician-administered questionnaire for assessing gambling thoughts/urges and behavior.

The primary endpoint was PG-YBOCS at week 16. All three dose groups demonstrated improvements, which were statistically significant compared to placebo for the 25 mg and 50 mg groups ($p = 0.005$ and $p = 0.045$, respectively), but the study data was compromised by high discontinuation rates, with only 73 patients completing the study. Incidents of adverse events were higher with increasing dosages. The most common adverse events included nausea, dizziness, headache and insomnia. No serious adverse events related to the trial drug were reported.

Clinical Development Plan

In October 2004, we met with the FDA for an End of Phase II meeting concerning nalmefene for the treatment of pathological gambling. In August 2005, we initiated a confirmatory Phase II/ III clinical trial evaluating the safety and efficacy of oral nalmefene in the treatment of patients with pathological gambling. This is a randomized, double-blind, placebo-controlled, outpatient, multi-center trial to assess the efficacy, safety and tolerability of nalmefene at daily dosages of 20 mg and 40 mg. This trial is being conducted in approximately 225 patients with a diagnosis of pathological gambling as defined by the DSM-IV criteria. The expected duration of trial participation for a patient is approximately 15 weeks. This trial has been designed to address historically high discontinuation rates and to enhance patient recruitment and retention with a focus on an improved dosing strategy, personalized patient support programs and integrated advertising and recruitment efforts. The primary efficacy endpoint will assess gambling thoughts/urges and behavior via the PG-YBOCS, while secondary endpoints include a number of additional physician and patient assessment measures. We anticipate that data from this trial will be available in early 2007.

Pending the results of our Phase II/ III clinical trial, the FDA has agreed to review our clinical protocols for future Phase III clinical trials under a Special Protocol Assessment, or SPA. Under an SPA, the FDA provides guidance on the design of a trial prior to its initiation. We also plan to conduct a number of additional preclinical studies and Phase I clinical trials to further assess the safety of nalmefene at the dosages targeted for pathological gambling and nicotine dependence. While nalmefene has been approved and marketed in an intravenous form under the brand name Revex for over ten years, the recommended intravenous dose results in blood levels that are below those observed at the anticipated oral dosages, necessitating further documentation and clinical research for regulatory approval.

Impulse control disorders share common characteristics with other addictions including substance abuse. In a Phase II clinical trial of nalmefene for the treatment of alcohol dependency, an investigator from the University of Miami observed that smokers who received 80 mg of nalmefene experienced a reduction in their cigarette consumption. As a result of these findings, we initiated a Phase II clinical trial of nalmefene for the treatment of nicotine dependency in September 2005. This is a single-center, randomized, placebo-controlled, double-blind, outpatient, pilot clinical trial to assess the efficacy and safety of nalmefene hydrochloride at daily dosage of 40 mg and 80 mg. This trial will be conducted in approximately 75 patients. Should this trial yield positive results in the treatment of patients with nicotine dependence, we will evaluate further development options.

Acamprosate for Movement Disorders

Disease Background and Market Opportunity

Tardive dyskinesia is a debilitating movement disorder that limits a person's ability to perform activities of daily living and impairs quality of life. Tardive dyskinesia is often caused by the long-term use of certain drugs used to treat some psychiatric or neurological conditions, such as schizophrenia or Parkinson's disease. It is characterized by involuntary and repetitive movements of the face, trunk and limbs. According to

Datamonitor, tardive dyskinesia affects approximately 600,000 people in the United States. We believe that fewer than 200,000 people in the United States exhibit moderate to severe symptoms.

Limitations of Current Therapies

There are a variety of medications prescribed off-label to lessen the symptoms associated with tardive dyskinesia, including benzodiazepines, dopamine depleting agents, serotonergic agents and calcium channel blockers. These therapies are associated with significant side effects, including cognitive effects, sedation, depression, physical dependency and parkinsonianism.

Acamprosate and its Advantages

Acamprosate calcium is a synthetic compound which works through two mechanisms; it is a GABA-receptor agonist and a NMDA-glutamate receptor antagonist. We believe that these two neurotransmitters — GABA and glutamate — may play an important role in mediating the effects of certain movement disorders. Acamprosate increases GABA transmission and diminishes the response to glutamate, potentially reducing the recurrent involuntary movements associated with tardive dyskinesia.

Our licensor has administered acamprosate to a small number of patients with severe movement disorders. All patients showed a clinically meaningful response with positive effects.

The FDA recently approved acamprosate for the maintenance of alcohol abstinence. It is marketed by Forest Laboratories, Inc. as Campral. The recommended daily dosage is approximately 2 grams dosed as two 333 mg tablets, three times daily. It has been marketed in Europe for alcohol abstinence since 1989 and has an established safety profile. More than 1 million patients with alcohol dependence have been treated with acamprosate worldwide. Side effects have been limited, with mild to moderate diarrhea cited most frequently (10% to 17%).

Development Plan

We in-licensed the patents associated with acamprosate's use in movement disorders, obsessive compulsive disorder and post-traumatic stress disorder. We are developing a new formulation of acamprosate prior to conducting any clinical trials. Acamprosate is a compound characterized by poor bioavailability (11%). As a result, the approved form of acamprosate requires that patients take two tablets, three times a day for the current indication. In the first quarter of 2005 we entered into a product formulation and development agreement to develop an improved, patent-protected form of acamprosate. If a formulation is achieved that can significantly reduce the amount of drug required to demonstrate a clinical effect, it may result in less frequent and/or lower dosages. Formulation development work is underway and, if we are successful in reformulating the product, we anticipate initiating required Phase I clinical trials during 2006 prior to initiating a dose-finding Phase II clinical trial in patients. We have filed an application under the Orphan Drug Act seeking a designation of acamprosate as an orphan drug for the treatment of moderate to severe tardive dyskinesia. The FDA grants orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. We intend to rely on and reference certain available data for our regulatory submission as a basis for FDA approval.

Commercialization Strategy

We currently do not have significant internal sales, distribution and marketing capabilities. In order to commercialize any of our product candidates, we must either acquire or internally develop sales, marketing and distribution capabilities, or enter into collaborations with partners to perform these services for us, or both. In connection with the final regulatory approval, if any, of our first product candidate, we intend to build a U.S. commercial operation tightly focused on promoting our products to psychiatrists and neurologists. We believe that we can achieve our goals by deploying an experienced sales organization supported by an internal

marketing infrastructure that targets the highest prescribers in the fields of psychiatry and neurology. We plan to partner our products with larger pharmaceutical companies where marketing and expanded reach to primary care physicians could expand the market penetration for our product candidates. In particular, we believe that, assuming favorable Phase III results, SILENOR™ will be an excellent candidate for partnering and we anticipate launching the product with a partner who has the resources and sales and marketing capabilities to be competitive in the insomnia market.

Our targeting of psychiatrists and neurologists will allow our commercial operations to stay focused and to leverage our infrastructure across brands. Psychiatrists and neurologists account for approximately 15% of branded prescriptions for insomnia and we believe they will account for a majority of the prescriptions for oral nalmefene and a reformulated acamprosate. Based on data from IMS Health regarding physician prescribing patterns, we estimate that a sales force of approximately 150 people can effectively cover more than 40% of the prescriptions written by psychiatrists for insomnia. We believe that a small number of additional sales representatives can be effective in promoting oral nalmefene for pathological gambling to psychiatrists and can reach the most influential neurologists and movement disorder specialists for acamprosate. We believe this infrastructure will also allow us to acquire or in-license additional products or to co-promote products targeted at these specialties.

Technology In-Licenses

ProCom One Agreement (SILENOR™)

In a license agreement entered into in August 2003, as amended in October 2003, we acquired the exclusive, worldwide license from ProCom One, Inc. to certain patents to develop and commercialize low dosages of doxepin for the treatment of insomnia. Although our license to the low-dose doxepin patents is a worldwide license, we currently intend to develop and commercialize SILENOR™ in the United States only, since patent protection for the current dosage form is limited to the United States. The term of the license extends until the last licensed patent expires, which is expected to occur in 2020. The license agreement is cancelable at any time by us with 30 days' notice if we believe that the use of the product poses an unacceptable safety risk or if it fails to achieve a satisfactory level of efficacy. Either party may terminate the agreement with 30 days' notice if the other party commits a material breach of its obligations and fails to remedy the breach within 90 days, or upon the filing of bankruptcy, reorganization, liquidation, or receivership proceedings.

As consideration for the license, we paid $100,000 as an option payment and $400,000 as the first milestone payment for a total of $500,000 for the period ended December 31, 2003. In December 2004, we accrued $500,000 for a milestone due upon the completion of the first Phase II clinical trial, which was paid in January 2005. We also issued 84,058 shares of common stock to ProCom One contemporaneous with our Series A preferred stock financing. Future payments of an aggregate of $1.5 million may be payable upon the achievement of various milestones related to the lapse of time or the occurrence of various clinical or regulatory events. We are also obligated to pay a royalty on worldwide net sales of the licensed products. We have the right to grant sublicenses to third parties.

BioTie Therapies Agreement (nalmefene for impulse control disorders)

In July 2004, we entered into an option agreement with BioTie Therapies to license oral nalmefene hydrochloride for the treatment of impulse control disorders, alcohol dependence, obsessive compulsive disorders, eating disorders and nicotine dependence. We paid $200,000 to BioTie Therapies for this option. We exercised the option in November 2004 and entered into an exclusive license with BioTie Therapies to certain patents to develop, manufacture, and market nalmefene in North America. We also agreed not to sell a competing product for a period of time after the first commercial sale of the product contemplated by the license agreement. As consideration for the license, we paid an upfront fee of $3.0 million to BioTie Therapies.

The term of the license extends through the expiration of each licensed patent or patent application, which is expected to occur in 2017. We may cancel the agreement with 30 days' written notice if the product poses an unacceptable safety risk for patients or fails to achieve efficacy in clinical development. Either party

may cancel the agreement with 60 days' written notice upon material breach of the contract and failure to cure such breach, or if either party becomes insolvent or is adjudged bankrupt.

Future payments of an aggregate of $10.0 million may be payable upon achievement of various regulatory events, with potential additional payments associated with any subsequent indications. We are also obligated to pay BioTie Therapies a royalty on net sales of licensed products. No milestones are due prior to NDA acceptance by the FDA. We have the right to sublicense to third parties and we are required to pay BioTie Therapies part of any sublicense revenue we receive.

University of Miami Agreement (nalmefene for smoking cessation)

In January 2005, we in-licensed exclusive worldwide rights from the University of Miami to a patent relating to the treatment of nicotine dependence. The patent expires in 2016. The term of the license extends generally through the expiration of the patent, and potentially longer under certain circumstances. The agreement is cancelable by us at any time with 60 days' written notice. The University of Miami may terminate the agreement upon a material breach of the contract, provision of a false report, or our insolvency or certain bankruptcy proceedings.

As consideration for the license, we paid $35,000 upon entering the license, $20,000 upon commencement of the Phase 1 clinical trial for the treatment of nicotine dependence, and are obligated to make immaterial annual license payments. Future payments of an aggregate of $375,000 may be payable upon achievement of various clinical, regulatory or commercial events. We are also obligated to pay the University of Miami a royalty on net sales of licensed products. We have the right to sublicense to third parties and we are required to pay the University of Miami part of any sublicense revenue we receive.

Synchroneuron Agreement (acamprosate for movement disorders)

In September 2004, we in-licensed exclusive worldwide rights from Synchroneuron, LLC to certain patents to develop, manufacture and market acamprosate for movement disorders, obsessive compulsive disorder and post-traumatic stress disorder. The term of the license extends through the expiration of the last patent, which is expected to occur in 2018. The agreement is cancelable by us at any time with 30 days' written notice. Synchroneuron may terminate the agreement upon 30 days' written notice to us of a material breach of the contract, including our failure to pay a quarterly license payment, subject to certain cure periods, or immediately upon written notice as to our insolvency or certain bankruptcy proceedings.

As consideration for the license, we paid $100,000 upon entering the license and currently make additional quarterly license payments. Future obligations include increased quarterly payments and equity issuances after the achievement of certain product development milestones, up to a maximum of $250,000 per quarter and an aggregate of 83,333 shares of our common stock. In addition, we are obligated to pay a royalty on net sales of the licensed product. The royalty payment will be reduced by the initial license fee and quarterly license payments until all such license fees are applied against any royalties earned. We also have the right to sublicense to third parties and we are required to pay to Synchroneuron part of any sublicense revenue we receive.

Intellectual Property

SILENOR™

We are the exclusive licensee of four U.S. patents from ProCom One claiming the use of low dosages of doxepin and other antidepressants. U.S. Patent No. 6,211,229, "Treatment of Transient and Short Term Insomnia," covers dosages of doxepin from 0.5 mg to 20 mg for use in the treatment of transient insomnia and expires in February 2020. U.S. Patent No. 5,502,047, "Treatment For Insomnia," claims the treatment of chronic insomnia using doxepin in a daily dosage of 0.5 mg to 20 mg and expires in March 2013. Due to some recently identified prior art, we initiated a reexamination of this patent. The reexamination proceedings now are terminated and the U.S. Patent and Trademark Office is expected to issue 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 chronic insomnia patients. Because we are seeking to develop SILENOR™ for indications consistent with the subject matter of our patent claims, we believe that our licensed patents will restrict the ability of competitors to market doxepin with identical drug labeling. In addition, we have 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.

Additionally, we have the exclusive license from ProCom One to a third patent in the series, U.S. Patent No. 5,643,897, which is a divisional of the '047 patent and claims the treatment of chronic insomnia using amitriptyline, trimipramine, trazodone and mixtures thereof in a daily dosage of 0.5 mg to 20 mg. This patent expires in March 2013. A fourth patent to which we have an exclusive license from ProCom One, U.S. Patent No. 6,344,487, claims a method of treating insomnia with low dosage forms (0.5 mg to 10 mg) of nortriptyline. This patent expires in June 2020.

Nalmefene

We are the exclusive licensee of U.S. Patent No. 5,780,479, "Use of opioid antagonists to treat impulse-control disorders," from BioTie Therapies. This patent expires in April 2017. The patent claims the use of opioid antagonists, including nalmefene, for the treatment of impulse control disorders with the exception of trichotillomania. We have also exclusively in-licensed U.S. Patent No. 5,852,032, "Method of treating nicotine dependence," from the University of Miami. This patent expires in November 2016. The patent claims the use of nalmefene to decrease nicotine dependence.

Acamprosate

We have exclusively in-licensed four U.S. issued patents from Synchroneuron covering the use of acamprosate. U.S. Patent No. 5,952,389, "Methods of treating tardive dyskinesia and other movement disorders," claims the use of agents which are GABA-receptor agonists and NMDA-glutamate receptor antagonists, including acamprosate, to treat hyperkinetic movement disorders. This patent expires in January 2018. We intend to amend a claim in the '389 Patent to eliminate the reference to homotaurine, which was apparently included by mistake at the time of filing. U.S. Patent No. 6,294,583, "Methods of treating tardive dyskinesia and other movement disorders," claims a composition for treating movement disorders comprising a compound that is both a GABA-receptor agonist and NMDA-glutamate receptor antagonist, and magnesium. This patent expires in January 2018. Additionally, U.S. Patents Nos. 6,391,922 and 6,689,816 claim the use of an agent that increases GABA neurotransmission and decreases NMDA-glutamate neurotransmission to treat anxiety disorders including post-traumatic stress disorder and obsessive compulsive disorder. These two patents also expire in January 2018. Our Synchroneuron license also provides us with exclusive rights to two pending U.S. applications on acamprosate for movement disorders and the rights to two families of foreign applications corresponding to the patents filed in the United States.

Other Intellectual Property

Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how, and we would not be able to prevent their use.

Third Party Intellectual Property

Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates may infringe.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates infringe their intellectual property rights. If one of these patents was found to cover our product candidates or their uses, we could be required to pay damages and could be restricted from commercializing our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable right, which could prohibit us from making, using or selling our product candidates.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including but not limited to:

- infringement and other intellectual property claims which, with or without merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, including treble damages and attorneys' fees, which we may be required to pay if a court decides that the product candidate at issue infringes on or violates the third party's rights;
- a court prohibiting us from selling or licensing the product candidate or using the proprietary technology unless the third party licenses its technology to us, which it is not required to do;
- if a license is available from the third party, we may have to pay substantial royalties, fees or grant cross-licenses to our technology; and
- redesigning our product candidates so they do not infringe, which may not be possible or may require substantial funds and time.

We have not conducted an extensive search of patents issued to third parties, and no assurance can be given that such patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering our product candidates or methods. Because of the number of patents issued and patent applications filed in our technical areas or fields, we believe there is a significant risk that third parties may allege that they have patent rights encompassing our product candidates or methods.

Research and Development

Our research and development expenses were $29.0 million in 2005, $7.6 million in 2004 and $0.2 million for the period from our inception in August 14, 2003 through December 31, 2003. Our research and development expenses consist primarily of salaries and related employee benefits, costs associated with clinical trials managed by our clinical research organizations, or 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.

Competition

SILENOR™

In addition to the currently approved products for the treatment of insomnia, a number of new products are expected to enter the insomnia market over the next several years. While the new entrants bring additional competition to the insomnia market, they are also expected to substantially increase the awareness of insomnia

and further expand the market. Additionally, market growth will be driven by the aging of the population and the emerging links between sleep, health and overall well-being.

Ambien, which is marketed by Sanofi-Synthélabo Inc., is the market leader in the insomnia segment. The drug accounted for approximately $2.3 billion in retail sales for the year ended December 31, 2005 according to data obtained from Wolters Kluwer. Ambien is patent-protected until October 2006. A new version of Ambien, Ambien CR, was launched in September 2005. This product is approved for the treatment of insomnia and has been shown to decrease sleep latency and increase sleep maintenance. Unlike Ambien, Ambien CR does not have a label restriction limiting the length of time of its use. Ambien CR accounted for approximately $53 million in sales during the year 2005.

Lunesta, marketed by Sepracor Inc., is a GABA-receptor agonist that was approved in December 2004 by the FDA and was launched in the second quarter of 2005. Lunesta accounted for approximately $312 million in retail sales for the year ended December 31, 2005. Lunesta is indicated for the treatment of insomnia and has been shown to decrease sleep latency and increase sleep maintenance. It was the first of several products to have the short-term use restriction removed from its label.

Rozerem was launched by Takeda Pharmaceuticals North America, Inc. in September 2005 and had retail sales of approximately $10 million for the year ended December 31, 2005 according to data obtained from Wolters Kluwer. Rozerem is indicated for the treatment of insomnia characterized by difficulty with sleep onset. It is the first drug approved for the treatment of insomnia that is not a Schedule IV controlled substance. With the exception of Rozerem, the approved medications for the treatment of insomnia all act on GABA receptors and are Schedule IV controlled substances.

Sonata, marketed by King Pharmaceuticals, accounted for approximately $132 million in retail sales for the year ended December 31, 2005 according to Wolters Kluwer. The remaining market was comprised of older generic benzodiazepines and sedative antidepressants.

New entrants are expected to include indiplon, to be marketed by Neurocrine Biosciences, Inc. and Pfizer Inc., and gaboxadol, to be marketed by H. Lundbeck A/ S and Merck & Co., Inc. These compounds act on GABA receptors, and, to date, all GABA-acting drugs have been designated Schedule IV controlled substances.

Several companies, including Eli Lilly and Company, Sanofi-Synthélabo, Arena Pharmaceuticals, Inc. and Sepracor are evaluating 5HT2 antagonists as potential hypnotics. Additionally, several companies are evaluating different compounds in Phase I and II clinical trials for the treatment of insomnia.

Nalmefene

There are no approved drugs for the treatment of pathological gambling or other impulse control disorders. The opioid antagonist naltrexone has been investigated in the treatment of pathological gambling but is used in clinical practice on a limited basis. Efficacy appears to require dosing at levels significantly higher than approved in the product's current label, which carries a "black box" warning related to liver toxicity. Currently, the standard of care of pathological gambling is behavioral and cognitive therapy. Various pharmacological interventions have shown inconsistent results in efficacy studies in the treatment of pathological gambling. SSRIs, such as Paxil from GlaxoSmithKline and Luvox from Solvay Pharmaceuticals, which have been demonstrated to have anti-compulsive and anti-impulsive effects, were theorized to have potential in treating impulse control disorders. The SSRIs have reportedly demonstrated mixed results in the treatment of pathological gambling and other impulse control disorders in controlled studies.

There are a number of approved products, including nicotine replacement therapy and the drug Zyban from GlaxoSmithKline, as an aid to smoking cessation treatment. Pfizer is developing varenicline and Nabi Biopharmaceuticals is developing a vaccine, both as aids to smoking cessation.

Acamprosate

There are no approved products for the treatment of tardive dyskinesia. A variety of medications are prescribed off-label to lessen the symptoms associated with tardive dyskinesia, including benzodiazepines, adrenergic antagonists, reserpine (an antihypertensive agent) and dopamine agonists. Requip, a dopamine agonist, has been shown to reduce the risk for developing dyskinesias in patients with Parkinson's disease, while maintaining comparable control of motor symptoms in patients on levodopa therapy. Merck KGaA is investigating sarizotan hydrochloride, a serotonin 5HT1A agonist, in Phase III clinical trials for treatment-associated dyskinesias in patients with Parkinson's disease. Additionally, Juvantia Pharma Ltd. is investigating fipamezole, an adrenergic antagonist, in Phase II clinical trials for treatment-associated dyskinesias in Parkinson's disease and Acadia Pharmaceuticals Inc. is investigating ACP-103, a 5-HT2A inverse agonist, in Phase I clinical trials for levodopa-induced dyskinesias in patients with Parkinson's disease.

Manufacturing

The active pharmaceutical ingredient, or API, doxepin hydrochloride is currently available from multiple suppliers. We utilized a contract laboratory to incorporate doxepin API into a pharmaceutically acceptable capsule formulation, which we used in our Phase II clinical trials of SILENOR™. We have contracted with Patheon Inc. to manufacture, test and quality-control Phase III clinical trial supplies of SILENOR™. Patheon has produced clinical supplies of both a capsule and tablet formulation of SILENOR™ which we are using in our Phase III clinical program. We intend to commercialize the tablet form of the product to allow for improved branding and distinction from the higher strength, generic capsule forms currently available.

In February 2006, we entered into a non-exclusive manufacturing services agreement with Patheon for the manufacture of commercial quantities of our SILENOR™ 1 mg, 3 mg and 6 mg tablets product candidate. Although we are not required to purchase any minimum quantity of SILENOR™ under the agreement, we have agreed to purchase from Patheon not less than specified percentages of our total annual commercial requirements from all suppliers of SILENOR™, which vary depending upon annual volume. The agreement provides for an initial five-year term beginning upon commencement of the manufacturing services, and thereafter automatically continues for successive twelve-month terms unless terminated by written notice at least eighteen months prior to the end of the then-current term. Either party may terminate the agreement upon written notice if the other party has failed to remedy a material breach of any of its representations, warranties or other obligations under the agreement within 60 days following receipt of written notice of such breach. In addition, either party may immediately terminate the agreement upon written notice if (1) the other party is declared insolvent or bankrupt by a court of competent jurisdiction, (2) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other party or (3) the agreement is assigned by such other party for the benefit of creditors. We may terminate the agreement upon 30 days' prior written notice in the event that any governmental agency takes any action, or raises any objection, that prevents us from importing, exporting, purchasing or selling the product candidate. In addition, we may terminate the agreement upon twelve months' prior written notice in connection with our partnering, collaboration, licensing, sublicensing, co-promotion, sale or divestiture of rights to the product candidate, provided that no such termination shall be effective before the third anniversary of the commencement date.

BioTie Therapies has contracted with Patheon to manufacture clinical supplies of nalmefene. Under the terms of our agreement with BioTie Therapies, we purchase clinical supplies manufactured by Patheon from BioTie Therapies. We are currently negotiating with Patheon for the direct supply of commercial quantities of nalmefene. We are currently developing a new formulation of acamprosate calcium; however, we have not yet entered into a definitive agreement for the long-term supply of this product candidate.

Government Regulation

Governmental authorities in the United States and other countries extensively regulate the testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution, among other things, of pharmaceutical products. In the United States, the FDA, under the Federal Food, Drug, and Cosmetic Act and other federal statutes and regulations, subjects pharmaceutical products to

rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

We and our manufacturers and CROs may also be subject to regulations under other federal, state, and local laws, including the Occupational Safety and Health Act, the Environmental Protection Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries.

FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

The process required by the FDA before a new drug may be marketed in the United States generally involves the following: completion of preclinical laboratory and animal testing in compliance with FDA regulations, submission of an investigational new drug application, or IND, which must become effective before human clinical trials may begin, performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use, and submission and approval of an NDA by the FDA. The sponsor typically conducts human clinical trials in three sequential phases, but the phases may overlap. In Phase I clinical trials, the product is tested in a small number of patients or healthy volunteers, primarily for safety at one or more dosages. In Phase II clinical trials, in addition to safety, the sponsor evaluates the efficacy of the product on targeted indications, and identifies possible adverse effects and safety risks in a patient population. Phase III clinical trials typically involve testing for safety and clinical efficacy in an expanded population at geographically-dispersed test sites.

Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at each clinical site and may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

The applicant must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. According to the FDA, the median total approval time for NDAs approved during calendar year 2004 was approximately 13 months for standard applications. If the FDA's evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA and issue a not approvable letter.

Section 505(b)(1) New Drug Applications

The approval process described above is premised on the applicant being the owner of, or having obtained a right of reference to, all of the data required to prove the safety and effectiveness of a drug product. This type of marketing application, sometimes referred to as a "full" or "stand-alone" NDA, is governed by Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act. A Section 505(b)(1) NDA contains full reports of investigations of safety and effectiveness, which includes the results of preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, in addition to other information. We intend to submit a Section 505(b)(1) application for nalmefene.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for new indications or improved formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA filing under Section 505(b)(1) as described above. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Amendments permit the applicant to rely upon the FDA's findings of safety and effectiveness for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or some of the label indications for which the referenced product has been approved, or the new indication sought by the Section 505(b)(2) applicant. We intend to submit a Section 505(b)(2) application for SILENOR™. This application will rely, in part, on the FDA's previous findings of safety and effectiveness for doxepin.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's findings for an already-approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product. A certification that the new product will not infringe the already approved product's Orange Book-listed patents or that such patents are invalid is called a paragraph IV certification. If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the NDA and patent holders once the NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. For drugs with five-year exclusivity, if an action for patent infringement is initiated after year four of that exclusivity period, then the 30-month stay period is extended by such amount of time so that 7.5 years has elapsed since the approval of the NDA with five-year exclusivity. This period could be extended by six months if the NDA sponsor obtains pediatric exclusivity. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay. There are currently no patents listed in the Orange Book for doxepin, nalmefene or acamprosate. Therefore, at this time we do not anticipate submitting a paragraph IV certification.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If these companies successfully challenge the FDA's interpretation of Section 505(b)(2), the FDA may be required to change its interpretation of Section 505(b)(2). This could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

The Hatch-Waxman Act

Under the Hatch-Waxman Act, newly-approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. Hatch-Waxman prohibits the submission of an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, as explained above, submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under Hatch-Waxman will not prevent the submission or approval of another full NDA; however, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages, or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. Acamprosate is currently protected by five years of new chemical entity exclusivity, which expires on July 29, 2009. This exclusivity would not prevent the FDA from approving our marketing application if it is submitted as a full Section 505(b)(1) NDA. We anticipate receiving three years of marketing exclusivity for SILENOR™, nalmefene and acamprosate if the FDA approves our marketing applications.

Orphan Drug Designation and Exclusivity

Some jurisdictions, including Europe and the United States, may designate drugs for relatively small patient populations as orphan drugs. The FDA grants orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. In the United States, orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Also, competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity. We have submitted to the FDA an orphan drug designation request for acamprosate for the treatment of moderate to severe tardive dyskinesia. If the FDA designates the drug and approves our marketing application, we will be granted seven years of orphan drug exclusivity. This period of exclusivity will run concurrently with any three-year period of exclusivity applicable to our product candidate awarded upon FDA approval.

Under European Union medicines laws, criteria for designation as an "orphan medicine" are similar but somewhat different from those in the United States. A drug is designated as an orphan drug if the sponsor can establish that the drug is intended for a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union or that is unlikely to be profitable, and if there is no approved satisfactory treatment or if the drug would be a significant benefit to those persons with the condition. Orphan medicines are entitled to ten years of market exclusivity, except under certain limited

circumstances comparable to U.S. law. During this period of market exclusivity, no "similar" product, whether or not supported by full safety and efficacy data, will be approved unless a second applicant can establish that its product is safer, more effective or otherwise clinically superior. This period may be reduced to six years if the conditions that originally justified orphan designation change or the sponsor makes excessive profits.

Pediatric Exclusivity

The Best Pharmaceuticals for Children Act, which was signed into law January 4, 2002, and which reauthorized Section 111 of the 1997 FDA Modernization Act, provides an additional six months of exclusivity and patent protection listed in the Orange Book for new or marketed drugs for specific pediatric studies conducted at the written request of the FDA. The Pediatric Research Equity Act of 2003, or PREA, authorizes the FDA to require pediatric studies for drugs to ensure the drugs' safety and efficacy in children. PREA requires that certain new NDAs or supplements to NDAs contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may also require this data for approved drugs that are used in pediatric patients for the labeled indication, or where there may be therapeutic benefits over existing products. The FDA may grant deferrals for submission of data, or full or partial waivers from PREA. Unless otherwise required by regulation, PREA does not apply to any drug for an indication with orphan designation. We plan to work with the FDA to determine the need for pediatric studies for our product candidates, and may consider attempting to obtain pediatric exclusivity for some of our product candidates.

Other Regulatory Requirements

We may also be subject to a number of post-approval regulatory requirements. If we seek to make certain changes to an approved product, such as promoting or labeling a product for a new indication, making certain manufacturing changes or product enhancements or adding labeling claims, we will need FDA review and approval before the change can be implemented. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications or product enhancements and, in some cases, for manufacturing and labeling claims, is generally a time-consuming and expensive process that may require us to conduct clinical trials under the FDA's IND regulations. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. In addition, adverse experiences associated with use of the products must be reported to the FDA, and FDA rules govern how we can label, advertise or otherwise commercialize our products.

There are current post-marketing safety surveillance requirements that we will need to meet to continue to market an approved product. The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal health care programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve

remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we and the manufacturers on which we rely for the manufacture of our products are subject to requirements that drugs be manufactured, packaged and labeled in conformity with current good manufacturing practice, or cGMP. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, record-keeping and other requirements. The FDA periodically inspects drug manufacturing facilities to evaluate compliance with cGMP requirements.

Also, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning record-keeping and control procedures.

Outside of the United States, our ability to market our products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process includes all of the risks associated with the FDA approval process described above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country.

Third-Party Reimbursement and Pricing Controls

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It will be time-consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

Employees

As of March 9, 2006, we had 25 employees, consisting of clinical development, regulatory affairs, manufacturing and program management, business development, marketing and administration.

Available Information

We make available free of charge on or through our Internet website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. Our Internet address is www.somaxon.com.

Item 1A. *Risk Factors*

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, 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 following risks 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.

SILENOR™ is currently being evaluated in four Phase III clinical trials for the treatment of insomnia and will require the successful completion of these Phase III clinical trials before we are able to submit an NDA to the FDA for approval. If our Phase III or other clinical trials fail to demonstrate that SILENOR™ is safe and effective, it will not receive regulatory approval. We are seeking a commercial partner for SILENOR™. If a partnership becomes effective prior to the filing of the NDA, actions on the part of the partner 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 expect intense competition in the insomnia marketplace for SILENOR™ and in the target markets for our other product candidates, and new products may emerge that provide different and/or better therapeutic alternatives for the disorders that our product candidates are intended to treat.

We are developing SILENOR™ for the treatment of insomnia, which will compete with well established drugs for this indication including Ambien and Sonata, both GABA-acting hypnotics. Recently, Sepracor Inc.'s Lunesta, a GABA-acting hypnotic, Takeda Pharmaceuticals North America, Inc.'s Rozerem, a melatonin receptor antagonist, and Sanofi-Synthélabo Inc.'s Ambien CR, a controlled-release formulation of the current product, Ambien, were approved by the FDA for the treatment of insomnia. An NDA for at least one other product, Neurocrine Biosciences, Inc.'s indiplon, a GABA-acting hypnotic, has reportedly been submitted to the FDA and is under review. Furthermore, the patent for the original form of Ambien, which accounted for $2.3 billion of the $3.3 billion insomnia market in 2005, expires in October 2006. As a result, generic versions of Ambien are expected to reach the market shortly thereafter. Generic versions of Ambien can be expected to be priced significantly lower than approved, branded insomnia products. Sales of all of these drugs may reduce the available market for, and the price we are able to charge for, any product developed by us for these indications.

We are developing nalmefene for the treatment of pathological gambling. Currently, there are no FDA-approved products for this indication. However, controlled clinical trials using the opioid antagonist, naltrexone, which is available in generic form, have demonstrated clinical benefit for patients diagnosed with pathological gambling. Additionally, some controlled clinical trials suggest that SSRIs, such as

GlaxoSmithKline plc's Paxil and Solvay Pharmaceuticals' Luvox, may have a potential clinical effect. TOPAMAX, marketed by Ortho-McNeil Neurologics, is also being studied for the treatment of pathological gambling.

We are developing acamprosate for the treatment of tardive dyskinesia. There are no FDA-approved products for the treatment of tardive dyskinesia, although several companies are reportedly in Phase II and Phase III clinical trials to evaluate product candidates for this condition. Merck KGaA is investigating sarizotan hydrochloride, a serotonin 5HT1A agonist, in Phase III clinical trials for treatment-associated dyskinesias in patients with Parkinson's disease. Additionally, Juvantia Pharma Ltd. is investigating fipamezole, an adrenergic antagonist, in Phase II clinical trials for treatment-associated dyskinesias in Parkinson's disease and Acadia Pharmaceuticals Inc. is investigating ACP-103, a 5-HT2A inverse agonist, in Phase I clinical trials for levodopa-induced dyskinesias in patients with Parkinson's disease. These product candidates may be approved by the FDA or other regulatory authorities and commercialized ahead of acamprosate.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render SILENOR™ or our other product candidates obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates obsolete or noncompetitive.

Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical trial experience;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, useful and less costly than ours and may also be more successful than we in manufacturing and marketing their products.

In addition, if we receive regulatory approvals for our products, manufacturing efficiency and marketing capabilities are likely to be significant competitive factors. We currently have no commercial manufacturing capability, sales force or marketing infrastructure. In addition, many of our competitors and potential competitors have substantially greater capital resources, research and development resources, manufacturing and marketing experience and production facilities than we. Many of these competitors also have significantly greater resources for undertaking clinical trials of new pharmaceutical products and obtaining FDA and other regulatory approvals.

Delays in the commencement or completion of clinical testing could result in increased costs to us and delay or limit our ability to generate revenues.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials will begin on time or be completed on

schedule, if at all. The commencement and completion of clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- manufacturing sufficient quantities of a product candidate;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the same indication as our product candidates; and
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same indications may have been introduced to the market and established a competitive advantage.

Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through preclinical testing and clinical trials that the product is safe and effective for use in each target indication. To date, we have not successfully completed any Phase III clinical trials and we have not completed all planned preclinical and Phase I clinical trials for each of our product candidates. For example, in addition to our ongoing Phase III clinical trials for SILENOR™, we are undertaking several Phase I clinical trials to evaluate the effect of food on the absorption of the drug and the effect of SILENOR™ when co-administered with other drugs. With regard to nalmefene, we plan to initiate a clinical trial evaluating the product candidate's cardiac effects on patients measured using an electrocardiogram. With regard to acamprosate, various preclinical and Phase I clinical trials are planned to facilitate the selection and evaluation of a formulation for the product candidate to be tested in subsequent trials. The results from preclinical testing and clinical trials that we have completed may not be predictive of results obtained in future preclinical and clinical trials, and there can be no assurance that we will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or result in marketable products. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. If our drug candidates are not shown to be safe and effective in clinical trials, the resulting delays in developing other compounds and conducting related preclinical testing

and clinical trials, as well as the potential need for additional financing, would have a material adverse effect on our business, financial condition and results of operations.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. For example, in a Phase I clinical trial of nalmefene performed by our licensor, two patients were reported by the investigator to have a prolonged QTc interval, which is an electrocardiogram change in patients which, if significantly prolonged, may result in an abnormal heart rhythm with adverse consequences including fainting, dizziness, loss of consciousness and death. In a final report, based on corrected values as determined by the cardiologist responsible for the central laboratory evaluation, these QTc findings were determined to be within the normal range of variation and incorrectly designated as adverse events. As with most new drugs, a Phase I clinical trial to evaluate the cardiac effects of nalmefene on patients measured using an electrocardiogram is planned and we will continue to assess the side effect profile of nalmefene and our other product candidates in our ongoing clinical development program.

In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- regulatory authorities may withdraw their approval of the product;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from its sale.

Additionally, the FDA has directed manufacturers of all antidepressant drugs to revise their product labels to include a "black box" warning and expanded warning statements regarding an increased risk of suicidal thinking and behavior in children and adolescents being treated with these agents. SILENOR™'s active ingredient, doxepin, is used in the treatment of depression and the package insert includes such a "black box" warning statement. Although SILENOR™ is not intended to be indicated for or used in the treatment of depression and our proposed insomnia dosage is less than one-tenth of that of doxepin for the treatment of depression, nor do we currently intend to evaluate SILENOR™ for the treatment of insomnia in children or adolescents, we cannot assure you that a similar warning statement will not be required.

There is no assurance that we will be granted regulatory approval for any of our product candidates.

The clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Prior to marketing, any product developed by us must undergo an extensive regulatory approval process. We have not requested nor received regulatory approval for any product from the FDA or any other regulatory body. This regulatory process, which includes preclinical testing and clinical trials of each compound to establish its safety and efficacy, can take many years and require the expenditure of substantial resources, and may include post-marketing studies and surveillance. Data obtained from preclinical testing and clinical trials are susceptible to varying interpretations which could delay, limit or prevent regulatory approval. In addition, delays or rejections may be encountered based upon changes in FDA policy for drug approval during the

period of product development and FDA regulatory review of each submitted NDA. Similar delays may also be encountered in foreign countries. There can be no assurance that regulatory approval will be obtained for any drugs developed by us. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope requested will delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, the label ultimately approved for SILENOR™, if any, may include a restriction on the term of its use, or it may not include one or more of our intended indications — the treatment of sleep onset, maintenance and duration. Similarly, although doxepin, at higher dosages than we plan to incorporate in SILENOR™, is not currently and has never been a Schedule IV controlled substance, we cannot be certain that SILENOR™ will be a non-scheduled drug until the FDA and the DEA complete their review. Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on potential royalties and product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If the manufacturers upon whom we rely fail to produce our products in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues.

We do not manufacture any of our product candidates, and we do not plan to develop any capacity to do so. Patheon Pharmaceuticals Inc. manufactures clinical supplies of our SILENOR™ and nalmefene product candidates, and we will also contract with a third party to manufacture our acamprosate product candidate. We have also entered into a manufacturing and supply agreement with Patheon Pharmaceuticals Inc. to manufacture our commercial supply of SILENOR™. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidates and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Our manufacturers may not perform as agreed or may terminate their agreements with us. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their contractual obligations, our ability to provide product candidates to patients in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial program and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

We do not have alternate manufacturing plans in place at this time. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must approve these manufacturers' facilities and processes prior to our use, which would require new testing and compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our products.

Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, entail higher costs or result in our being unable to effectively commercialize our products. Furthermore, if our manufacturers failed to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

In addition, all manufacturers of our products must comply with current good manufacturing practice, or cGMP, requirements enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products.

We rely on third parties to conduct our clinical trials and prepare our electronic NDA filings. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We rely on CROs, primarily Synteract, Inc., to conduct our clinical trials for our SILENOR™ and nalmefene product candidates, and we may depend on other CROs and independent clinical investigators to conduct our future clinical trials. CROs play a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. We also will rely on a CRO to prepare our electronic NDA filing. CROs and investigators are not our employees, and we cannot control the amount or timing of resources that

they devote to our programs. If Synteract, other CROs or independent investigators fail to devote sufficient time and resources to our programs, or if their performance is substandard, it will delay the approval of our FDA applications and our introductions of new products. Failure of the CROs to meet their obligations could adversely affect clinical development of our products. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may compete with us. If independent investigators and CROs assist our competitors at our expense, it could harm our competitive position.

Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.

We rely on the manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce the compounds for our clinical trials and will rely on them for commercial distribution if we obtain marketing approval for any of our product candidates. Suppliers may not sell these materials to our manufacturers at the time we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, product testing and potential regulatory approval of our product candidates would be delayed, significantly impacting our ability to develop our product candidates. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of our product candidates.

If we are unable to establish a sales and marketing infrastructure or enter into collaborations with partners to perform these functions, we will not be able to commercialize our product candidates.

We currently do not have significant internal sales, distribution and marketing capabilities. In order to commercialize any of our product candidates, we must either acquire or internally develop sales, marketing and distribution capabilities, or enter into collaborations with partners to perform these services for us. In the United States, we plan to build our own sales force to market our products directly to psychiatrists and neurologists and other targeted physicians. The acquisition or development of a sales and distribution infrastructure for our domestic operations will require substantial resources, which may divert the attention of our management and key personnel and negatively impact our product development efforts. Moreover, we may not be able to hire a sales force that is sufficient in size or has adequate expertise.

To maximize the value of our product candidates, we will need to enter into collaborations with larger pharmaceutical partners to commercialize our products outside of the psychiatric and neurology specialty markets. We may not be able to enter into collaborations on acceptable terms, if at all. We also face competition in our search for partners with whom we may collaborate. By entering into these strategic collaborations, we may rely on our partners for financial resources and for development, commercialization and regulatory expertise. Our partners may fail to develop or effectively commercialize our product candidates because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints, such as limited cash or human resources;
- decide to pursue a competitive potential product that had been developed outside of the collaboration; or
- cannot obtain the necessary regulatory approvals.

We face potential product liability exposure, and, if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials with a $5 million annual aggregate coverage limit, and our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

The commercial success of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by the medical community and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- prevalence and severity of any adverse side effects;
- limitations or warnings contained in a product's FDA-approved labeling, including, for example, potential "black box" warnings associated with the active ingredient in SILENOR™;
- availability of alternative treatments, including, in the case of SILENOR™, a number of competitive products already approved for the treatment of insomnia or expected to be commercially launched in the near future;
- pricing and cost effectiveness;
- effectiveness of our or our collaborators' sales and marketing strategies; and
- our ability to obtain sufficient third-party coverage or reimbursement.

If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

Our failure to successfully acquire, develop and market additional product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we intend to acquire, develop and market additional products and product candidates. Because we neither have, nor currently intend to establish, internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies, university scientists and other researchers to sell or license products to us. The success of this strategy depends upon our ability to identify, select and acquire promising pharmaceutical product candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any products that we develop or approved products that we acquire will be manufactured or produced profitably, successfully commercialized or widely accepted in the marketplace.

Our business depends on our ability to acquire or in-license products and if we do not successfully acquire or license related product candidates or integrate them into our operations, we may incur unexpected costs and disruptions to our business.

An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our business and complement our existing product candidates. Future acquisitions, however, may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and

in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

We are subject to uncertainty relating to health care reform measures and reimbursement policies which, if not favorable to our product candidates, could hinder or prevent our product candidates' commercial success.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- our ability to set a price we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the future revenues and profitability of our potential customers, suppliers and collaborators; and
- the availability of capital.

In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription drugs and the reform of the Medicare and Medicaid systems. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 provides a new Medicare prescription drug benefit which became effective in January 2006 and mandates other reforms. While we cannot predict the full outcome of the implementation of this legislation, it is possible that the new Medicare prescription drug benefit, which will be managed by private health insurers and other managed care organizations, will result in additional government reimbursement for prescription drugs, which may make some prescription drugs more affordable but may further exacerbate industry-wide pressure to reduce prescription drug prices. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable.

Our ability to commercialize our product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate coverage and reimbursement levels for the cost of our products and related treatments. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, legislative proposals to reform health care or reduce government insurance programs may result in lower prices for our product candidates or exclusion of our product candidates from coverage and reimbursement programs. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could harm our ability to market our products and significantly reduce our revenues from the sale of any approved product.

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

As of March 9, 2006, we had 25 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 distinct 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 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 partnership or 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 December 31, 2005 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.

Raising additional funds by issuing securities or through licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us.

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 $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.

The use of our net operating loss and tax credit carryforwards may be limited.

Net operating loss carryforwards and research and development credits may expire and not be used. As of December 31, 2005, we had federal net operating loss carryforwards of approximately $41.4 million and state net operating loss carryforwards of approximately $39.8 million, the majority of which were generated in California. We have federal research and development tax credits of $1.5 million and California research and development tax credits of $1.6 million. Both federal net operating loss carryforwards and research and development tax credits have a 20 year carry forward period and begin to expire in 2023 and 2024, respectively. California net operating loss carryforwards have a 10 year carry forward period and begin to expire in 2013. California research and development tax credits have no expiration.

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 the Company's 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 approximately $284,000 of our California net operating loss carryforwards were effectively eliminated. Additionally, approximately $18,291,000 and $17,335,000 of our federal and California net operating loss carryforwards, respectively, and $887,000 of our federal research and development credits were subject to limitation at December 31, 2005. A portion of the limited net operating loss carryforwards become 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 not subject to limitations. At December 31, 2005, we had federal and state net operating loss carryforwards of approximately $23,060,000 and $22,436,000, respectively, and research and development credits of $600,000 that were generated after the ownership change and therefore not limited. These net operating loss carryforwards and credit carryforwards could be subject to future limitations if additional ownership changes occur.

Risks Relating to Intellectual Property

The patent rights that we have in-licensed covering SILENOR™ are limited to certain low-dosage strengths in the United States, and our market opportunity for this product candidate may be limited by the lack of patent protection for higher dosage strengths and the lack of patent protection in other territories.

Although we have an exclusive, worldwide license for SILENOR™ for the treatment of insomnia through the life of the last patent to expire, which is expected to occur in 2020, we do not have patent protection for SILENOR™ in any jurisdiction outside the United States. In addition, although our licensed patent for the treatment of transient insomnia is scheduled to expire in 2020, our licensed patent for the treatment of chronic insomnia is scheduled to expire in March 2013. Accordingly, a competitor could file an NDA for the development of doxepin for a chronic insomnia indication as early as March 2013. 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 the 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 in 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. In addition, others may attempt to commercialize low-dose doxepin in the European Union, Canada, Mexico or other markets where we do not have patent protection for SILENOR™. Due to the lack of patent protection for doxepin in territories outside the United States and the potential for correspondingly lower prices for the drug in those markets, it is possible that patients will seek to acquire low-dose doxepin in those other territories. The off-label use of doxepin in the United States or the importation of doxepin from foreign markets could adversely

affect the commercial potential for SILENOR™ and adversely affect our overall business and financial results.

We have initiated a reexamination and a reissue of one of our patents covering SILENOR™ which will result in the U.S. Patent and Trademark Office 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 is expected to issue 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 chronic insomnia patients. In addition, we have 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 proceeding U.S. Patent and Trademark Office's pending reissue.

We have licensed our product candidates from third parties. If we default on any of our obligations under those licenses, we could lose rights to product candidates that are important to our business.

We license rights to product candidates that are important to our business, and we expect to enter into similar licenses in the future. For instance, we acquired our three product candidates through exclusive licensing arrangements. Under these licenses we are subject to commercialization and development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. Loss of any of these licenses or the exclusivity rights provided therein could harm our financial condition and operating results. For example, our license agreement for SILENOR™ requires us to use commercially reasonable efforts to develop, obtain regulatory approval of and commercialize the product candidate. To the extent we are unable to comply with these obligations, the license may be terminated.

Restrictions on our patent rights relating to our product candidates may limit our ability to prevent third parties from competing against us.

Our success will depend on our ability to obtain and maintain patent protection for our products, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. The patent rights that we have in-licensed relating to our product candidates are limited in ways that may affect our ability to exclude third parties from competing against us if we receive regulatory approval to market these product candidates. In particular, we do not hold composition of matter patents covering the active pharmaceutical ingredients of any of our product candidates. Composition of matter patents on active pharmaceutical ingredients are the strongest form of intellectual property protection for pharmaceutical products as they apply without regard to any method of use or other type of limitation. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredients as our products so long as the competitors do not infringe any method of use or formulation patents that we may hold.

The principal patent protection that covers, or that we expect will cover, our product candidates is method of use patents. This type of patent protects the product only when used or sold for the specified method. However, this type of patent does not limit a competitor from making and marketing a product that is identical to our product for an indication that is outside of the patented method. Moreover, physicians may prescribe such a competitive identical product for off-label indications that are covered by the applicable patents.

Although such off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Because products with active ingredients identical to ours have been on the market for many years, there can be no assurance that these other products were never used off-label in such a manner that such prior usage would not affect the validity of our method of use patents. One of our licensed patents is currently involved in post-issuance proceedings in the U.S. Patent and Trademark Office, and no assurance can be given that any claims will survive those proceedings in their current form, or at all.

Patent applications in the United States are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months. As a result, we cannot be certain that the inventors of the issued patents that we in-licensed were the first to conceive of inventions covered by pending patent applications or that the inventors were the first to file patent applications for such inventions.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and certain consultants. There can be no assurance that inventions relevant to us will not be developed by a person not bound by an invention assignment agreement with us. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by our competitors.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

In addition, as is commonplace in the biotechnology industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing products. As the biotechnology and pharmaceutical industry expands and more patents are issued, the risk increases that our potential products may give rise to claims that our products infringe the patent rights of others. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. If one of these patents was found to cover our product candidates, proprietary technologies or their uses, we or our collaborators could be required to pay damages and could be unable to commercialize our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us or our collaborators on acceptable terms, if at all. In

addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable right which could prohibit us from making, using or selling our products, technologies or methods.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, with or without merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, including treble damages and attorneys' fees, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights;
- a court prohibiting us from selling or licensing the product unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross-licenses to our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial funds and time.

We have conducted a search of patents issued to third parties, however no assurance can be given that patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering our products, technology or methods. Because of the number of patents issued and patent applications filed in our field, we believe there is a risk that third parties may allege they have patent rights encompassing our products, technology or methods.

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 March 9, 2006, the trading prices for our common stock ranged from a high of $21.05 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.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders, and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We will incur increased costs as a result of changes in laws and regulations relating to corporate governance matters.

As a public reporting company, we must comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations adopted by the Securities and Exchange Commission and by the Nasdaq Stock Market, including expanded disclosures, accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and other requirements will increase our costs and require additional management resources. Additionally, these laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Based on our current public float, we are required to comply with Section 404 by December 31, 2006. We are presently evaluating and monitoring developments with respect to these laws and regulations and cannot predict or estimate the amount or timing of additional costs we may incur to respond to their requirements.

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 December 31, 2005, 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.

We may allocate the net proceeds from our initial public offering in ways that you and other stockholders may not approve.

We intend to use the net proceeds from our initial public offering:

- to fund clinical trials for our three development programs;
- for marketing, general and administrative expenses; and
- for other research and development expenses.

Our management and directors will, however, have broad discretion in the application of the net proceeds from the offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock.

Future sales of our common stock may cause our stock price to decline.

Persons who were our stockholders prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock that they will be able to sell in the public market in the near future. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, the holders of a substantial number of shares of common stock may have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. In addition, certain of our directors and executive officers may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act for the purpose of effecting sales of common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Item 1B. *Unresolved Staff Comments*

Not applicable.

Item 2. *Properties*

We lease approximately 6,500 square feet of space in our headquarters in San Diego, California under a sublease and a lease that expire in 2006 and 2007, respectively. We have no laboratory, research or manufacturing facilities. We expect to require additional space to accommodate our projected 2006 growth. As such suitable additional space is being sought which will accommodate expansion of our operations on commercially reasonable terms.

Item 3. ***Legal Proceedings***

We are not engaged in any legal proceedings.

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

On October 21, 2005, the holders of our preferred stock acted by written consent to approve a change in the required date of delivery of our operating budget and plan respecting the next fiscal year. Stockholders holding an aggregate of 8,624,583 shares of our preferred stock approved the matters set forth in the action by written consent and stockholders holding approximately 3,616,826 shares of our preferred stock did not consent with respect to such matters.

On November 29, 2005, our stockholders also acted by written consent to take the following actions in connection with the initial public offering of our common stock:

(1) the approval and adoption of a Certificate of Amendment to our Amended and Restated Certificate of Incorporation to be filed prior to the effectiveness of our initial public offering to implement a 1-for-6 reverse stock split of our outstanding common stock;

(2) the approval and adoption of our Amended and Restated Certificate of Incorporation to become effective upon the closing of our initial public offering;

(3) the approval and adoption of our Amended and Restated Bylaws to become effective upon the closing of our initial public offering;

(4) the approval and adoption of the classification of our board of directors into three classes;

(5) the approval and adoption of our 2005 Equity Incentive Award Plan;

(6) the approval and adoption of our 2005 Employee Stock Purchase Plan;

(7) the approval and adoption of our Director Compensation Policy; and

(8) the approval of the form of indemnity agreement between us and each of our directors and executive officers.

Stockholders holding an aggregate of 10,337,172 shares approved the matters set forth in the action by written consent and stockholders holding approximately 2,571,628 shares did not consent with respect to such matters.

All of the above actions were effected pursuant to actions by written consent of our stockholders in compliance with Section 228 of the Delaware General Corporation Law.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information

Our common stock has been traded on the Nasdaq National Market since December 15, 2005 under the symbol SOMX. Prior to such time, there was no public market for our common stock. The following table sets forth the high and low sales prices per share of our common stock as reported on the Nasdaq National Market for the period indicated.

	High	Low
Year Ended December 31, 2005		
Fourth Quarter	$11.20	$9.69

As of March 6, 2006, there were approximately 1,122 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. 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. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

Securities Authorized for Issuance under Equity Compensation Plans

The following table summarizes securities available under our equity compensation plans as of December 31, 2005.

	Shares Issuable Upon Exercise of Outstanding Awards	Weighted Average Exercise Price	Number of Securities Available for Future Issuance
Equity compensation plans approved by security holders:			
2004 Equity Incentive Award Plan	1,088,332	$ 2.89	—
2005 Equity Incentive Award Plan	315,000	$11.00	1,710,074
2005 Employee Stock Purchase Plan	—	—	300,000
Equity compensation plans not approved by security holders:			
None			

The 2005 Equity Incentive Award Plan and 2005 Employee Stock Purchase Plan were adopted at the time of the initial public offering which coincided with the discontinuance of the 2004 Equity Incentive Award Plan. Stock options under the 2005 Equity Incentive Award Plan have an exercise price equal to the fair market value of the underlying common stock at the date of grant, generally vest over a period of between two and four years, and have a ten year life. The 2005 Equity Incentive Award Plan and 2005 Employee Stock Purchase Plan contain "evergreen" provisions which allow for annual increases in the number of shares available for future issuance. The 2005 Equity Incentive Award Plan's evergreen provision provides for annual increases in the number of shares available for grant equal to the lesser of: (i) 2,000,000 shares, (ii) 5% of outstanding capital stock (18,045,366 as of December 31, 2005), or (iii) such lesser amount as determined by the board of directors. The 2005 Employee Stock Purchase Plan's evergreen provision provides for annual increases in the number of shares available for grant equal to the lesser of: (i) 300,000 shares, (ii) 1% of the outstanding capital stock (18,045,366 as of December 31, 2005), or (iii) such lesser amount as determined by the board of directors.

Recent Sales of Unregistered Securities

During the year ended December 31, 2005, we issued and sold the following unregistered securities:

- In June and September 2005, we issued and sold an aggregate of 48,148,455 shares of Series C preferred stock to certain existing and new investors at a per share price of $1.35, for an aggregate consideration of $65,000,414. Upon completion of our initial public offering, these shares of Series C preferred stock converted into 8,024,721 shares of our common stock.
- From January 1, 2005 to December 13, 2005, which is the day before we priced our initial public offering of common stock, we granted stock options to purchase 921,328 shares of our common stock at exercise prices ranging from $1.20 to $13.62 per share to our employees, consultants and directors under our 2004 equity incentive award plan and our 2005 equity incentive award plan. During this period, 28,402 options were surrendered resulting in a net of 892,926 options granted. From January 1, 2005 to December 13, 2005, we issued and sold an aggregate of 80,761 shares of our common stock to our employees, consultants and directors at prices ranging from $1.20 to $3.00 per share pursuant to exercises of options granted under our 2004 equity incentive award plan.

The sales and issuances of securities in the transactions described above were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance upon Section 4(2) of the Securities Act of 1933, as amended, Regulation D promulgated thereunder or Rule 701 promulgated under Section 3(b) of the Securities Act of 1933, as amended, as transactions by an issuer not involving any public offering or transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of securities in each transaction represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. All recipients had adequate access, through employment or other relationships, to information about us.

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 9, 2006, we had invested the $49.8 million in net proceeds from the offering in commercial paper with strong credit ratings and United States government agency notes with maturities under one year. Through March 9, 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 6. *Selected Financial Data*

The selected statement of operations data for the years ended December 31, 2005 and 2004, and the period from August 14, 2003 (inception) through December 31, 2003 and the balance sheet data as of December 31, 2005 and 2004 have been derived from our audited financial statements included elsewhere in this annual report. The balance sheet data as of December 31, 2003 has been derived from audited financial statements which are not included in this Form 10-K. Historical results are not necessarily indicative of future results. The selected financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this annual report.

	Year Ended December 31,		August 14, 2003 (inception) through December 31,	August 14, 2003 (inception) through December 31,
	2005	2004	2003	2005
	(in thousands, except per share data)			
Statement of Operations Data:				
Operating expenses:				
License fees	$ 482	$ 4,038	$ 520	$ 5,040
Research and development	28,955	7,574	166	36,695
Marketing, general and administrative expense	4,814	2,143	778	7,735
Remeasurement of Series C warrant liability	5,649	—	—	5,649
Total operating expenses	39,900	13,755	1,464	55,119
Loss from operations	(39,900)	(13,755)	(1,464)	(55,119)
Interest and other income	1,413	157	1	1,571
Net loss	(38,487)	(13,598)	(1,463)	(53,548)
Accretion of redeemable convertible preferred stock to redemption value	(86)	—	—	(86)
Net loss applicable to common stockholders	$ (38,573)	$(13,598)	$ (1,463)	$(53,634)
Basic and diluted net loss applicable to common stockholders per share(1)	$ (33.30)	$ (38.08)	$ (10.03)	
Shares used to calculate net loss applicable to common stockholders per share(1)	1,158,347	357,123	145,833	

(1) See Note 1 of the Notes to Financial Statements for an explanation of the method used to calculate net loss per common share and the number of shares used in the computation of the per share amount.

	As of December 31,		
	2005	2004	2003
		(in thousands)	
Balance Sheet Data:			
Cash, cash equivalents and investments	$103,965	$ 12,835	$ 906
Working capital	93,088	9,900	811
Total assets	106,256	13,599	919
Deficit accumulated during the development stage	(53,548)	(15,061)	(1,463)
Total stockholders' equity	$ 93,455	$ 10,274	$ 819

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with "Selected Financial Data" and our financial statements and related notes appearing

elsewhere in this Form 10-K. 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 this filing.

Overview

Background

We are a specialty pharmaceutical company focused on the in-licensing and development of 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 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 or alternative delivery systems, or 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.

We have incurred significant net losses since our inception. As of December 31, 2005, we had an accumulated deficit of approximately $53.5 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.

On December 20, 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 partnership or 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 Note 1 of 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 partnering, 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. 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 salaries, 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.

Remeasurement of Series C Warrant Liability

In conjunction with our Series C redeemable convertible preferred stock financing in June 2005, we issued a warrant that provided for the sale of additional shares of redeemable preferred stock at the election either by us or by the Series C preferred stock investors. The warrant instrument was treated as a net liability and periodically remeasured to its fair value with corresponding expense or income recognized within operating expenses. In September 2005, we exercised our right to require the Series C preferred stock investors to purchase additional shares of Series C preferred stock. Immediately prior to exercise, the value of the warrant was remeasured to its fair value, resulting in total expense relating to the warrant of $5.6 million for the year ended December 31, 2005. Because the Series C warrant was exercised, we will not record any future remeasurement of the Series C warrant liability in future periods.

Interest and Other Income

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

Critical Accounting Policies and Estimates

Our 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 U.S. generally accepted accounting principles. 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.

While our significant accounting policies are described in more detail in Note 1 of Notes to Financial Statements included elsewhere in this report, 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 CROs 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 completed to date and the related expense. The date on which services commence, 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 study beginning with patient enrollment. We adjust our estimates as actual costs become known to us and 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.

Stock-based Compensation

We account for employee stock options using the intrinsic value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, and provide pro-forma disclosures of net income (loss) as if a fair value method had been applied in measuring compensation expense. Under APB Opinion No. 25, stock compensation expense, which is a non-cash charge, is measured as the excess, if any, of the fair value of our underlying common stock at the date of grant over the amount an employee must pay to acquire such stock and is recognized over the related vesting periods which generally range from one to four years for us.

Prior to the existence of a public market for our common stock, we determined the fair value of our common stock by evaluating a number of factors, including our financial condition and business prospects, our stage of development and achievement of key technical and business milestones, private and public market conditions, the terms of our private financings and the valuations of similar companies in our industry. Our retrospective analysis of the fair value of our stock prices utilized a predominantly linear growth assumption

and also incorporated significant step-ups in value upon the achievement of major events and changes in underlying market conditions.

Series C Net Warrant Liability

In conjunction with our Series C redeemable convertible preferred stock financing in June 2005, we issued a warrant that provided for the sale of additional shares of Series C redeemable convertible preferred stock at the election either by us or the Series C preferred stockholders. The fair value of each component of this instrument was determined at the time of grant, resulting in the recording of a net warrant liability equal to the net fair value of each component. The warrant is classified as a liability in accordance with guidance provided in Financial Accounting Standards Board, or FASB, Staff Position 150-5, *Issuer's Accounting under Statement 150 for Freestanding Warrants and Other Similar Instruments on Shares That Are Redeemable.* The proceeds received in the Series C preferred stock financing were allocated first to the fair value of the net warrant liability instrument with the remainder to the Series C redeemable convertible preferred stock. In accordance with the guidance provided in Emerging Issues Task Force, or EITF, No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, we periodically remeasured the fair value of this financing instrument with the resulting expense, or income, recorded within operating expenses. The warrant was exercised in September 2005 and the corresponding net warrant liability was reclassified as equity.

Net Operating Losses and Tax Credit Carryforwards

At December 31, 2005, we had federal net operating loss carryforwards of approximately $41.4 million and state net operating loss carryforwards of approximately $39.8 million, the majority of which were generated in California. We have federal research and development tax credits of $1.5 million and California research and development tax credits of $1.6 million. Both federal net operating loss carryforwards and research and development tax credits have a 20 year carry forward period and begin to expire in 2023 and 2024, respectively. California net operating loss carryforwards have a 10 year carry forward period and begin to expire in 2013. California research and development tax credits have no expiration.

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 the Company's 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 approximately $284,000 of our California net operating loss carryforwards were effectively eliminated. Additionally, approximately $18,291,000 and $17,335,000 of our federal and California net operating loss carryforwards, respectively, and $887,000 of our federal research and development credits were subject to limitation at December 31, 2005. A portion of the limited net operating loss carryforwards become 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 not subject to limitations. At December 31, 2005, we had federal and state net operating loss carryforwards of approximately $23,060,000 and $22,436,000, respectively, and research and development credits of $600,000 that were generated after the ownership change and therefore not limited. These net operating loss carryforwards and credit carryforwards could be subject to future limitations if additional ownership changes occur.

Results of Operations

License fees. License fees decreased by $3.5 million to $0.5 million for the year ended December 31, 2005 compared to $4.0 million for the year ended December 31, 2004. License fees increased by $3.5 million to $4.0 million for the year ended December 31, 2004 compared to $0.5 million for the period from August 14, 2003 (inception) through December 31, 2003. The following table summarizes the key components of our license fees.

	Year Ended December 31,		Period from August 14, 2003 (inception) through December 31,	Dollar Change		Percent Change	
	2005	2004	2003	2005 vs. 2004	2004 vs. 2003	2005 vs. 2004	2004 vs. 2003
	(dollar amounts in thousands)						
SILENOR™	$ —	$ 601	$520	$ (601)	$ 81	(100)%	16%
Nalmefene	69	3,200	—	(3,131)	3,200	(98)%	100%
Acamprosate	413	237	—	176	237	74%	100%
Total license fees	$ 482	$4,038	$520	$(3,556)	$3,518	(88)%	677%

There were no license fees for SILENOR™ during 2005, while 2004 license fees consisted of a $0.5 million payment owed to our licensor, ProCom One upon the satisfactory completion of the first Phase II clinical trial, and the value of stock granted to designees of ProCom One. License fees during the period ended December 31, 2003 consisted primarily of initial license payments to ProCom One.

Nalmefene license fees of $3.2 million during 2004 consisted primarily of initial license payments made to BioTie Therapies, our licensor. Acamprosate license fees reflected a $0.1 million initial license payment made in 2004 as well as quarterly payments made under the license agreement with Synchroneuron.

Research and Development Expenses. Research and development expenses increased by $21.4 million to $29.0 million for the year ended December 31, 2005 compared to $7.6 million for the year ended December 31, 2004. Research and development expenses increased by $7.4 million to $7.6 million for the year ended December 31, 2004 compared to $0.2 million for the period from August 14, 2003 (inception) through December 31, 2003. The following table summarizes the key components of our research and development expense.

	Year Ended December 31,		Period from August 14, 2003 (inception) through December 31,	Dollar Change		Percent Change	
	2005	2004	2003	2005 vs. 2004	2004 vs. 2003	2005 vs. 2004	2004 vs. 2003
	(dollar amounts in thousands)						
Clinical trials for SILENOR™	$21,210	$6,522	$ —	$14,688	$6,522	225%	100%
Clinical trials for nalmefene	4,780	96	—	4,684	96	4,879%	100%
Clinical trials for acamprosate	215	—	—	215	—	100%	0%
Personnel and other costs	2,598	952	166	1,646	786	173%	473%
Stock-based compensation	152	4	—	148	4	3,700%	100%
Total research and development expense	$28,955	$7,574	$166	$21,381	$7,408	282%	4,463%

SILENOR™ clinical trial expense increased $14.7 million for 2005 compared to 2004 primarily due to the commencement of Phase III clinical trials during 2005. SILENOR™ clinical trial expense increased $6.5 million for 2004 compared to 2003 due to initiating the clinical study program for the drug with two Phase II trials starting in 2004.

Nalmefene clinical trial expense increased $4.7 million for 2005 compared to 2004 due to the commencement of the Phase II/III clinical trial on pathological gambling and a Phase II clinical trial on smoking cessation during 2005.

Personnel and other costs included in research and development expense experienced year-over-year increases as a result of increased headcount and higher clinical and drug development activities.

Marketing, General and Administrative Expenses. Marketing, general and administrative expenses increased by $2.7 million to $4.8 million for the year ended December 31, 2005 compared to $2.1 million for the year ended December 31, 2004. Marketing, general and administrative expenses increased by $1.3 million to $2.1 million for the year ended December 31, 2004 compared to $0.8 million for the period from August 14, 2003 (inception) through December 31, 2003. The following table summarizes the key components of our marketing, general and administrative expenses.

	Year Ended December 31,		Period from August 14, 2003 (inception) through December 31, 2003	Dollar Change		Percent Change	
	2005	2004		2005 vs. 2004	2004 vs. 2003	2005 vs. 2004	2004 vs. 2003
	(dollar amounts in thousands)						
Marketing expense	$ 471	$ 106	$ 3	$ 365	$ 103	344%	3,433%
Personnel and general costs	3,457	2,027	775	1,430	1,252	71%	162%
Stock-based compensation	886	10	—	876	10	8,760%	100%
Total marketing, general and administrative expenses	$4,814	$2,143	$778	$2,671	$1,365	125%	175%

Marketing expense increased each year as a result of greater market research and branding efforts. Personnel and general costs increased primarily due to an increase in headcount as we expanded general and administrative functions, as well as the adoption of our corporate bonus plan during 2005. Stock-based compensation results from the amortization of deferred compensation from stock options granted at a price under the fair value of the underlying stock as determined by our retrospective stock price analysis conducted in conjunction with our initial public offering.

Remeasurement of Series C Warrant Liability. The remeasurement to fair value of the warrant which was issued in June 2005 in conjunction with our Series C preferred stock financing resulted in expense of $5.6 million for the year ended December 31, 2005.

Interest and Other Income. Interest and other income increased by $1.2 million to $1.4 million for the year ended December 31, 2005 compared to $0.2 million the year ended December 31, 2004. The increase is due to higher average cash balances during 2005 as a result of raising $64.8 million in the Series C redeemable convertible preferred stock financing in June and September, 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 2005 compared to 2004.

Liquidity and Capital Resources

Since inception, our operations have been financed through the private placement of equity securities and our initial public offering. Through December 31, 2005, we 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 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 December 31, 2005, we had $100.9 million in cash and cash equivalents and $3.0 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 year ended December 31, 2005, net cash used in operating activities was $23.6 million, compared to $10.9 million for the year ended December 31, 2004. 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, sublicenseable licenses to the patent rights and know-how for certain indications. 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 December 31, 2005:

	Payments Due by Period				
	2006	2007 through 2008	2009 through 2010	After 2010	Total
	(in thousands)				
Operating lease obligations	$ 153	$ 24	$ —	$ —	$ 177
Minimum payments under license agreements	1,115	1,230	1,230	7,290	10,865
Total	$1,268	$1,254	$1,230	$7,290	$11,042

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. Minimum 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.

Recent Accounting Pronouncements

In December 2004, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 123(R), *Share-Based Payment*, a revision of SFAS No. 123, *Accounting for Stock-Based Compensation.* SFAS No. 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and requires all companies to measure compensation cost for share-based payments, including grants of employee stock options, at fair value and recognize the cost in the statements of operations over the service period of the award. Under SFAS No. 123(R), the pro-forma disclosure in the Notes to Financials Statements previously allowed by SFAS No. 123 will not be an acceptable alternative to recognition of expenses in the financial statements. We adopted SFAS No. 123(R) on January 1, 2006 using the modified prospective method.

The adoption of SFAS No. 123(R) will have a material effect on our results of operations and net loss per share. The impact of adopting SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share-based awards granted in the future. However, had we adopted SFAS No. 123(R) in prior periods, the impact on our statements of operations would have approximated the pro-forma results from SFAS No. 123 as described in the Notes to Financial Statements. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow rather than an operating cash flow as required under current literature. To the extent we experience tax deductions in excess of recognized compensation costs, our statements of cash flows will show a decrease in net operating cash flows and an increase in net financing cash flows.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections," which addresses the accounting and reporting for changes in accounting principles and replaces APB 20 and SFAS 3. SFAS No. 154 requires retrospective application of changes in accounting principle to prior periods' financial statements unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, SFAS No. 154 requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings for that period rather than being reported in the income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, SFAS No. 154 requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. SFAS No. 154 becomes effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not expect the adoption of SFAS No. 154 to have a material effect on our financial position or results of operations.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk***

Our cash and investments at December 31, 2005 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 8. ***Financial Statements and Supplementary Data***

See the list of financial statements filed with this report under Item 15 below.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***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.

Item 9B. ***Other Information***

Not applicable.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

The information required by this item will be contained in our definitive proxy statement, or Proxy Statement, to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of our Stockholders, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2005, and is incorporated in this report by reference.

We have adopted a code of ethics that applies to our chief executive officer, chief financial officer, and to all of our other officers, directors, employees and agents. The code of ethics is available on our website at www.somaxon.com. We intend to disclose future amendments to, or waivers from, certain provisions of our code of ethics on the above website within five business days following the date of such amendment or waiver.

Item 11. ***Executive Compensation***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 13. ***Certain Relationships and Related Transactions***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 14. ***Principal Accounting Fees and Services***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) *Documents filed as part of this report.*

1. The following financial statements of Somaxon Pharmaceuticals, Inc. and Report of PricewaterhouseCoopers LLP, independent registered public accounting firm, are included in this report:

- Report of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
- Balance Sheets as of December 31, 2005 and 2004

- Statements of Operations for the years ended December 31, 2005 and 2004 and the period from August 14, 2003 (inception) through December 31, 2003
- Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity for the years ended December 31, 2005 and 2004 and the period from August 14, 2003 (inception) through December 31, 2003
- Statements of Cash Flows for the years ended December 31, 2005 and 2004 and the period from August 14, 2003 (inception) through December 31, 2003
- Notes to Financial Statements

2. List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. List of exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) *Exhibits.*

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
10.1(1)	Form of Director and Executive Officer Indemnification Agreement
10.2#(3)	2004 Equity Incentive Award Plan and forms of option agreements thereunder
10.3#(1)	Director Compensation Policy
10.4#(4)	2005 Equity Incentive Award Plan and forms of option and restricted stock agreements thereunder
10.5#(4)	2005 Employee Stock Purchase Plan and form of Offering Document thereunder
10.6#(3)	2005 Incentive Plan
10.7#(3)	Employment Agreement between the Registrant and Kenneth M. Cohen dated August 15, 2003
10.8#(3)	Employment Agreement between the Registrant and Susan E. Dubé dated August 15, 2003
10.9#(3)	Employment Agreement between the Registrant and Philip Jochelson, M.D. dated April 4, 2005
10.10#(3)	Employment Agreement between the Registrant and Meg M. McGilley dated August 15, 2003
10.11#(3)	Employment Agreement between the Registrant and Jeffrey W. Raser dated August 15, 2003
10.12#(3)	Form of Restricted Stock Purchase Agreement
10.13(3)	Lease dated January 14, 2004 by and between the Registrant and Square 24 Associates L.P.
10.14(3)	Sublease dated June 12, 2005 by and between the Registrant and Ascenta Therapeutics, Inc.
10.15†(5)	License Agreement dated August 25, 2003 by and between the Registrant and ProCom One, Inc.
10.16†(3)	Amendment No. 1 to License Agreement dated October 20, 2003 by and between the Registrant and ProCom One, Inc.
10.17†(5)	License Agreement dated November 12, 2004 by and between the Registrant and BioTie Therapies Corp.
10.18†(5)	License Agreement dated September 1, 2004 by and between the Registrant and Synchroneuron, LLC.
10.19†(5)	License Agreement dated January 31, 2005 by and between the Registrant and the University of Miami
10.20(3)	Master Agreement for Services dated May 10, 2004 by and between the Registrant and Synteract, Inc.
10.21(3)	Consulting Agreement dated August 25, 2003 by and between the Registrant and Terrell A. Cobb

Exhibit Number	Description
10.22(3)	Common Stock Purchase Agreement by and among the Registrant, ProCom One, Inc. and Terrell A. Cobb
10.23	Amendment No. 1 to Consulting Agreement effective September 23, 2005 by and between the Registrant and Terrell A. Cobb
23.1	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm
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

† Confidential treatment has been granted as to certain portions, which portions have been omitted and filed separately with 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.

(4) Filed with the Registrant's Registration Statement on Form S-8 on December 15, 2005.

(5) Filed with Amendment No. 2 to the Registrant's Registration Statement on Form S-1 on November 23, 2005.

* These certifications are being furnished solely to accompany this annual 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.

(c) *Financial Statement Schedule.* Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SOMAXON PHARMACEUTICALS, INC.

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

Dated: March 22, 2006

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ KENNETH M. COHEN Kenneth M. Cohen	President, Chief Executive Officer and Director (Principal Executive Officer)	March 22, 2006
/s/ MEG M. MCGILLEY Meg M. McGilley	Vice President, Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 22, 2006
/s/ DAVID F. HALE David F. Hale	Chairman of the Board of Directors	March 22, 2006
/s/ LOUIS C. BOCK Louis C. Bock	Director	March 22, 2006
/s/ TERRELL A. COBB Terrell A. Cobb	Director	March 22, 2006
/s/ CAM L. GARNER Cam L. Garner	Director	March 22, 2006
/s/ SCOTT L. GLENN Scott L. Glenn	Director	March 22, 2006
/s/ JESSE I. TREU, PH.D. Jesse I. Treu, Ph.D.	Director	March 22, 2006
/s/ DANIEL K. TURNER III Daniel K. Turner III	Director	March 22, 2006
/s/ KURT VON EMSTER Kurt von Emster	Director	March 22, 2006
/s/ KURT C. WHEELER Kurt C. Wheeler	Director	March 22, 2006

Somaxon Pharmaceuticals, Inc.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Somaxon Pharmaceuticals, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, of changes in redeemable convertible preferred stock and stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Somaxon Pharmaceuticals, Inc. (a development stage company) at December 31, 2005 and 2004, and the results of its operations and its cash flows for the years ended December 31, 2005 and 2004, and for the period from August 14, 2003 (inception) to December 31, 2003, and, cumulatively, for the period from August 14, 2003 (inception) to December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Diego, California
March 22, 2006

Somaxon Pharmaceuticals, Inc.
(A development stage company)

BALANCE SHEETS

	December 31, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$100,918,088	$ 12,835,318
Short-term investments	3,047,086	—
Other current assets	1,923,466	389,515
Total current assets	105,888,640	13,224,833
Property and equipment, net	190,045	98,654
Other assets	177,259	275,350
Total assets	$106,255,944	$ 13,598,837
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,881,616	$ 2,479,604
Accrued liabilities	919,090	845,130
Total current liabilities	12,800,706	3,324,734
Commitments and contingencies: (Note 4)		
Stockholders' equity:		
Preferred stock, $.0001 par value; 10,000,000 shares authorized, no shares issued or outstanding at December 31, 2005	—	—
Series A convertible preferred stock, $.0001 par value; zero and 2,300,000 shares authorized, issued and outstanding at December 31, 2005 and 2004, respectively	—	2,300,000
Series B convertible preferred stock, net of issuance costs; $.0001 par value; zero and 24,000,000 shares authorized at December 31, 2005 and 2004, respectively; zero and 23,000,000 shares issued and outstanding at December 31, 2005 and 2004, respectively	—	22,902,705
Common stock, $.0001 par value; 100,000,000 and 35,000,000 shares authorized at December 31, 2005 and 2004, respectively; 18,045,366 and 723,224 shares issued and outstanding at December 31, 2005 and 2004, respectively	1,804	72
Additional paid-in capital	150,802,850	229,770
Deferred compensation	(3,801,897)	(97,492)
Deficit accumulated during the development stage	(53,547,519)	(15,060,952)
Total stockholders' equity	93,455,238	10,274,103
Total liabilities and stockholders' equity	$106,255,944	$ 13,598,837

The Accompanying Notes are an Integral Part of these Financial Statements

Somaxon Pharmaceuticals, Inc.
(A development stage company)

STATEMENTS OF OPERATIONS

	Year Ended December 31,		Period from August 14, 2003 (inception) through December 31, 2003	Period from August 14, 2003 (inception) through December 31, 2005
	2005	2004		
Operating expenses				
License fees	$ 482,460	$ 4,038,370	$ 519,235	$ 5,040,065
Research and development	28,954,063	7,574,194	166,272	36,694,529
Marketing, general and administrative expense	4,814,487	2,142,550	778,220	7,735,257
Remeasurement of Series C warrant liability	5,648,612	—	—	5,648,612
Total operating expenses	39,899,622	13,755,114	1,463,727	55,118,463
Loss from operations	(39,899,622)	(13,755,114)	(1,463,727)	(55,118,463)
Interest and other income	1,413,055	157,344	545	1,570,944
Net loss	(38,486,567)	(13,597,770)	(1,463,182)	(53,547,519)
Accretion of redeemable convertible preferred stock to redemption value	(86,102)	—	—	(86,102)
Net loss applicable to common stockholders	$(38,572,669)	$(13,597,770)	$(1,463,182)	$(53,633,621)
Basic and diluted net loss applicable to common stockholders per share	$ (33.30)	$ (38.08)	$ (10.03)	
Shares used to calculate net loss applicable to common stockholders per share	1,158,347	357,123	145,833	

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
For the period from August 14, 2003 (inception) through December 31, 2005

	Series C Redeemable Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Stock Compensation	Deficit Accumulated During the Development Stage	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
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

The Accompanying Notes are an Integral Part of these Financial Statements

Somaxon Pharmaceuticals, Inc.
(A development stage company)

STATEMENTS OF CASH FLOWS

	Year Ended December 31,		Period from August 14, 2003 (inception) through December 31, 2003	Period from August 14, 2003 (inception) through December 31, 2005
	2005	2004		
Cash flows from operating activities				
Net loss	$(38,486,567)	$(13,597,770)	$(1,463,182)	$(53,547,519)
Adjustments to reconcile net loss to net cash used in operating activities Depreciation	50,349	25,862	314	76,525
Expense related to stock option issuance	1,174,487	27,630	—	1,202,117
Issuance of stock for license agreement	—	100,870	—	100,870
Remeasurement of Series C warrant	5,648,612	—	—	5,648,612
Loss on disposal of equipment	1,782	—	—	1,782
Changes in operating assets and liabilities				
Other current assets	(1,533,951)	(384,453)	(5,062)	(1,923,466)
Other assets	98,091	(275,350)	—	(177,259)
Accounts payable	9,402,012	2,476,604	3,000	11,881,616
Accrued liabilities	68,233	684,399	97,231	849,863
Net cash used in operating activities	(23,576,952)	(10,942,208)	(1,367,699)	(35,886,859)
Cash flows from investing activities				
Purchases of property and equipment	(143,522)	(116,338)	(8,492)	(268,352)
Purchases of short-term investments	(3,047,086)	—	—	(3,047,086)
Net cash used in investing activities	(3,190,608)	(116,338)	(8,492)	(3,315,438)
Cash flows from financing activities				
Issuance of common stock, net of issuance costs	49,820,220	—	350	49,820,570
Issuance of preferred stock, net of issuance costs	64,847,703	22,921,167	2,281,538	90,050,408
Exercise of stock options	182,407	67,000	—	249,407
Net cash provided from financing activities	114,850,330	22,988,167	2,281,888	140,120,385
Increase in cash and cash equivalents	88,082,770	11,929,621	905,697	100,918,088
Cash and cash equivalents at beginning of the period	12,835,318	905,697	—	—
Cash and cash equivalents at end of the period	$100,918,088	$ 12,835,318	$ 905,697	$100,918,088
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

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.

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.

Cash, Cash Equivalents and Investments

The Company invests its available cash balance in money market funds, United States government notes, and other investment grade debt securities that have strong credit ratings. The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. The Company's short-term investments consist of United States government agency notes with maturities at the date of purchase exceeding three months and which mature in less than one year from the balance sheet date. The Company classifies these investments as available-for-sale securities with their balance reported at fair value. Any unrealized holding gains or losses are recorded as a separate component of stockholders' equity. Dividends and interest, including amortization of premiums or discounts at time of acquisition, are recorded in interest income as it is earned.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and is depreciated using the straight-line method over the estimated useful life of the asset or the lease term for leasehold improvements, if shorter. Useful lives generally ranging from three years for computer equipment to five years for office furniture and equipment.

Fair Value of Financial Instruments

The Company's financial instruments, including cash, cash equivalents, investments, accounts payables, and accrued liabilities are carried at cost which approximates fair value due to the relative short-term maturities of these instruments.

Impairment of Long-Lived Assets

The Company assesses the recoverability of its long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. There have been no indicators of impairment through December 31, 2005.

License Fees and Research and Development Expenses

Costs related to patents and the acquisition of intellectual property are expensed as incurred and included in license fees. These costs are expensed since the underlying technology associated with these expenditures relates to the Company's research and development efforts and has no alternative future use.

Research and development costs are expensed as incurred and include costs associated with services provided by contract organizations for clinical trials, costs to treat the patients, and manufacturing of clinical materials. The total cost of a given clinical trial is based on the terms of the related contracts. The Company monitors the status of the trials and recognizes expenses as services are provided. A portion of the clinical trial cost generally relates to the cost to treat a patient. These expenses are recognized over the term of the study based on the estimated costs incurred for the patients treated. The Company adjusts its estimates as actual costs become known.

Reverse Stock Split

On November 29, 2005, the Company's board of directors approved a one-for-six reverse stock split of the Company's outstanding common stock, which was effected on December 9, 2005. In connection with the reverse stock split, every six shares of the Company's outstanding common stock were replaced with one share of the Company's common stock. All references to common stock, common shares outstanding and per share amounts in these financial statements and notes to financial statements prior to the effective date of the reverse stock split have been restated to reflect the one-for-six reverse stock split on a retroactive basis for all periods presented.

Stock-based Compensation

As allowed by Statement of Financial Accounting Standards ("SFAS") No. 123, *Accounting for Stock Based Compensation* ("SFAS No. 123"), the Company has elected to account for its stock options issued to employees and directors using the intrinsic value method of accounting prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"). Under APB 25, compensation expense is recognized over the vesting period of the option to the extent that the fair value of the stock exceeds the exercise price of the stock option at the date of grant.

Had compensation expense for employee and director stock options been determined based on their fair value at the date of grant consistent with SFAS No. 123, the Company's net loss applicable to common stockholders and basic and diluted net loss applicable to common stockholders per share would have been changed to the following pro forma amounts:

	Year Ended December 31,		August 14, 2003 (inception) to December 31, 2003
	2005	2004	
Net loss applicable to common stock holders as reported	$(38,572,669)	$(13,597,770)	$(1,463,182)
Add: Stock-based employee compensation expense included in net loss	1,037,204	13,425	—
Less: Stock-based employee compensation expense using fair value method	(1,340,547)	(38,278)	—
Pro-forma net loss applicable to common stockholders	$(38,876,012)	$(13,622,623)	$(1,463,182)
Basic and diluted net loss applicable to common stockholders per share as reported	$ (33.30)	$ (38.08)	$ (10.03)
Pro-forma basic and diluted net loss applicable to common stockholders per share	$ (33.56)	$ (38.15)	$ (10.03)

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

	Year Ended December 31,		August 14, 2003 (inception) to December 31, 2003
	2005	2004	
Weighted average risk free interest rate	4.12%	4.23%	—
Expected life	6 years	6 years	—
Expected volatility	58% to 64%	66% to 68%	—
Expected dividend yield	0%	0%	—
Fair value of underlying stock	$4.68 to $13.62	$1.20 to $2.10	—

The Company accounts for options granted to consultants and advisors under SFAS No. 123 and Emerging Issues Task Force ("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.* As such, stock options granted to non-employees are periodically re-measured and expense (or income) is recognized over their vesting terms.

Series C Warrant

In conjunction with the Company's Series C financing in June 2005, a financing instrument was issued which provided for the sale of additional shares of Series C redeemable convertible preferred stock at either the election of the Company or the election of the Series C investors. This warrant instrument provided for the issuance of shares which were potentially redeemable and therefore may ultimately have required cash settlement by the Company. In accordance with guidance provided in FASB Staff Position 150-5, *Issuer's Accounting under Statement 150 for Freestanding Warrants and Other Similar Instruments on Shares That*

Are Redeemable, the fair value of each component of this instrument was determined at the time of grant, resulting in the recording of a net liability. A portion of the proceeds received in the Series C financing equal to the net fair value of the financing instrument were allocated to the instrument. In accordance with the guidance provided in EITF No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, the Company periodically remeasured the fair value of this financing instrument with the resulting expense recorded in operating expenses.

In September 2005, the Company exercised its right and issued an additional 7,407,407 shares of Series C redeemable convertible preferred stock at $1.35 per share for gross proceeds of $10,000,000. Immediately prior to the exercise, the warrant instrument was remeasured to its fair value of $6,296,296. Upon exercise, the warrant instrument net liability was extinguished with its value charged to additional paid-in capital.

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. The Company has reported comprehensive income (loss) in the statement of stockholders' equity as net loss since no other items were charged directly to stockholders' equity.

Net Loss per Share

Net loss applicable to common stockholders per share is calculated in accordance with SFAS No. 128, *Earnings Per Share*, and Staff Accounting Bulletin ("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.

	Year Ended December 31, 2005	Year Ended December 31, 2004	August 14, 2003 (inception) to December 31, 2003
Numerator:			
Net loss	$(38,486,567)	$(13,597,770)	$(1,463,182)
Accretion of redeemable convertible preferred stock to redemption value	(86,102)	—	—
Net loss applicable to common stockholders	$(38,572,669)	$(13,597,770)	$(1,463,182)
Denominator:			
Weighted average common shares	1,276,403	647,054	583,333
Weighted average unvested common shares subject to repurchase	(118,056)	(289,931)	(437,500)
Denominator for basic and diluted net loss per share	1,158,347	357,123	145,833
Basic and diluted net loss applicable to common stockholders per share	$ (33.30)	$ (38.08)	$ (10.03)
Outstanding anti-dilutive securities not included in diluted net loss per share calculation:			
Convertible preferred stock	—	4,216,667	380,256
Options to purchase common stock	1,403,332	276,166	—
Common stock subject to repurchase	126,023	247,361	402,777
	1,529,355	4,740,194	783,033

Segment Information

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

Income Taxes

The Company accounts for income taxes under the provisions of SFAS No. 109, *Accounting for Income Taxes*, which requires companies to account for deferred income taxes using the asset and liability method. Under the asset and liability method, current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credits and loss carry-forwards. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Tax rate changes are reflected in income during the period such changes are enacted. Changes in ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income (see Note 6).

New Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123(R), *Share-Based Payment*, which amends SFAS No. 123, and supersedes APB 25. SFAS No. 123(R) requires the fair value of all share-based payments to employees and directors, including grants of employee stock options, be recognized in the statements of operations. The pro forma disclosure previously permitted under SFAS No. 123 will not be an acceptable alternative to recognition of expenses in the financial statements. The Company will adopt the standard in the first quarter of 2006 using the modified prospective method. Under the modified prospective method of adoption, compensation cost is recognized for all share-based payments granted after adoption and for all unvested awards granted prior to the effective date of SFAS No. 123(R).

The Company expects the adoption of SFAS No. 123(R) will have a material effect on its results of operations and net loss per share. The impact of adopting SFAS No. 123(R) cannot be predicted at this time because it will depend on the amount of share-based awards granted in the future. However, had the Company adopted SFAS No. 123(R) in prior periods, the impact on the Company's statements of operations would approximate the pro-forma results of SFAS No. 123 as described in the stock-based compensation section presented earlier in this footnote. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost be reported as a financing cash flow rather than an operating cash flow as required under current literature.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections," which addresses the accounting and reporting for changes in accounting principles and replaces APB 20 and SFAS 3. SFAS No. 154 requires retrospective application of changes in accounting principle to prior periods' financial statements unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, SFAS No. 154 requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings for that period rather than being reported in the income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, SFAS No. 154 requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. SFAS No. 154 becomes effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company does not expect the adoption of SFAS No. 154 to have a material effect on its financial position or results of operations.

Note 2. Composition of Certain Balance Sheet Items

Property and Equipment

Property and equipment consists of the following:

	December 31,	
	2005	2004
Office furniture and equipment	$169,002	$ 83,535
Computer equipment	96,842	41,295
Property and equipment, at cost	265,843	124,830
Less: accumulated depreciation	(75,798)	(26,176)
Property and equipment, net	$190,045	$ 98,654

Depreciation expense was $50,349, $25,862, and $314 for the years ended December 31, 2005, 2004 and for the period from August 14, 2003 (inception) through December 31, 2003, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2005	2004
Accrued license fees	$138,750	$562,500
Accrued compensation and benefits	610,863	43,380
Refundable proceeds from unvested exercised stock options	69,227	63,500
Accrued professional fees	95,000	10,500
Withholding tax	—	160,000
Other accrued liabilities	5,250	5,250
Total accrued liabilities	$919,090	$845,130

Withholding tax at December 31, 2004 resulted from federal taxes owed on certain licensing fees paid to an entity in a foreign country.

Note 3. License Agreements

The following summarizes the Company's license agreements and activity. Costs associated with 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 $10,865,000 for milestone and license payments. The Company is also obligated to make additional milestone payments of up to $11,375,000 upon the achievement of 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.

SILENOR™

In August 2003 and as amended in October 2003, the Company acquired an exclusive worldwide license from ProCom One, Inc. ("ProCom") to develop and commercialize SILENOR™ (doxepin hydrochloride) for the treatment of insomnia. The term of the license extends until the last licensed patent expires, which is expected to occur in 2020. The license agreement is cancelable at any time by the Company with 30 days' notice if the Company believes that the use of the product poses an unacceptable safety risk or if it fails to achieve a satisfactory level of efficacy. Either party may terminate the agreement with 30 days' notice if the other party commits a material breach of its obligations and fails to remedy the breach within 90 days, or upon the filing of bankruptcy, reorganization, liquidation, or receivership proceedings.

For the period ended December 31, 2003, the Company paid ProCom $100,000 for the right to negotiate an exclusive agreement and $400,000 as the first milestone payment for a total of $500,000. The Company was obligated to issue shares of the Company's common stock in conjunction with the Series A convertible preferred stock issuance. In April 2004, the Company issued 84,058 shares to ProCom and recorded licensing expense for the fair value of the stock of $100,870. The license agreement also required a $500,000 payment upon the completion of a Phase II clinical trial, which took place in December 2004 and was included in the accrued liability balance at December 31, 2004. The obligation was paid shortly thereafter. Future milestones are payable upon achievement of various clinical or regulatory events, and the Company is obligated to pay a

royalty on worldwide net sales of the licensed products. The Company has the right to grant sublicenses to third parties.

Nalmefene

In November 2004, the Company entered into an agreement with BioTie Therapies Corp. ("BioTie") for the license of oral nalmefene hydrochloride for the treatment of impulse control disorders and substance abuse disorders. The term of the license extends through the expiration of each licensed patent or patent application which is expected to occur in 2017. The Company may cancel the agreement with 30 days' written notice if the product poses an unacceptable safety risk for patients or fails to achieve efficacy in clinical development. Either party may cancel the agreement with 60 days' written notice upon material breach of the agreement and failure to cure such breach, or if either party becomes insolvent or is adjudged bankrupt.

The Company paid BioTie $200,000 in July 2004 for the right to negotiate an exclusive agreement, followed by a $3,000,000 payment in November 2004 upon entering the licensing agreement. Future milestones are payable upon achievement of various clinical or regulatory events and the Company is obligated to pay BioTie a royalty on net sales of licensed products. The Company has the right to grant sublicenses to third parties and is required to pay BioTie part of any sublicense revenue received.

In January 2005, the Company in-licensed from the University of Miami the exclusive worldwide rights for a patent relating to the treatment of nicotine dependence. The term of the license extends generally through the expiration of the patent, which is expected to occur in 2016, and potentially longer under certain circumstances. The agreement is cancelable by the Company at any time with 60 days' written notice. The University of Miami may terminate the agreement upon a material breach of the agreement, provision of a false report, or our insolvency or certain bankruptcy proceedings.

As consideration for the license, the Company paid the University of Miami $35,000 upon entering the license, $20,000 upon commencement of a Phase 1 clinical trial for the treatment of nicotine dependence, and is obligated to make immaterial future annual payments. In addition, the Company is required to pay a royalty on net sales in the United States on the licensed product, subject to credits for prior annual payments already made.

Acamprosate

In September 2004, the Company in-licensed the exclusive worldwide rights from Synchroneuron, LLC ("Synchroneuron") to certain patents to develop, manufacture, and market acamprosate for movement disorders, obsessive compulsive disorder and post-traumatic stress disorder. The term of the license extends through the expiration of the last patent which is expected to occur in 2018. The agreement is cancelable by the Company at any time with 30 days' written notice. Synchroneuron may terminate the agreement upon 30 days' written notice to the Company of a material breach of the contract, including the Company's failure to pay a quarterly license payment, subject to certain cure periods, or immediately upon written notice as to insolvency or certain bankruptcy proceedings.

As consideration for the license, in July 2004, the Company paid Synchroneuron an upfront license fee of $100,000 and is obligated to make future license payments increasing to a maximum of $250,000 per quarter. In addition, the Company may be required to issue up to 83,333 shares of the Company's common stock subject to achieving certain milestones. The Company is also obligated pay a royalty on net sales of the licensed product, subject to credits for the initial license fee and prior quarterly license payments already made. The Company has the right to grant sublicenses to third parties and is required to pay to Synchroneuron part of any sublicense revenue received.

In April 2005, the Company entered into an agreement for the reformulation of acamprosate. The agreement defines various development stages for the reformulation and establishes the related fee for each stage. The agreement is cancelable at any time by either party. The Company paid $275,000 related to this agreement for the year ended December 31, 2005.

Note 4. Commitments

In January 2004, the Company entered into a three-year operating lease for its office facility with monthly rental payments of $8,450 which increase 3% per year and expire in January 2007. Under the terms of the lease agreement, the Company paid a security deposit of $33,800 which is reduced by approximately one month's rental payment on each anniversary date of the lease agreement, resulting in a deposit balance of $24,297 at December 31, 2005.

In June 2005, the Company entered into an operating lease agreement to sublease additional adjoining office space. The sublease requires monthly rental payments of $8,294 and expires in April, 2006. Under the terms of the sublease agreement, the Company paid a security deposit of $24,882 of which $8,294 was returned in October 2005 and a similar amount will be returned in February 2006, resulting in a deposit balance of $16,588 at December 31, 2005. The Company is also obligated under various operating leases for office equipment.

Rent expense was $165,686, $102,191, and zero for the years ended December 31, 2005 and 2004, and for the period from August 14, 2003 (inception) through December 31, 2003, respectively.

At December 31, 2005, the future minimum lease payments for the years then ended are as follows:

2006	153,335
2007	17,322
2008	6,326
Total	$176,983

The Company has contracted with a drug manufacturer to develop certain drug supplies. The contracts are cancelable at any time, but obligate the Company to reimburse the manufacturer for any unpaid actual costs incurred at the time of cancellation. The Company has also contracted with a clinical research organization ("CRO") and other vendors to assist in clinical trial work. The 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.

Note 5. Redeemable Convertible Preferred Stock and Stockholders' Equity

Preferred Stock

Since inception, the Company has issued Series A convertible preferred stock, Series B convertible preferred stock, and Series C redeemable convertible preferred stock. These preferred shares were convertible into common stock at a ratio of six shares of preferred stock into one share of common stock at any time at the option of the stockholder, and were automatically converted into 12,241,382 shares of common stock upon completion of the Company's IPO on December 20, 2005. Effective with the IPO, 10,000,000 shares of preferred stock were authorized, none of which are issued and outstanding at December 31, 2005.

Series A Convertible Preferred Stock

From inception in August 2003 through December 31, 2003, the Company issued 2,281,538 shares of Series A convertible preferred stock at $1.00 per share for cash proceeds of $2,281,538. In January 2004, an additional 18,462 shares of Series A convertible preferred stock were issued at $1.00 per share for cash proceeds of $18,462. In total, the Company issued 2,300,000 shares of Series A convertible preferred stock for total proceeds of $2,300,000.

Series B Convertible Preferred Stock

In April and June 2004, the Company issued 17,000,000 and 6,000,000 shares, respectively of Series B convertible preferred stock at $1.00 per share for total cash proceeds of $23,000,000. Net proceeds were $22,902,705 after deducting issuance costs of $97,295.

Series C Redeemable Convertible Preferred Stock and Related Warrant

In June 2005, the Company issued 40,741,048 shares of Series C redeemable convertible preferred stock at $1.35 per share for gross proceeds of $55,000,415 and net proceeds of $54,847,703 after deducting offering costs of $152,712. In conjunction with this financing, a warrant instrument (the "Warrant") was issued which provided for the sale of an additional $10 million of redeemable convertible preferred stock. The Warrant was exercisable by either the Company (the "Company Option") or by the majority of the Series C preferred stockholders (the "Investor Option"). If the Warrant was exercised by the Company, additional shares of Series C redeemable convertible preferred shares would be issued at $1.35 per share. If the Warrant was exercised by the Series C preferred stockholders, additional shares of Series C-1 redeemable convertible preferred shares would be issued at $1.45 per share.

The Warrant instrument was considered a liability in accordance with guidance provided in FASB Staff Position 150-5, *Issuer's Accounting under Statement 150 for Freestanding Warrants and Other Similar Instruments on Shares That Are Redeemable*, because the Warrant provided for the issuance of redeemable preferred stock which may have ultimately required cash settlement by the Company. At the close of the Series C financing, the fair value of the Company Option and the Investor Option was determined using the Black-Scholes valuation model to arrive at the net Warrant liability, which is the extent to which the fair value of the Investor Option exceeded the Company Option. The proceeds from the Series C financing were allocated first to the fair value of the net Warrant liability instrument of $647,684 with the remainder to the Series C redeemable convertible preferred stock. The net Warrant liability was periodically remeasured to its fair value in accordance with the terms of EITF No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, with the change in value recorded in operating expense.

In September 2005, the Company exercised the Warrant and 7,407,407 shares of Series C redeemable convertible preferred stock were issued at $1.35 per share for total proceeds of $10,000,000. Immediately prior to exercise, the value of the Warrant was $6,296,296 and the liability was remeasured accordingly, resulting in a $5,648,612 remeasurement expense. Upon exercise, the Warrant liability was eliminated with the contribution recognized as a component of additional paid-in capital.

The redemption provision of the Series C redeemable convertible preferred stock provided that after June 1, 2010, upon the request of a majority of the holders, the Company was obligated to redeem the outstanding shares of the Series C preferred stock. The redemption price was equal to the original issuance price of $1.35 per share, plus any declared but unpaid dividends. The Company was not obligated to declare a dividend and dividends were not cumulative. Per share prices were subject to adjustment for stock splits or similar equity recapitalizations, and no sinking fund was required for the redemption. The Company increased

the carrying amount of the Series C redeemable convertible preferred stock through periodic accretions so that the carrying amount will equal the minimum redemption value at the earliest possible redemption date. The accretion charges were recorded to additional paid-in capital because the Company currently does not have retained earnings, and would be charged to accumulated deficit if additional paid-in capital was unavailable. Accretion charges increased the net loss applicable to common stock holders in the calculation of basic and diluted net loss per share. At the time of conversion into shares of common stock at the time of the IPO, $86,102 of accretion charges were incurred. Because the redemption features were not in effect during the periods presented, the Series C preferred stock was considered contingently redeemable and therefore not classified as a liability. Under the provisions of SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, if after June 1, 2010 the majority of the Series C holders exercised the redemption provision, the Series C redeemable convertible preferred stock would have been reclassified as a liability.

Common Stock

In August 2003, in conjunction with the founding of the Company, 583,333 shares of common stock were issued to the founders at a price of $0.0006 per share for total proceeds of $350. A portion of the founder shares vest over periods between two and four years and the Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. Any unvested shares immediately vest in the event of termination for reasons other than cause, and vesting accelerates in the event of a merger, sale, or other change in control of the Company.

In April 2004, the Company issued 84,058 shares of common stock to designees of ProCom with a fair value of $100,870 in accordance with the SILENOR™ license agreement. Also, certain stock options were exercised resulting in the issuance of 55,833 shares for cash proceeds of $67,000 during the year ended December 31, 2004 and 80,760 shares for cash proceeds of $182,407 for the year ended December 31, 2005.

On December 20, 2005, the Company completed its initial public offering ("IPO") which resulted in the issuance of 5,000,000 shares of common stock at a price of $11 per share for gross proceeds of $55,000,000. Issuance costs related to the offering were $5,179,780 resulting in net proceeds from the offering of $49,820,220. In conjunction with the completion of the IPO, all outstanding shares of convertible preferred stock were converted into 12,241,382 shares of common stock at a conversion rate of one share of common stock for every six shares of preferred stock.

There were a total of 100,000,000 and 35,000,000 shares of common stock authorized at December 31, 2005 and 2004, respectively. The following table summarizes the number of shares of the Company's common stock reserved for future issuance:

	December 31,	
	2005	2004
Shares of common stock authorized	100,000,000	35,000,000
Shares of common stock issued and outstanding	18,045,366	723,224
Common stock issuable upon conversion of preferred shares	—	4,216,667
Stock options outstanding	1,403,332	276,166
Authorized for future issuance under equity compensation plans	2,010,074	84,668
Total common and potential common shares	21,458,772	5,300,725
Common stock reserved for future issuance	78,541,228	29,699,275

Stock Options

The Company has stock options outstanding under two stock option plans for the benefit of its eligible employees, consultants, and independent directors. In January 2004, the stockholders approved the Somaxon Pharmaceuticals, Inc. 2004 Equity Incentive Award Plan (the "2004 Plan") which authorized the Company to issue options to purchase up to 416,667 shares of its common stock as of December 31, 2004 and was later amended in June 2005 to provide for the issuance of up to 1,250,000 shares. Under the terms of the 2004 Plan, nonqualified and incentive options were to be granted at prices not less than 85% and 100% of the fair value on the date of grant, respectively. 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. The Company has initially reserved 2,000,000 shares of common stock for issuance under the 2005 Plan, plus an additional 25,073 shares from stock options which were available for issuance under the 2004 Plan as of the date of adopting the 2005 Plan. The number of shares available for issuance will be further increased by any options that are forfeited, cancelled, expire, or are repurchased 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 are exercisable in advance of becoming vested. Any unvested shares obtained from the early exercise of stock options are subject to repurchase by the Company in the event of termination or separation at the original exercise price. The Company recognized a liability for the proceeds received from the exercise of unvested options of $69,227 and $63,500 at December 31, 2005 and 2004, respectively. No unvested shares were repurchased by the Company as of December 31, 2005.

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

	Shares	Weighted Average Exercise Price	Weighted Average Fair Value of Common Stock at Grant Date	Weighted Average Intrinsic Value per Share
Outstanding at December 31, 2003	—	$ —		
Stock options granted during 2004:				
April 2004	20,000	1.20	$ 1.20	$ —
June 2004	247,500	1.20	1.50	0.30
September 2004	48,666	1.20	2.10	0.90
Total 2004 stock options granted	316,166	1.20	$ 1.56	$0.36
Stock options exercised during 2004:				
August 2004	(10,000)	1.20		
October 2004	(45,833)	1.20		
Total 2004 stock options exercised	(55,833)	1.20		
Outstanding at December 31, 2004	260,333	1.20		
Stock options granted during 2005:				
March 2005	147,250	2.40	$ 4.68	$2.28
April 2005	54,167	2.40	5.22	2.82
July 2005	671,750	3.00	9.30	6.30
September 2005	4,416	8.40	12.54	4.14
October 2005	2,910	8.40	13.08	4.68
November 2005	13,333	13.62	13.62	—
December 2005	315,000	11.00	11.00	—
Total 2005 stock options granted	1,208,826	5.13	$ 9.08	$3.95
Stock options exercised during 2005:				
April 2005	(20,000)	2.40		
September 2005	(37,500)	2.82		
October 2005	(19,094)	1.20		
Total 2005 stock options exercised	(76,594)	2.32		
Stock options forfeited during 2005:				
May 2005	(26,736)	1.20		
Outstanding at December 31, 2005	1,365,829	$ 4.62		

The Company has historically granted stock options at exercise prices that equaled the fair value of its common stock at the date of grant as estimated by its board of directors. Since prior to the Company's IPO there had not been a public market for the Company's common stock, the board of directors determined the fair value of its common stock by considering a number of objective and subjective factors, including the pricing of convertible preferred stock, the superior preferences and rights of the Company's preferred stock

over the common stock, important operational events, the risk and non-liquid nature of the common stock, and underlying market conditions. The Company had not historically obtained contemporaneous valuations by an unrelated valuation specialist because, at the time of the issuances of stock options, the Company believed its estimates of the fair value of its common stock to be reasonable based on the foregoing factors.

In connection with the IPO, the Company retrospectively assessed the fair value of its common stock. In reassessing the fair value, the Company considered the factors used in its historical determinations of fair value, the likelihood of a liquidity event such as an IPO, and feedback received from investment banks relating to an initial public offering upon beginning such discussions in August 2005. In reassessing the fair value of the common stock, the Company determined that an increase in the estimated fair value of the underlying common stock for options granted after April 2004 was appropriate.

As allowed by SFAS No. 123, *Accounting for Stock Based Compensation*, the Company accounts for its stock options granted to employees and directors under APB 25, *Accounting for Stock Issued to Employees.* Accordingly, deferred stock compensation is recognized to the extent that the price of the underlying common stock, as determined in the retrospective fair value analysis, exceeds the exercise price of the stock options at the date of grant. Deferred stock compensation is amortized over the vesting period of the related options which is generally four years for employees and two years for directors.

For the year ended December 31, 2005, the Company granted 1,208,826 stock options to employees and directors with a weighted average intrinsic value of $3.95 per share, resulting in deferred stock compensation of $4,765,832. Related compensation expense for the year 2005 was $1,037,204 of which $151,587 was included in research and development expense and $885,617 was included in marketing, general and administrative expense. For the year ended December 31, 2004, the Company granted 316,166 stock options to employees and directors with a weighted average intrinsic value of $0.36 per share, resulting in deferred stock compensation of $110,917. Related compensation expense for the year 2004 was $13,425. In May 2005, an employee separated from the Company and deferred compensation was reduced by the unamortized amount relating to this employee's stock options of $24,223. Previously recognized expense was not reversed.

The following table summarizes the Company's stock option activity for consultant stock options.

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2003	—	$ —
Stock options granted during 2004:		
April 2004	10,000	1.20
June 2004	4,167	1.20
November 2004	1,666	1.20
Total 2004 stock options granted	15,833	1.20
Outstanding at December 31, 2004	15,833	1.20
Stock options granted during 2005:		
January 2005	5,000	1.20
March 2005	2,500	2.40
November 2005	20,003	13.62
Total 2005 stock options granted	27,503	10.34
Stock options exercised during 2005:		
August 2005	(4,167)	1.20
Total 2005 stock options exercised	(4,167)	1.20
Stock options forfeited during 2005:		
March 2005	(1,666)	1.20
Outstanding at December 31, 2005	37,503	$ 7.90

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. Stock options granted to consultants resulted in expense of $137,283 and $14,205 for the year ended December 31, 2005 and 2004, respectively which is included in research and development expense. In March 2005, an advisor surrendered 1,666 stock options which were granted during 2004. In accordance with EITF No. 96-18, previously recognized expense was not reversed for these surrendered options.

A summary of the stock options outstanding at December 31, 2004 is as follows:

	Options Outstanding			Vested Options	
Exercise Price	Number	Weighted Average Remaining Life	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
$1.20	276,166	9.4 Years	$1.20	8,472	$1.20

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

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 December 31, 2005, no shares were issued under the ESPP.

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 authorized at December 31, 2003	—	—
Increase in authorized shares	416,667	—
Grants and issuances	(331,999)	—
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

Note 6. Income taxes

The Company has incurred losses since inception, therefore no current income tax provision or benefit has been recorded. Significant components of the Company's net deferred tax assets are shown in the table below.

	December 31, 2005	December 31, 2004
Deferred Tax Assets:		
Net operating loss carryforwards	$ 16,363,090	$ 4,162,825
Research and development credits	2,529,484	506,846
Capitalized research and development	1,890,873	1,781,870
Other, net	405,410	29,323
Total deferred tax assets	21,188,857	6,480,864
Valuation allowance	(21,188,857)	(6,480,864)
Net deferred tax assets	$ —	$ —

At December 31, 2005, the Company had federal and state net operating loss carryforwards of $41,350,728 and $39,770,796, respectively (the deferred tax assets presented in the table above are tax rate affected). Unless previously utilized, the federal and state tax loss carryforwards will begin to expire in 2023 and 2013, respectively. The Company has federal and state research and development tax credit carryforwards of $1,487,257 and $1,579,132, respectively. The federal research and development credits will begin to expire in 2024 and the state research and development credits do not expire.

Pursuant to Sections 382 and 383 of the Internal Revenue Code (the "IRC"), annual use of the Company's 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. The Company determined that an ownership change occurred as of June 30, 2005 as defined in the provisions of Section 382 of the IRC as a result of various stock issuances performed to finance the Company's development activities. Such ownership change resulted in limitations on the utilization of tax attributes, including net operating loss carryforwards and tax credits.

The change of control provisions under the provisions of Section 382 effectively eliminated the Company's ability to utilize approximately $284,000 of the California net operating loss carryforwards. The Company estimates that an additional $18,291,000 and $17,335,000 of the Company's federal and California net operating loss carryforwards, respectively, and $887,000 of the Company's federal research and development credits are also subject to limitation under Section 382 at December 31, 2005. A portion of the restricted net operating loss carryforwards becomes available for use each year and the Company estimates 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 not subject to limitations. At December 31, 2005, the Company had federal and state net operating loss carryforwards of approximately $23,060,000 and $22,436,000, respectively, and research and development credits of $600,000 that were generated after the ownership change and therefore not limited. These net operating loss carryforwards and credit carryforwards could be subject to future limitations if additional ownership changes occur.

Note 7. Related Party Transactions

The Company licenses certain technologies from ProCom which, as part of the license agreement, grants to ProCom 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 $214,974, $200,000, and $70,430 to the affiliates during the years ended December 31, 2005 and 2004, and period from August 2003 (inception) through December 31, 2003, respectively. In addition, the two affiliates have been granted a total of 89,999 stock options as of December 31, 2005 with a weighted average exercise price of $9.96 per share. See Note 3 for further discussion of the license agreement, payment information, and related outstanding liabilities with ProCom.

The Company's outside counsel purchased 50,000 shares of convertible preferred stock during the Series A financing in November 2003 as well as 33,418 shares of redeemable convertible preferred stock during the Series C financing in June and September 2005. In conjunction with the IPO in December 2005, these shares were converted into 13,899 shares of common stock. The Company paid $761,919, $316,268, and $72,441 during the years ended December 31, 2005 and 2004, and the period from August 13, 2003 (inception) through December 31, 2003, respectively for legal services rendered by the Company's outside counsel.

Note 8. Selected Quarterly Financial Information (Unaudited)

The following table presents the Company's unaudited quarterly results of operations for 2005 and 2004. The sum of the quarterly per share amounts may not equal the amounts presented for the full year due to differences in the weighted average number of shares outstanding as calculated on a quarterly compared to an annual basis.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Year
	(In thousands, except per share data)				
2005:					
Loss from operations	$(3,048)	$(8,090)	$(15,488)	$(13,274)	$(39,900)
Net loss	(2,989)	(7,917)	(14,968)	(12,613)	(38,487)
Net loss applicable to common stockholders	(2,989)	(7,931)	(15,007)	(12,646)	(38,573)
Basic and diluted net loss applicable to common stockholders per share	(5.85)	(13.77)	(24.59)	(4.33)	(33.30)
2004:					
Loss from operations	$ (717)	$(1,581)	$ (4,191)	$ (7,266)	$(13,755)
Net loss	(717)	(1,559)	(4,122)	(7,200)	(13,598)
Net loss applicable to common stockholders	(717)	(1,559)	(4,122)	(7,200)	(13,598)
Basic and diluted net loss applicable to common stockholders per share	(3.33)	(4.44)	(10.21)	(15.71)	(38.08)

Note 9. Subsequent Events

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.

Corporate Information

Management Team

Kenneth M. Cohen
President and Chief Executive Officer

Susan E. Dubé
Senior Vice President, Business Development

Jeffrey W. Raser
Senior Vice President, Sales and Marketing

Philip Jochelson, MD
Senior Vice President, Chief Medical Officer

Meg M. McGilley
Vice President and Chief Financial Officer

Board of Directors

David F. Hale
Chairman of the Board,
President and CEO, CancerVax Corporation

Kenneth M. Cohen
President and Chief Executive Officer

Terrell A. Cobb
President, ProCom One

Cam L. Garner
Chairman and CEO, Verus Pharmaceuticals

Scott L. Glenn
Managing Member,
Windamere Venture Partners

Jessie I. Treu, Ph.D.
Managing Member, Domain Associates, L.L.C.

Daniel K. Turner III
General Partner, Montreux Equity Partners

Kurt von Emster, CFA
General Partner, MPM Capital

Kurt C. Wheeler
Managing Director, Clarus Ventures

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Latham & Watkins LLP

Independent Auditors
PriceWaterhouseCoopers LLP

Transfer Agent
American Stock Transfer & Trust Company, who may be reached at 59 Maiden Lane, New York, NY 10038, 212.936.5100

SEC Form 10-K
A copy of the Company's annual report to the Securities and Exchange Commission on Form 10-K is available without charge, upon written request to:

Investor Relations

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Somaxon's press releases and other information are located on Somaxon's web site: www.somaxon.com.

Annual Meeting

The Annual Meeting of Stockholders of Somaxon Pharmaceuticals will be held on May 31, 2006 at 1:30 PM at the San Diego Marriott Del Mar. All stockholders are cordially invited to attend.

Market Information

The Company's common stock trades on the Nasdaq National Market under the symbol "SOMX".

This report contains forward-looking statements, including statements regarding the progress and timing of clinical trials, the safety and efficacy of our product candidates, the goals of our development activities, prospects for a strategic partner, estimates of the potential markets for our product candidates, and discussion of our operations, expenditures and projected cash needs. *Forward-looking statements include all statements that are not historical facts. Actual results may differ materially from those set forth in this report due to the risks and uncertainties inherent in* Somaxon's business, including, without limitation: the results of pending clinical trials; unexpected adverse side effects or inadequate therapeutic efficacy of Somaxon's product candidates that could delay or prevent regulatory approval or commercialization, or that could result in recalls or product liability claims; the potential to attract a strategic partner and the terms of any related transaction; the scope and validity of patent protection for SILENOR™ and Somaxon's other product candidates; the market potential for insomnia and Somaxon's other target markets; and other risks detailed in Somaxon's filings with the SEC, including the annual report on Form 10-K, which accompanies this report.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. All forward-looking statements are qualified in their entirety by this cautionary statement. Somaxon undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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