



United States
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For The Fiscal Year Ended **December 31, 2005**

Commission File Number **333-31932**

HYTHIAM, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

88-0464853
(I.R.S. Employer Identification Number)

11150 Santa Monica Boulevard, Suite 1500
Los Angeles, California 90025
(Address of principal executive offices, including zip code)
(310) 444-4300
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, \$0.0001 par value**

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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of the 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 Exchange Act). Yes No

As of June 30, 2005, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$90,777,518 based on the \$5.60 closing price on NASDAQ on that date. This amount excludes the value of 13,966,666 shares of common stock directly or indirectly held by the registrant's affiliates.

As of March 15, 2006 there were 39,575,246 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for its 2006 annual meeting of stockholders to be held on June 16, 2006, are incorporated by reference into Part III of this report.



HYTHIAM, INC.
Form 10-K Annual Report
For The Fiscal Year Ended December 31, 2005

TABLE OF CONTENTS

PART I	1
Item 1. Business	1
Item 1A. Risk Factors	21
Item 1B. Unresolved Staff Comments	34
Item 2. Property	34
Item 3. Legal Proceedings	34
Item 4. Submission of Matters to a Vote of Security Holders	34
PART II	35
Item 5. Market for Registrant's Common Equity and Related Stockholder Matters	35
Item 6. Selected Financial Data	36
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	37
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	43
Item 8. Financial Statements and Supplementary Data	43
Item 9A. Controls and Procedures	43
Item 9B. Other Information	44
PART III	45
PART IV	46
Item 15. Exhibits, Financial Statement Schedules	46

PART I

Forward-Looking Statements

This report contains forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those discussed due to factors such as, among others, limited operating history, difficulty in developing, exploiting and protecting proprietary technologies, intense competition and substantial regulation in the healthcare industry. Additional information concerning factors that could cause or contribute to such differences can be found in the following discussion, as well as in Item 1.A Risk Factors and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

ITEM 1. BUSINESS

Overview

We research, develop, license and commercialize innovative physiological treatment protocols designed for use by healthcare providers to treat individuals diagnosed with dependencies to alcohol, cocaine and methamphetamine, as well as combinations of these drugs. Unlike traditional treatment methodologies, our proprietary PROMETA™ treatment protocols include medically supervised treatments designed to address both the neurochemical imbalances in the brain and some of the nutritional deficits caused or worsened by substance dependence. Changes in brain chemistry and function play an important role in the physical and behavioral symptoms of substance dependence, including tolerance, withdrawal symptoms, craving and relapse. PROMETA represents an innovative approach to managing substance dependence that is designed to address physiological, nutritional and psychosocial aspects of the disease, and is thereby intended to offer patients an opportunity to achieve sustained recovery.

We have been unprofitable since our inception and may incur substantial additional operating losses for at least the next twelve months as we incur expenditures on research and development, continue to implement commercial operations and allocate significant and increasing resources to sales, marketing and other activities. Accordingly, our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and our historical operations and financial information are not necessarily indicative of the future operating results or financial condition or ability to operate profitably as a commercial enterprise.

Traditional treatment approaches for substance dependence focus mainly on group therapy, abstinence, and behavioral modification, while the disease's underlying physiology and pathology is rarely addressed, resulting in fairly high relapse rates. Currently therapies are beginning to target brain receptors thought to play a central role in the disease process. We believe that our PROMETA protocols offer an improvement to traditional treatments because treatments with PROMETA are designed to directly target the pathophysiology induced by chronic use of alcohol or other drugs. Without specific treatment, the abnormalities in brain function induced by chronic drug dependence may take months to years of drug abstinence to return to normal function. We believe the PROMETA protocols offer an advantage to traditional alternatives because they provide a treatment methodology that is discreet, mildly sedating and that can be initiated in only two to three days, with a second two-day treatment three weeks later for addictive stimulants. Our PROMETA protocols also provide for one-month of prescription medication and nutritional supplements, combined with psychosocial or other recovery-oriented therapy chosen by the patient in conjunction with their treatment provider. Initial clinical observations suggest that our protocols may improve cognitive function, reduce withdrawal symptoms, be associated with higher initial completion rates than conventional treatments, and reduce physical cravings which can be a major factor in relapse, thus allowing patients to more meaningfully engage in counseling or other forms of psychosocial therapy. These conclusions were reached



during treatment of approximately 400 patients and may not be confirmed by clinical research studies, may not be statistically significant, have not been subjected to close scientific scrutiny, and may not be indicative of the long-term future performance of our protocols.

We believe the short initial treatment period when using our PROMETA protocols is a major advantage over traditional inpatient treatments and residential treatment programs, which typically consist of approximately 21 days of combined inpatient detoxification and recovery in a rehabilitation or residential treatment center. Treatment with PROMETA does not require an extensive stay at an inpatient facility. Rather, the protocols offer the convenience of a two to three day treatment (addictive stimulants require a second two day treatment three weeks later) and can generally be administered on an outpatient basis. This is particularly relevant since approximately 77% of adults classified with dependence or abuse are employed, and loss of time from work can be a major deterrent for seeking treatment. Moreover, we believe PROMETA can be used at various stages of recovery, including initiation of abstinence and during early recovery, and can complement other forms of alcohol and drug abuse treatments. As such, our protocols offer a potentially valuable alternative or addition to traditional behavioral or pharmacotherapy treatments that does not require chronic administration of a pharmacotherapy, thus minimizing compliance issues. Many medications marketed to treat alcohol or drug dependence are not administered until the patient is already abstinent, require long-term chronic administration and must be taken several times a day to achieve the desired effect.

We believe that the structure of our business and operations as outlined above will be in substantial compliance with applicable laws and regulations. However, the healthcare industry is highly regulated, and the criteria are often vague and subject to change and interpretation by various federal and state legislatures, courts, and enforcement and regulatory authorities. Our commercial viability is therefore subject to the legal and regulatory risks outlined in Item 1.A Risk Factors.

Our Operations

We commenced operations in July 2003 and signed our first licensing agreement in November 2003. Under our licensing agreements, we provide treatment providers access to our PROMETA protocols and marketing and sales support to attract patient referrals. We receive a fee for the licensed technology and related services generally on a per patient basis. As of December 31, 2005, we had entered into licensing agreements with hospitals and healthcare providers for 32 sites throughout the United States. We intend to enter into agreements with additional hospitals and other healthcare providers to increase both geographic penetration and the number of patients treated. As revenues are generally related to the number of patients treated, key indicators of our financial performance will be the number of facilities and healthcare providers that license our technology, and the number of patients that are treated by those providers using our PROMETA protocols. Since July 2003, over 400 patients have completed treatment using our PROMETA protocols at our licensed sites and in research studies and commercial pilots being conducted to study our protocols.

In December 2005, our senior vice president, medical affairs and renowned addiction medicine specialist, David Smith, M.D., opened the PROMETA Center, a new medical practice operating in a state-of-the-art outpatient facility located in Santa Monica, California, that we built out under a lease agreement. Under the terms of a full service management agreement with Dr. Smith's professional corporation, we manage the medical practice in exchange for management and licensing fees. The practice has a primary focus on offering the PROMETA protocols for dependencies on alcohol, cocaine and methamphetamines but will also offer medical interventions for other substance dependencies, including buprenorphine therapy for the treatment of opiate dependence. The PROMETA Center is the first location primarily dedicated to the treatment of alcohol, cocaine or methamphetamine dependence with the PROMETA protocols. The revenues and expenses of the PROMETA center are included in our consolidated financial statements.



Over the coming year, we will continue to expand our commercial operations, commence substantial direct to consumer marketing activities, and allocate significant and increasing resources to sales and marketing. To date, patients treated with the PROMETA protocols have been primarily self-pay patients. However, in the first quarter 2006, Comprehensive Behavioral Care, Inc. (CompCare), a leading managed behavioral health care organization, approved PROMETA as reimbursable and entered into an agreement with us to market the PROMETA protocols to its managed care network providers. We have also announced several pilot studies with state programs and drug court systems to study the results of using of the PROMETA protocols in their programs. Significant positive results from these studies would help in our efforts to gain third-party reimbursement for providers using our protocols.

We do not currently operate our own healthcare facilities, employ our own treating physicians or provide medical advice or treatment to patients. The hospitals, licensed healthcare facilities, and physicians that contract for the use of our technology own their facilities or professional licenses, and control and are responsible for the clinical activities provided on their premises. Patients receive medical care in accordance with orders from their attending physicians. Physicians with license rights to use the PROMETA protocols are responsible for exercising their independent medical judgment in determining the specific application of our protocols, and the appropriate course of care for each patient. Following the treatment procedure, local clinics and healthcare providers specializing in drug abuse treatment administer and provide continuing care treatment.

Our Market

Substance dependence is a worldwide problem with prevalence rates continuing to rise despite the efforts by national and local health authorities to curtail its growth. Substance dependence disorders affect many people and have wide-ranging social consequences. In 2004, an estimated 22.5 million Americans suffered from alcohol or other forms of drug abuse or dependence, according to the National Survey on Drug Use and Health published by the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency of the U.S. Department of Health and Human Services. Furthermore, according to the survey, approximately 12 million Americans age 12 and older, or 5 percent of the population, are reported as having tried methamphetamine, and the percentage of methamphetamine use characterized as abuse or dependence doubled from 2002 to 2004. Findings from The Drug and Alcohol Services Information System (DASIS) Report published by SAMHSA's Office of Applied Studies in September 2004 show that methamphetamine hospital admissions as a percent of substance abuse treatment admissions increased from 1% in 1992 to 7% in 2002.

It is commonly reported that addiction to methamphetamine is an epidemic rapidly spreading throughout the U.S. Methamphetamine addicts are highly resistant to treatment and, even after intervention, relapse at very high rates. Methamphetamine use is also spreading to the workplace. A study funded by the Wal-Mart Foundation in 2004 determined that each methamphetamine-using employee costs his or her employer \$47,500 per year in terms of lost productivity, absenteeism, higher healthcare costs and higher workers' compensation costs. For county governments and their taxpayers, methamphetamine abuse causes legal, medical, environmental and social problems. A study entitled "The Criminal Effect of Meth on Communities" conducted in 2005 by the National Association of Counties, which surveyed 500 counties in 45 states, reported that 58% of counties surveyed reported methamphetamine as their largest drug problem, with 87% reporting increases in arrests involving methamphetamine starting 3 years ago. Cocaine was reported as the number one drug problem in 19% of the counties. There are currently no generally accepted medical treatments for cocaine or methamphetamine dependence.

Summarizing data from the Office of National Drug Control Policy (ONDCP) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the economic cost of alcohol and drug abuse exceeds \$345 billion annually in the U.S., including \$41 billion in healthcare costs and approximately \$245 billion in productivity losses. Despite these staggering figures, it is a testament to the unmet need in the market that only 17% of those who need treatment actually receive help. Traditional treatment methods are often not particularly effective, especially when

it comes to those who are dependent on stimulants. Often faith, willpower, and counseling are the only options available. Compounding the lack of efficacious treatment options is the enormous stigma of leaving one's life, income, and loved ones for weeks at a time to seek inpatient treatment.

There are approximately 13,000 facilities reporting to SAMHSA that provide substance abuse treatment on an inpatient or outpatient basis. Historically, the disease of substance dependence has been treated primarily through behavioral intervention, with fairly high relapse rates. The DASIS report states that in 2000 only 54% of those treated for alcoholism and 51% of those treated for cocaine and other stimulants complete detoxification, and that combined alcohol and cocaine outpatient treatment completion rates were only 41%. For patients who do complete treatment, the NIAAA reports relapse rates three months following treatment for alcohol dependence to be 50%. Relapse rates are higher for those suffering from cocaine dependence as opposed to alcohol. For the behavioral treatment of cocaine dependence, the Drug Abuse Treatment Outcome Survey reports a relapse rate of 69% one year following outpatient treatment lasting 90 or fewer days and 80% one year following long-term residential treatment lasting 90 or fewer days.

While pharmacological options for alcohol dependence exist, none has proven to be effective enough to be generally accepted as a treatment in and of itself. A number of pharmaceutical companies have introduced or intend to introduce drugs to treat alcohol dependence; however, many may require chronic or long-term administration and their safety and tolerability profiles and relapse rates remain to be determined over periods of prolonged administration. In addition, several of these drugs should not be used until the patient has already achieved abstinence, and must be administered on a chronic or long-term continuing basis.

Substance Dependence as a Disease

Recent scientific research provides evidence that not only can drugs interfere with normal brain functioning but can also have long-lasting effects that persist even after the drug is no longer being used. At some point, changes may occur in the brain that can turn drug and alcohol abuse into substance dependence, a chronic, relapsing and sometimes fatal disease. Those dependent on drugs may suffer from compulsive drug craving and usage and be unable stop drug use or remain drug abstinent without treatment. Professional medical treatment is often necessary to end this physiologically based compulsive behavior. We believe that the ability to successfully treat the physiological basis of substance dependence can improve treatment outcome, reduce the cost of treating dependence, and reduce the cost to society of the adverse consequences of alcohol and drug abuse by decreasing related criminality and violence and mitigating the costs associated with high risk behavior.

Methamphetamine

According to a National Institute on Drug Abuse (NIDA) research report "Methamphetamine: Abuse and Addiction" (January 2002), the effects of methamphetamine use can include addiction, psychotic behavior, and brain damage. Methamphetamine is highly addictive and users trying to abstain from use may suffer withdrawal symptoms that include depression, anxiety, fatigue, paranoia, aggression, and intense cravings for the drug. Chronic methamphetamine use can cause violent behavior, anxiety, confusion, and insomnia. Users can also exhibit psychotic behavior including auditory hallucinations, mood disturbances, delusions, and paranoia, possibly resulting in homicidal or suicidal thoughts. According to NIDA's report "Methamphetamine Linked to Long-Term Damage to Brain Cells" (March 2000), use of methamphetamine can cause damage to the brain that is detectable months after the use of the drug. The damage to the brain caused by methamphetamine use is similar to damage caused by Alzheimer's disease, stroke, and epilepsy.

Alcohol

According to NIAAA, 44% of all deaths due to liver cirrhosis are alcohol related, with most of these deaths occurring in people 40 to 65 years old. One study found that 20 to 37% of all emergency room trauma cases involve alcohol use (Roizen, J., Alcohol and Trauma, 1988). Another study found that 46% of asymptomatic alcoholic men exhibited evidence of cardiomyopathy (Rubin, E., The Effects of Alcoholism on Skeletal and Cardiac Muscle, 1989).

The consequences of alcoholism and alcohol abuse affect most American families. One study estimated that 20-25% of all injury-related hospital admissions are the result of alcoholism or alcohol problems (Waller J., Diagnosis of Alcoholism in the Injured Patient, 1988). According to the National Commission Against Drunk Driving, nearly 600,000 Americans are injured in alcohol-related traffic crashes each year, resulting in 17,000 fatalities.

Cocaine and Crack Cocaine

Cocaine and crack use place a heavy load upon our criminal justice system. According to a Bureau of Justice Statistics Bulletin, "Prisoners in 2004," published in October 2005, 55% of the 170,000 federal prisoners and 21% of the 1.2 million state prisoners were convicted of drug offenses. The ONDCP reports that over 30% of all arrestees test positive for cocaine or crack. In 2001, over 17% of all Federal defendants were charged with cocaine/crack drug offenses.

The consequences of cocaine and crack use extend beyond the criminal justice system. NIDA reports the medical complications of cocaine use to include heart arrhythmias and heart attacks, chest pain and respiratory failure, strokes, seizures, and headaches, as well as abdominal pain and nausea. NIDA also notes that there have been no medications available to treat cocaine dependence.

Our Solution: PROMETA™

Those suffering from alcohol and/or drug dependence have often been characterized as having social disorders or a lack of self-discipline and, as noted above, there are relatively high relapse rates utilizing conventional treatment methods. While we believe the psychological approach to substance dependence treatment is important, we recognize that physiological factors of substance dependence should be addressed first to provide patients with an improved chance for recovery. We believe our physiological approach, focused on addressing the neurochemical imbalances in the brain caused or worsened by substance dependence, provides a substantial commercial opportunity.

Current research indicates that substance dependence is associated with altered cortical activity and changes in neurotransmitter function, which are critical to brain function. Moreover, changes in the neurochemistry of the brain underlie the hallmarks of substance dependence, including tolerance, withdrawal symptoms, craving, decrease in cognitive function and relapse. Our PROMETA protocols include medically supervised treatments, prescription medications and nutritional supplements, combined with psychosocial or other recovery-oriented therapy chosen by the patient in conjunction with their treatment provider.

The PROMETA treatment protocols provide for:

- A comprehensive physical exam, including specific laboratory tests, prior to initiation of treatment by the treating physician, to determine if the patient is appropriate for the PROMETA protocol
- Medically supervised administration of prescription medications and nutritional supplements
- One-month of prescription medications and nutritional supplements following the initial treatment
- Individualized continuing care options



Treatment with PROMETA involves the oral and intravenous administration of pharmaceuticals in a medically supervised setting. The medications used in the PROMETA treatment protocols have been approved by the FDA for uses other than treatment of substance dependence. The PROMETA treatment is discreet and does not require long periods away from home or work. Treatment takes place at a hospital facility, clinic or properly equipped outpatient setting by healthcare providers who have licensed the rights to use our PROMETA protocols. The treatment begins with a two-to-three day course of prescription medications and nutritional supplements. The PROMETA protocol for stimulant dependence provides for a second, two-day course of treatment at the facility, which takes place about three weeks after the initial treatment. Some patients may require an additional day of treatment, subject to the treating physician making this decision during the course of the treatment. In general, the intravenous treatment session typically lasts about an hour. Some patients may receive their treatment in a hospital, or “in-patient” setting. For these patients, the balance of time spent at the treatment facility or hospital is intended to ensure that the patient is well-rested and comfortable between the relatively short treatment periods. Most patients take meals and choose to sleep much of the time between treatments. For the patients receiving care in an “outpatient” facility, such as a physician’s office or treatment center, their doctor may monitor them for a few hours following the treatment session. Typically, the patient would then be released to an accompanying person and return the following day for completion of their treatment. Following the medically supervised treatments, our protocols provide that patients receive one month of prescription medication and nutritional supplements, and participation in psychosocial or other recovery-oriented therapy they select with their physician.

While there may be mild discomfort from inserting and removing the I.V. needle (for intravenous administration of medications), the PROMETA protocols are designed to ensure that the patient is as comfortable as possible throughout the medically supervised procedures. The PROMETA protocols are designed to minimize patient sedation. Some of the medications in the treatment regimen may cause temporary drowsiness.

Based on our limited initial experience with a small number of patients in the U.S., patients who have been through prior treatment programs report that cravings for alcohol or stimulants are significantly reduced or eliminated with the PROMETA protocols, and that they emerge from treatment with greater mental clarity.

We believe PROMETA can offer an advantage to traditional alternatives for several reasons:

- Treatment provided using PROMETA is designed to address a spectrum of patient needs, including physiological, nutritional and psychological elements
- The PROMETA treatment protocols are targeted, medically supervised procedures designed to address the neurochemical imbalances in the brain caused or worsened by substance dependence. The rationale for the approach is that by addressing the underlying physiological aspects of substance dependence, dependent persons may be better able to address the behavioral/psychological and environmental components of their disease
- Treatment using PROMETA does not require long periods away from home or work. PROMETA offers the convenience of a two to three day treatment (for addictive stimulants there is a second two day treatment three weeks later), as compared to traditional inpatient treatments which typically consist of approximately 21 days of combined inpatient detoxification and recovery in a rehabilitation or residential treatment center
- Our protocols may be appropriate for use at various stages of recovery, including initiation of abstinence and during early recovery, and can complement existing treatments.

Additionally, we provide proprietary administrative services to assist physicians and facilities with staff education, marketing and sales support, and outcomes tracking for data analysis.

Our Strategy

Our business strategy is to provide quality, standard-of-care treatment protocols for those suffering from alcoholism and other substance dependencies. We intend to grow our business through increased penetration to new licensees and increased patient volumes.

Key elements of our business strategy include:

- Seeking to expand our base of treatment sites, focusing on major metropolitan service areas within the U.S.
- Increasing awareness about PROMETA among consumers and professional audiences through enhanced marketing and sales initiatives
- Pursuing clinical data to make PROMETA a standard of care for treatment of alcohol, cocaine, and methamphetamine dependence
- Establishing initiatives to help gain third-party reimbursement for providers from private insurers, managed care, state Medicaid programs and criminal justice systems
- Acquiring or licensing new substance dependence treatment protocols that may be developed in the future

Our plan is to apply our technology to an existing industry we view as fragmented with participants that include healthcare providers such as physicians, psychologists, nurses, therapists, interventionists, counselors, hospitals, residential treatment centers, outpatient treatment facilities, and self-help groups. Over time, we expect patients to be referred for treatment to physicians and treatment centers using our technology and through self-referrals, patients' family members, friends, employers and associated unions, as well as employee assistance programs, criminal justice systems, healthcare providers, third party payors, and government agencies. We believe that the PROMETA protocols can provide a significant improvement to current treatment methodologies by addressing a spectrum of patient needs, including both physiological and psychological elements of substance dependence.

Expand Number of Licensees in U.S.

We will focus on expanding our presence in the U.S. private payor market by targeting major metropolitan service areas with high numbers of substance dependent individuals, and licensing our protocols and providing our services to healthcare providers in those areas. We intend to add new licensees in our existing markets where we have established capacity in order to leverage our sales and marketing efforts on a cost-effective basis. We intend to utilize both local and national marketing initiatives to raise awareness of the PROMETA approach in order to increase patient awareness of the treatment protocols. The marketing strategy will initially focus on consumers, by providing education and information that emphasizes substance dependence as a medically-treatable disease, highlighting the potential benefits of PROMETA as an innovative, discreet and convenient medically supervised treatment approach, and encouraging consumers to consult their treatment providers or to phone our national call center for more information. As data from our research studies become available, we plan to expand our marketing initiatives to more aggressively educate the professional community (e.g., physicians, counselors, therapists, payors and other allied professionals). This staged strategic approach to our marketing efforts takes into account: (i) the need to increase patient awareness of licensee sites; and (ii) that a more robust data dossier will be needed to facilitate broader adoption of PROMETA by the professional community.

The PROMETA Center

Under the guidance of Dr. David Smith, the PROMETA Center should result in creating and expanding awareness of our protocols in the key metropolitan service area of Los Angeles. By establishing a brand identity around this discreet, high-end medical facility for addiction treatment, we intend to help lessen the stigma that surrounds those who are afflicted with this disease. The added advantage that PROMETA is offered on an outpatient basis should encourage busy professionals to seek treatment. With the addition of this center to our area licensees,



we are in position to begin an aggressive marketing campaign for Los Angeles and the Southern California region beginning in the first half of 2006. After our campaign gains momentum, the PROMETA Center and all Southern California licensees should benefit from the heightened visibility, resulting in increased patient volumes and inquiries from referral sources. Furthermore, any press or media exposure received by the PROMETA Center will create name recognition for our protocols, thereby benefiting PROMETA licensees throughout the country. Clinical knowledge of PROMETA gathered by the physicians of the Center will be available to current and potential licensees allowing third parties to witness the PROMETA treatment paradigm.

Clinical Data from Research Studies

We believe that a key to our success will be the publication of results from research studies evaluating the PROMETA protocols conducted by leading research institutions and preeminent researchers in the field of alcohol and substance abuse. To date, studies that we have announced include:

- A multi-site, randomized double-blind placebo controlled study of PROMETA for the treatment of methamphetamine dependence conducted by Dr. Walter Ling of UCLA
- A randomized, double-blinded, placebo controlled study of PROMETA for the initiation, and extension of abstinence of alcoholism conducted by Dr. Raymond Anton at Medical University of South Carolina
- An open label study of PROMETA for methamphetamine dependence conducted by Dr. Harold Urschel
- A controlled study of Hythiam's PROMETA protocols in the treatment of alcohol dependence conducted by Dr. Jeffery Wilkins at Cedars-Sinai Medical Center in Los Angeles
- A pharmacoeconomic study to be conducted by the Parallax Center in New York City to compare outcomes achieved with the PROMETA protocol for alcohol dependency to the treatment program's current protocol.

We expect the results from Dr. Harold Urschel's study will be available in the first half of 2006 and will be significant, since we believe it may provide the first formal third-party validation of PROMETA. Methamphetamine and cocaine dependence are top priorities at the state and drug court levels, and because of the similar pathophysiology of these drugs, a treatment validated for one should be readily adopted for the other. We believe the results from these studies will validate PROMETA as a method of care for treating alcoholism and stimulant dependence, as well as serve to accelerate our growth.

Statewide Agencies (Including Medicaid), Criminal Justice Sectors

We plan to establish treatment using PROMETA as a covered treatment for state and county agencies in the public and criminal justice sectors in several states in 2006 through leveraging outcomes data results from the Dr. Urschel methamphetamine study and the results of several commercial pilot studies that will be conducted in 2006 in these states. We anticipate that the results of these pilots will serve as a template to rapidly increase adoption of PROMETA through the public and criminal justice systems of these states and other states throughout the country. To date, we have announced the following pilot studies:

- A pilot study by the City Court of Gary, Indiana to evaluate our PROMETA protocols for use in drug courts for participants who are dependent on cocaine or cocaine and alcohol
- A 30-patient, open label study conducted by Southern University in the state of Louisiana to test the efficacy of PROMETA for treatment of alcohol and substance dependent offenders accepted for drug court



- A pilot study, funded by the Idaho Department of Health and Welfare in collaboration with the criminal justice system as represented by the Idaho Supreme Court's Statewide Drug Court and Mental Health Court Coordinating Committee, using PROMETA to evaluate its effectiveness as a medical treatment method for methamphetamine dependency, as well as its effect on reducing recidivism among criminal offenders
- A commercial pilot conducted by the Department of Social and Health Services and funded by the Pierce County Alliance in the State of Washington to evaluate the success of treating methamphetamine dependent participants in the drug court system using the PROMETA protocols

Managed Care

We plan to position PROMETA with managed care providers and disease state management programs in order to become a covered benefit within the next two years. In the first quarter 2006, CompCare, a leading managed behavioral health care organization, approved PROMETA as reimbursable and entered into an agreement with us to market the PROMETA protocols to its managed care network providers. Through this agreement, we will extend awareness of the PROMETA protocols to the employer groups and third party payors serviced by CompCare, and its strategic marketing partner will work with CompCare to market PROMETA to additional large employers, government groups and third party payers that are not current CompCare customers.

The pharmacoeconomic study to be conducted by the Parallax Center in New York City will compare outcomes achieved with out PROMETA protocol for alcohol dependency to the Parallax protocol, which is currently reimbursed by several insurers, including the largest membership based HMO in New York. We believe that validation in this study will lead toward direct reimbursement for treatment using the PROMETA protocols not only by the Parallax third party payors, but ultimately by other managed care providers as we intend to leverage these initial results for use as a template nationwide.

In 2006 we are planning to initiate several commercial pilot studies to demonstrate the feasibility and effectiveness of PROMETA to additional managed care organizations.

International Operations

We intend to begin offering PROMETA at a clinic in Europe in the first half of 2006. We also plan to begin operating small clinics on a pilot basis in Europe for the treatment of nicotine or other dependencies in the first half of 2006. We will evaluate the success of these initial programs before we pursue additional international expansion.

Sales and Marketing

We will focus our direct sales efforts on recruiting new healthcare providers in identified target markets to expand our number of treatment site customers. Our primary focus will be in major metropolitan service areas where we have already established a market presence in order to leverage our site managers, marketing efforts and brand awareness of PROMETA and benefit from resulting treatment volumes without capacity constraint.

Our marketing strategy is based on developing and promoting a comprehensive treatment approach that integrates proprietary state-of-the-art treatment protocols, assessment tools, education, and information about continuing care programs. We will co-promote programs with our licensees through community outreach initiatives, local sponsorship of professional education programs, public relations, local advocacy development and direct mail. On a national level, we will promote our proprietary brands through Internet marketing, advocacy development, targeted advertising, and public relations.

Our marketing of the PROMETA protocols will be done in two ways:

- Promoting broad awareness
- Focused target market initiatives

Broad awareness will be conducted via our consumer website, press releases, endorsements, printed media advertising, Internet promotions and local radio, television and print media coverage. We will support local targeted marketing efforts of the hospitals, healthcare facilities and other healthcare providers that license our PROMETA protocols. Additional target market campaigns may be accomplished via local publications, direct mail, seminars, forums, tradeshows, community outreach and email to generate referral sources and referrals.

Community Relations

As noted above, a cornerstone to our marketing strategy will be to increase awareness among consumer audiences by providing education and information about substance dependence as a brain disease, and the PROMETA protocols as an innovative, convenient medically supervised treatment approach. Working in concert with our licensees, we intend to create or leverage community forums (e.g., community presentations, health fairs, etc.) that will provide opportunities to engage our target segments, most notably consumers (i.e., potential patients, their families and friends), leaders from the local business communities and professional referral sources within the healthcare community. We also intend to utilize direct mail or other outreach vehicles to offer branded educational and informational materials to promote a direct and iterative “dialogue” with consumers (and, pending data availability, professional constituents).

Our community relations activities may also involve partnering with third-party organizations – on either a local or national level – to further increase the penetration of these initiatives within targeted market segments, as well as provide a potential public relations platform to enhance the reach of the initiatives. In January 2006, we announced an award to the Gay and Lesbian Medical Association (GLMA) of an unrestricted educational grant to examine methamphetamine use in the gay community and related treatment options. The methamphetamine epidemic has been ravaging the gay community for the last decade. Crystal meth is now directly linked to new HIV infections as well as an unprecedented resurgence of syphilis and other sexually transmitted diseases related to unsafe sexual behavior. Our grant will allow GLMA to examine the extent of methamphetamine use among gay and bisexual men and the most promising options for treating methamphetamine addiction, and to develop recommendations about how health care providers can get patients dependent on methamphetamine into treatment.

Public Relations

The goal of our public relations program will be primarily to promote awareness and generate leads from consumers (i.e., potential patients, their families and friends), with a secondary emphasis on referral sources, healthcare professionals and third-party organizations. This may be done via press releases, endorsements, and media placement campaigns. The forms of media that will be targeted for placement will be print media, local radio segments and stories, Internet postings, local, regional, and national television segments and stories. We believe this form of awareness/lead generation to be superior to advertising both in terms of quality of awareness and number of leads generated.

Advertising

We anticipate that advertising will generally be limited to local publications in regional treatment center areas, specific trade publications for occupations with high substance dependence rates, healthcare professional publications with subscribers who would be good referral sources and top Internet search engines.



We plan to test market direct-to-consumer advertising campaigns for the PROMETA Center and our PROMETA protocols beginning in Los Angeles in the first half of 2006, through the use of billboards, local radio and major newspapers. If initial results are encouraging, we plan to begin rolling out an aggressive marketing campaign for the Southern California area and other major markets.

Target Payor Groups

In developing our marketing plan, we have taken into consideration the following market dynamics for our efforts:

Traditional Payors

Private Pay

To date, patients treated with the PROMETA protocol have been primarily self-pay patients. Until February 2006, when a leading managed behavioral health care organization approved PROMETA as reimbursable for its provider network, our protocols had not been approved for payment by any health insurance companies or other third-party payors.

According to reports by SAMHSA, of persons aged twelve or older who received any alcohol or illicit drug treatment, more paid for all or part of their most recent treatment with their own savings or earnings (or those of family or friends) than any other source (47.4%). We will continue to focus our efforts on targeted communication to private pay patients (and their families) emphasizing the convenience and potential benefits of treatment using the PROMETA protocols. Moreover, as we are aware of no generally accepted medical treatments for methamphetamine dependence, we will have the opportunity to communicate the potential benefits of the PROMETA protocol to persons affected by methamphetamine dependence.

Managed Care, Insurance and other Third-Party Reimbursement

In addition to our goal of the PROMETA protocols becoming a preferred treatment method for individuals seeking to pay for treatment privately, we believe that third party payors, including entities from both the government and private sectors, will be important to our long-term growth. We will conduct business development initiatives to secure the acceptance and endorsement of treatment using our protocols as appropriate for reimbursement by third party payors, nationally recognized substance dependence treatment organizations and governmental organizations.

In order to compete effectively for managed care agreements and receive adequate reimbursement from payors for treatment using our protocols, clinical evidence must demonstrate that use of the PROMETA protocols is a beneficial and cost effective treatment approach. We will, through our clinical and market research activities, gather and disseminate appropriate data to the payor community that should validate the benefits and cost effectiveness of treatment using the PROMETA protocols. We believe that studies involving the PROMETA protocols have the potential to demonstrate cost effectiveness across patient populations.

In December 2005, we announced a pharmacoeconomic study by a preeminent researcher and executive director of a substance abuse treatment center in New York City to compare outcomes achieved with the PROMETA protocol for alcohol dependency to the treatment program's current protocol, which is currently reimbursed by several insurers including the largest membership based HMO in New York. As standardized treatment outcomes are significant for the third party payor community, we anticipate that validation in this study will lead toward direct reimbursement for PROMETA and ultimately, will allow

for a solution that can be replicated across their entire network. If successful, our intent is to leverage these initial results nationwide for use as a template that other managed care providers can rapidly integrate into their networks.

In February 2006, we announced that our PROMETA protocols have successfully passed review by the technology committee of CompCare, and are now approved as reimbursable treatments. CompCare is a leading provider of behavioral health care services to managed care organizations, serving Medicaid, Medicare, and commercial payors. CompCare and its strategic marketing partner will market PROMETA to its existing and new third party payor clients as an integral component of a new substance abuse and addiction disease management program.

Other Payor Groups

Criminal Justice Systems

Drug and alcohol offenders impact all divisions of criminal justice including law enforcement, drug courts, probation, and correctional facilities. According to a Bureau of Justice Statistics Bulletin, "Prisoners in 2004," published in October 2005, approximately 21% of the 1.2 million state and 55% of the 170,000 federal prisoners were convicted of drug offenses. A significant number of state and federal prisoners receive alcohol treatment after admission into prison, or after incarceration during the re-entry period while under community supervision. The ONDCP estimates that more than 40% of the sentenced federal inmate population will have a diagnosable substance disorder which requires some type of drug abuse treatment program. We believe that state and federal prison systems are in need of a more beneficial and convenient treatment alternative and we intend to solicit major prison systems to utilize our protocols. More importantly, we will seek to work with state and federal criminal justice systems to intervene prior to incarceration with a goal of reducing the number of drug offenders admitted into prison.

Drug courts first came to prominence in 1989 as a means to deal with the growing number of alleged offenders involved with substance abuse. According to the National Drug Court Institute there were over 1,600 drug courts in 2004 located in all 50 states. Drug courts generally encourage the user to seek treatment in lieu of incarceration. We will seek to engage and educate all parties (judges, attorneys, physicians, counselors) that influence the selection of the drug treatment facility.

As discussed above, we have announced commercial pilots with the states of Louisiana, Indiana, Idaho and Washington in to evaluate the effectiveness of our PROMETA protocols as a medical treatment method for methamphetamine dependency, cocaine or cocaine and alcohol, as well as its effect on reducing recidivism among criminal offenders.

If these and other state government and criminal justice system studies that we plan to initiate over the coming year are successful in validating PROMETA as an effective treatment approach, our intent is to leverage these initial results by marketing the outcomes from these studies to other state agencies and criminal justice systems throughout the country.

Initial Data

The PROMETA treatment protocols have been in use since 2002 at The Little Company of Mary—San Pedro Hospital. Retrospective data collected on 53 alcohol and stimulant dependent patients treated with PROMETA from November 2002 through December 2004 suggest promising results in terms of treatment completion rates, abstinence rates and reduction of cravings based on patient follow-up ranging from three to twelve months post-treatment.



The outcome results are summarized below for 34 alcohol patients and 19 stimulant patients, of whom approximately 70% had unsuccessfully undergone prior treatment, who were followed for 90 days and 180 days post treatment:

Alcohol	Days post treatment			
	90		180	
Continuous Abstinence	20	59%	18	53%
Use with No Problems*	5	15%	6	18%
Relapsed	8	23%	9	26%
Unknown	1	3%	1	3%
Total Patients	34	100%	34	100%

Stimulants (Cocaine and Methamphetamine)	Days post treatment			
	90		180	
Continuous Abstinence	11	58%	10	53%
Use with No Problems*	1	5%	1	5%
Relapsed	6	32%	7	37%
Unknown	1	5%	1	5%
Total Patients	19	100%	19	100%

* Patients reporting use of the substance at least once post treatment, but not returning to harmful or compulsive use.

Following treatment, patient self-reports include elimination of cravings and increased mental clarity and focus (cognitive function). Further, patients were asked to rate their quality of life before and after treatment, most of whom reported both immediate and sustained post-treatment improvement in sleep, appetite, mood, concentration, memory, work, relationships and stress.

The outcomes shown above are for patients treated with the current PROMETA protocols in one treatment center. Outcome information was obtained by follow-up phone interview by the clinical site manager. The limited initial results of the retrospective evaluation were not obtained in a formal research study, may not provide a sufficient sample size to draw any conclusions regarding effectiveness, and may not be indicative of the long-term future performance of our protocols. In addition, patients' statuses may change after longer periods of post-treatment follow-up, negatively affecting the overall results of the treatment outcomes that were collected during the post treatment period.

We have awarded and are in the process of awarding additional unrestricted grants for research studies in special populations and controlled studies to evaluate the use of the PROMETA protocols. Formal research, further studies, independent research reports or reviews may qualify or contradict the limited results that we have observed.

Research and Development

We have announced a number of clinical studies by preeminent researchers in the field of substance dependence to evaluate the use of PROMETA in treating alcohol and stimulant dependence. We anticipate that these studies will be the basis for publication in scientific journals. We expect initial data from the first methamphetamine study to be made available in the first half of 2006. In addition, we have contracted with a contract research organization (CRO) to establish a clinical outcomes registry for the monitoring and evaluation of up to 750 patients undergoing treatment using PROMETA at our commercial licensee sites. We have also announced several pilot studies with state programs and drug court systems to study the results of using the PROMETA protocols in their programs. Significant positive results would help in our efforts to gain third-party reimbursement for providers using our protocols. Patients treated to date with PROMETA have been substantially self-pay patients. We believe that favorable clinical data in combination with third-party reimbursement would help accelerate broader adoption of PROMETA.



We intend to continually enhance our substance dependence treatment technology and products as well as research and develop new products to maintain technological competitiveness and deliver increasing value to new and existing customers. We also intend to continue to expand our target markets by acquiring or licensing treatment methods for other substance dependencies as new technology is developed and becomes available.

Competition

Conventional forms of treatment for alcohol dependence are usually divided into phases: detoxification or withdrawal, which is typically conducted in medically supervised environments; and relapse prevention, which is often conducted through short- or long-term therapeutic facilities or programs, most of which do not offer medical management options. Typically such medically managed programs require long-term usage of pharmaceuticals, resulting in low patient compliance. Conventional forms of treatment for stimulant dependence consist only of relapse prevention, which is conducted through therapeutic programs, which do not offer medical management options. Regardless of the approach, there is great variability in the duration of treatment procedures, level of medical supervision, cost to the patients and relapse rates.

Currently accepted practice for withdrawing patients from a dependence on alcohol consists of heavily sedating the patient at an inpatient hospital facility for a period of 3 to 5 days. Due to the heavy sedation, the patient typically is stabilized for an additional 5 to 7 days. This procedure, while medically necessary to prevent medically severe withdrawal seizures or delirium tremens when withdrawing alcoholics from alcohol, does not relieve the patient's cravings or desire to drink. Further, the drugs typically used during this procedure (the most commonly utilized medications are Valium® (diazepam), Ativan® (lorazepam), and Xanax® (alprazolam)) can be addictive, require a time-intensive dose tapering and washout period and may cause side effects.

While withdrawal from cocaine dependence is not considered to involve a significant risk of death, withdrawal symptoms from current detoxification procedures are unpleasant. Following an extended period of dependence, cocaine addicts generally are unable to experience the feeling of pleasure during and following detoxification as a result of the effects of cocaine on the brain. Detoxification procedures typically involve the use of sedatives to assist patients through this difficult period. Following treatment, cue induced cravings, however, are especially pronounced and may re-occur for months to years.

Treatment Programs

There are approximately 13,000 facilities reporting to the Substance Abuse and Mental Health Services Administration (SAMSHA) that provide substance dependence medical treatment services on an inpatient or outpatient basis. Well-known examples of residential treatment programs include the Betty Ford Center, Caron Foundation, Hazelden and Sierra Tucson. In addition, individual physicians may provide substance dependence treatment in the course of their practices.

There appears to be no reliable information about the success rates of these programs, nor agreed upon standards of how outcomes should be measured (e.g., self-reported abstinence or reduction in days of heavy drinking).

Many of these traditional treatment programs have established name recognition and their treatments may be covered in large part by insurance or other third party payors. To date, treatments using our protocols have generally not been covered by insurance, and patients treated with the PROMETA protocols have been substantially self-pay patients, currently our primary market for the PROMETA protocol. However, in February 2006, a leading managed behavioral health care organization approved PROMETA as reimbursable, and entered into an agreement with us to market the PROMETA protocols to its managed care network providers.

Treatment Medications

There are currently no accepted medical treatments for methamphetamine dependence. Anti-depressants and dopamine agonists have been investigated as possible maintenance therapies, but none have been FDA approved or are generally accepted for medical practice.

There are a number of companies developing or marketing medications for reducing craving in the treatment of alcoholism. These include:

- The addiction medication naltrexone, an opiate receptor antagonist, is marketed by a number of generic pharmaceutical companies as well as under the trade name ReVia® by Bristol Myers Squibb, for treatment of alcohol dependence. However, naltrexone must be administered on a chronic or continuing basis and is associated with relatively high rates of side effects, including nausea. U.S. sales are estimated to be just under \$25 million per year for this treatment.
- Alkermes is developing a long-acting injectable form of naltrexone, VIVITROL, intended to be administered by a physician via monthly injections. The company reported results from a phase III clinical study indicated that in the overall study population, patients treated with VIVITROL 380 mg experienced approximately a 25% reduction in the rate of heavy drinking relative to placebo. Alkermes, in partnership with Cephalon, reports it intends to launch VIVITROL in the second quarter of 2006, pending final FDA approval.
- Forest Laboratories holds the license in the U.S. to market Campral® Delayed-Release Tablets (acamprosate calcium), approved by the FDA in 2004. Acamprosate is an NMDA receptor antagonist. The product must be taken two to three times per day on a chronic or long-term basis. Clinical studies supported the effectiveness in the maintenance of abstinence for alcohol-dependent patients who had undergone inpatient detoxification and were already abstinent from alcohol, but the product was not effective for patients who had not undergone detoxification and who were not abstinent prior to treatment.

Several classes of pharmaceutical agents have been investigated as potential maintenance agents (e.g., anti-depressants and dopamine agonists) for cocaine dependence; however, none are FDA approved for treatment of cocaine dependence or generally accepted in medical practice. Their effects are variable in terms of providing symptomatic relief, and many of the agents may cause side effects or may not be well tolerated by patients.

As noted above, we believe the PROMETA protocols can be used at various stages of recovery, including initiation of abstinence and during early recovery, and can complement other existing treatments. As such, our protocols offer a potentially valuable addition to traditional medical treatment. Moreover, because treatment with the PROMETA protocols is designed to target neurochemical imbalances in the brain over a short course of treatment, we do not view the current medical therapies as directly competitive. We believe that the total cost of providing treatment using the PROMETA protocols falls within the typical range of prices for conventional treatment programs. We also believe, based on the limited initial results discussed below, that treatment using our protocols may have higher completion rates, greater compliance, reduction or elimination of withdrawal symptoms, reduction or elimination of cravings, improved cognitive functioning and potentially lower relapse rates.

Development of Our Technology

Much of our proprietary, patented and patent pending substance dependence technology, known as the PROMETA treatment protocols, was developed by Dr. Juan José Legarda, a European scientist educated at University of London who has spent most of his professional career conducting research related to substance abuse. Through his studies and research, Dr. Legarda identified some of the adverse physical effects of substance abuse on



the brain and began to develop technologies that specifically focused on the neurochemistry of the brain as a core part of addictive behavior modification. In 2002, Dr. Legarda filed Patent Cooperation Treaty (PCT) applications in Spain for treatment protocols that he developed for dependencies to alcohol and cocaine. We acquired the rights to these patent filings in March 2003 through a technology purchase and license agreement with Dr. Legarda's company, Tratamientos Avanzados de la Adiccion S.L., to which we pay a royalty of three percent of the amount the patient pays for treatment using our protocols. After acquiring these rights, we filed U.S. patent applications and other national phase patent applications based on the PCT filings, as well as provisional U.S. patent applications for additional treatment protocols for alcohol, cocaine and other addictive stimulants. If any of these patents are issued, they will expire 20 years from the dates of original filing.

Proprietary Rights and Licensing

Our success depends upon a number of factors, including our ability to protect our proprietary technology and operate without infringing on the proprietary rights of others. We rely on a combination of patent, trademark, trade secret and copyright laws and contractual restrictions to protect the proprietary aspects of our technology. To help ensure compliance with our license/joint venture agreements, we employ site managers in each of our major markets. We have the following branded trade names:

- Hythiam®
- PROMETA™
- PROMETA Protocol™
- PROMETA Protocols™
- PROMETA Treatment Protocol™
- PROMETA Treatment Protocols™
- PROMETA Center™
- PROMETA Centers™
- PROMETA Treatment™
- PROMETA Treatments™

We impose restrictions in our protocol license agreements on our customers' rights to utilize and disclose our technology. We also seek to protect our intellectual property by generally requiring employees and consultants with access to our proprietary information to execute confidentiality agreements and by restricting access to our proprietary information. We require that, as a condition of their employment, employees assign to us their interests in inventions, original works of authorship, copyrights and similar intellectual property rights conceived or developed by them during their employment with us.

Financial Information about Segments

We currently operate in one reportable segment. Substantially all of our services are provided within the United States, and substantially all of our assets are located within the United States.

Employees

As of December 31, 2005, we employed approximately 90 persons. We anticipate hiring additional employees over the next year to meet our growth expectations.

Our Offices

We are incorporated under the laws of the State of Delaware. Our principal executive offices are located at 11150 Santa Monica Boulevard, Suite 1500, Los Angeles, California 90025, and our telephone number is (310) 444-4300.



Executive Officers and Directors

The following table sets forth certain information regarding our directors and executive officers.

Name	Age	Position	Director Since
Terren S. Peizer	46	Director, Chairman of the Board and Chief Executive Officer	2003
Richard A. Anderson	36	Director, Chief Administrative Officer	2003
Anthony M. LaMacchia	52	Director, Chief Operating Officer	2003
Chuck Timpe	59	Chief Financial Officer	
Monica Alfaro Welling	45	Senior Vice President – Marketing	
David E. Smith, M.D.	67	Senior Vice President – Medical Affairs	
Sanjay Sabnani	35	Senior Vice President – Strategic Development	
Donald R. Wesson, M.D.	64	Senior Vice President – Scientific Affairs	
Leslie F. Bell, Esq.	65	Director, Chair of Audit Committee, Member of Compensation Committee	2003
Hervé de Kergrohen, M.D.	48	Director, Chair of Nominations and Governance Committee, Member of Audit Committee	2003
Ivan M. Lieberburg, Ph.D., M.D.	56	Director, Chair of Compensation Committee	2003
Marc G. Cummins	46	Director, Member of Audit Committee, Nominations and Governance Committee	2004
Andrea Grubb Barthwell, M.D.	51	Director	2005

Terren S. Peizer served until October 2003 as Chief Executive Officer of Clearant, Inc., which he founded in April 1999 to develop and commercialize a universal pathogen inactivation technology. He served as Chairman of its board of directors from April 1999 to October 2004 and a Director until February 2005. From February 1997 to February 1999, Mr. Peizer served as President and Vice Chairman of Hollis-Eden Pharmaceuticals, Inc., a NasdaqNM listed company. In addition, from June 1999 through May 2003 he was a Director, and from June 1999 through December 2000 he was Chairman of the Board, of supercomputer designer and builder Cray Inc., a NasdaqNM company, and remains its largest beneficial stockholder. Mr. Peizer has been the largest beneficial stockholder and held various senior executive positions with several technology and biotech companies. In these capacities he has assisted the companies with assembling management teams, boards of directors and scientific advisory boards, formulating business and financial strategies, investor and public relations, and capital formation. Mr. Peizer has a background in venture capital, investing, mergers and acquisitions, corporate finance, and previously held senior executive positions with the investment banking firms Goldman Sachs, First Boston and Drexel Burnham Lambert. He received his B.S.E. in Finance from The Wharton School of Finance and Commerce.

Richard A. Anderson has more than a decade of experience in business development, strategic planning and financial management. He was the Chief Financial Officer of Clearant, Inc. from November 1999 until becoming our Chief Administrative Officer in March 2005, and served as a Director from November 1999 to March 2006. He served as Chief Financial Officer of Intellect Capital Group from October 1999 through December 2001. From February through September 1999, he was an independent financial consultant. From August 1991 to January 1999, Mr. Anderson was with PriceWaterhouseCoopers, LLP, most recently a Director and founding member of



PriceWaterhouseCoopers Los Angeles Office Transaction Support Group, where he was involved in operational and financial due diligence, valuations and structuring for high technology companies. He received a B.A. in Business Economics from University of California, Santa Barbara.

Anthony M. LaMacchia is a senior healthcare executive who, prior to joining the company in July 2003, was the Business Development Principal of GME Solutions, a healthcare financial consulting company providing Medicare graduate medical education and kidney acquisition cost recovery services, since October 2002. From November 1999 to April 2002, he was President & Chief Executive Officer of Response Oncology, Inc., a diversified physician practice management company. He was recruited to this financially distressed company to direct a high-risk turnaround, and when continued market declines and debt covenant breaches compelled a bankruptcy filing, directed the company through all phases of the chapter 11 process, the sale of all assets and the closure of its facilities. In June 1999, Mr. LaMacchia left Salick Health Care, Inc., which developed and operated outpatient cancer and kidney treatment centers and a clinical research organization engaging in pharmaceutical and clinical treatment trials, as Executive Vice President & Chief Operating Officer, having started with the company as Director of Strategic Planning & Reimbursement in 1984. Previously, Mr. LaMacchia held positions of increasing responsibility with Blue Cross of California, Ernst & Young and Cedars-Sinai Medical Center. He is a Certified Public Accountant who received his B.S. in Business Administration, Accounting from California State University, Northridge.

Chuck Timpe is a senior healthcare financial executive with over 35 years experience in the healthcare industry. Since March 1998 he has served as a Director and since June 2002 as Chairman of the Audit Committee for IPC-The Hospitalist Company, a \$100 million physician specialty practice business. Prior to joining the company in June 2003, Mr. Timpe was Chief Financial Officer from its inception in February 1998 of Protocare, Inc., a clinical research and pharmaceutical outsourcing company which merged with Radiant Research, Inc. in March 2003, creating one of the country's largest clinical research site management organizations. Previously, he was a principal in private healthcare management consulting firms he co-founded, Chief Financial Officer of National Pain Institute, Treasurer and Corporate Controller for American Medical International (now Tenet Healthcare Corp., an NYSE company), and a member of Arthur Andersen LLP's healthcare practice, specializing in public company and hospital system audits. Mr. Timpe received his B.S. from University of Missouri, School of Business and Public Administration, and is a Certified Public Accountant.

Monica Alfaro Welling has over 15 years of experience in all areas of U.S. and global marketing, sales and new product planning within endocrinology, nephrology, osteoporosis, CNS, gastroenterology, and genitourology. Prior to joining the company in March 2004, she was Senior Director Global Strategic Marketing for BOTOX™ for Allergan, Inc., where she directed market development, product development, and strategic planning for a brand with annual sales exceeding \$360 million. Prior to joining Allergan, from August 1989 to February 2000, Ms. Welling held various positions at Novo Nordisk A/S in Denmark, most recently as Head of International hGH Strategic Marketing. As the head of marketing, new business development and new product marketing for all growth hormone related products/devices and therapeutic areas, she was responsible for brands with annual global sales of \$260 million. She received a B.S. in Biology from University of California, Irvine and an M.B.A. in International Marketing from South Danish University.

David E. Smith, M.D. has more than thirty-five years of experience in the treatment of addictive disease, the psychopharmacology of drugs, and research strategies in the management of drug abuse problems. Until March 2006, Dr. Smith served as President and Medical Director of Haight Ashbury Free Clinics, Inc. which he founded in 1967, and has been Medical Consultant, Professional Recovery Program at The Betty Ford Center since 1994, and Medical Director of the California State Alcohol and Drug Programs and of the California Collaborative Center for Substance Abuse Policy Research since 1998. He has held consultancies and other positions at numerous professional organizations, including Doping Control Officer for the Winter Olympics in February 2002. Dr. Smith has authored over 300 scientific articles and has been named to a number of honors, including a Drug Abuse

Treatment Award, National Association, State Alcohol and Drug Abuse Coordinators in 1984, Career Achievement Award, National Association of State Alcohol and Drug Abuse Directors in 1994, and Best Doctors in America, Pacific Region in 1996-97. He is a member of the Editorial Boards of numerous professional publications, has been Editor-in-Chief of AlcoholMD.com, a medical education and information website focusing on alcohol problems and alcoholism, since January 2000, and is Executive Editor of the Journal of Psychoactive Drugs which he founded in 1967. He was granted Fellow status by the American Society of Addiction Medicine (A.S.A.M.) in 1996, is past President of A.S.A.M. and the California Society of Addiction Medicine, and was named to the Council of Fellows of the California Association of Alcoholism and Drug Abuse Counselors in 1998. Dr. Smith received a B.S. in Zoology from University of California, Berkley and an M.S. in Pharmacology and his M.D. from University of California, San Francisco, where he has been an Associate Clinical Professor of Clinical Toxicology since 1967.

Sanjay Sabnani prior to joining the company in April 2004 was acting Director of Business Development and Strategy at OSI Systems, Inc., where he was part of a senior team that delivered tremendous growth in revenues and market capitalization. Prior to joining OSI Systems, from May 1999 to December 2000, Mr. Sabnani was President and Director at Venture Catalyst, Inc., where he spearheaded the Company's venture capital division, as well as managed the Company's web services business. Mr. Sabnani has authored or co-authored numerous articles and served as an expert speaker on topics as diverse as mergers and acquisitions, homeland security, entrepreneurship, and internet strategy. He received his B.A. in English from University of California, Los Angeles.

Donald R. Wesson, M.D. is a psychiatrist with more than 35 years of experience in private practice and drug development focused upon medications for treating central nervous system disorders. Prior to joining the company in November 2004, he was in private practice. He has been the principal investigator for more than 20 clinical trials sponsored by the National Institute on Drug Abuse or pharmaceutical companies. From 1998 to 2002 Dr. Wesson was with Drug Abuse Sciences, Inc., where his most recent position was Senior Vice President of Scientific Affairs. He has authored or co-authored more than 100 articles, and many books and book chapters. Dr. Wesson is the medical advisor to the California Health Care Professional's Diversion Program, a member of the Executive Council of the California Society of Addiction Medicine, a member of the Research Advisory Panel of California, Editor of the California Society of Addiction Medicine News, a member of the Advisory Board of Journal of Psychoactive Drugs, and of the editorial board of Journal of Addictive Diseases. Dr. Wesson received a B.S. degree in chemistry from the University of Alabama and his M.D. from Medical College of Alabama.

Leslie F. Bell has more than 35 years of experience in business and the practice of corporate and healthcare law. He is a director and senior executive of Salick Cardiovascular Centers LLC. From late 1997 until 2004 he was a Director and Senior Executive of Bentley Health Care, Inc. and certain of its subsidiaries, each of which was a developer and provider of disease-state outpatient, health care facilities and services. Mr. Bell was Co-Chairman and Co-Chief Executive Officer of Tractus Medical, Inc., a provider of patented relocatable ambulatory surgical center/operating rooms, which he co-founded in January 2002 until its sale in October 2004. From its inception in 1983 through several public offerings and until its sale completed in 1997 for a total of approximately \$480 million, he served as a Director, Executive Vice President and Chief Financial Officer and from 1996 to 1997 was President of Salick Health Care, Inc. Mr. Bell has also served as a Director of YES Clothing Co. from 1990 to 1995. He was previously a Deputy Attorney General of the State of California, and managing partner of the law firm Katz, Hoyt & Bell. Mr. Bell attended the University of Illinois, received a J.D. (with honors) from University of Arizona College of Law, and is a member of the University of Arizona College of Law Board of Visitors and Dean's Economic Council. Mr. Bell is licensed to practice law and is the sole director and President of Leslie F. Bell, Inc., a professional law corporation. He is also a director of various tax-exempt organizations principally formed to support research and education for specified health problems.

Hervé de Kergrohen, M.D. since August 2002 has been a Partner with CDC Enterprises Innovation in Paris, a European venture capital firm, and since January 2001 has been Chairman of BioData, an international

healthcare conference in Geneva. He sits on several boards with U.S. and European private health care companies, including Kuros BioSurgery and Bioring SA in Switzerland since January 2003, Praxim SA and Exonhit in France since September 2002, and Clearant, Inc. since December 2001. From February 1999 to December 2001 he was Head Analyst for Darier Hentsch & Co., then the third largest Geneva private bank and manager of its CHF 700 million health care fund. From February 1997 to February 1998 he was the Head Strategist for the international health care sector with UBS AG in Zurich. Dr. de Kergrohen started his involvement with financial institutions in 1995 with Bellevue Asset Management in Zug, Switzerland, the fund manager of BB Biotech and BB Medtech, where he covered the healthcare services sector. He was previously Marketing Director with large U.S. pharmaceutical companies such as Sandoz USA and G.D. Searle, specialized in managed care. Dr. de Kergrohen received his M.D. from Université Louis Pasteur, Strasbourg, and holds an M.B.A. from Insead, Fontainebleau.

Ivan M. Lieberburg, Ph.D., M.D. is currently Executive Vice President, Chief Medical Officer at Elan Company, plc, a worldwide biopharmaceutical company listed on the NYSE, where he has held a number of positions over the last 18 years, most recently Senior Vice President of Research. Dr. Lieberburg is a director of Neuromolecular Pharmaceuticals, and he sits on the scientific advisory boards of Health Care Ventures, Flagship Ventures, NewcoGen, Neuromolecular Pharmaceuticals, CovX, and the Keystone Symposium. Prior to joining Elan in 1987, he performed his postdoctoral research at The Rockefeller University and his medical residency and postdoctoral fellowship at University of California, San Francisco, where he is presently a Clinical Professor of Medicine. He previously held faculty positions at Albert Einstein School of Medicine and Mt. Sinai School of Medicine. Dr. Lieberburg has authored over 100 scientific publications, and has been named to a number of honors including Rockefeller University Fellow, Public Health Corps Scholar, National Research Service Award, Hartford Foundation Scholar and McKnight Foundation Fellow in Neuroscience. He is board certified in internal medicine and endocrinology/metabolism. Dr. Lieberburg received an A.B. in biology from Cornell University, a Ph.D. in Neurobiology from The Rockefeller University and an M.D. from University of Miami School of Medicine.

Marc G. Cummins is a Managing Partner of Prime Capital, LLC, a private investment firm focused on consumer companies. Prior to founding Prime Capital, Mr. Cummins was managing partner of Catterton Partners, a private equity investor in consumer products and service companies with over \$1 billion of assets under management. Prior to joining Catterton in 1998, Mr. Cummins spent fourteen years at Donaldson, Lufkin & Jenrette Securities Corporation where he was Managing Director of the Consumer Products and Specialty Distribution Group, and was also involved in leveraged buyouts, private equity and high yield financings. Mr. Cummins received a B.A. in Economics, magna cum laude, from Middlebury College, where he was honored as a Middlebury College Scholar and is a member of Phi Beta Kappa. He also received an M.B.A. in Finance with honors from The Wharton School at University of Pennsylvania.

Andrea Grubb Barthwell, M.D. has served as the founder and Chief Executive Officer of the global health care and policy-consulting firm EMGlobal LLC since February 2005. From January 2002 through July 2004, she served as Deputy Director for Demand Reduction in the Office of National Drug Control Policy with the title of Deputy Drug Czar, was a principal advisor in the Executive Office of the President on policies aimed at reducing the demand for illicit drugs, and was an active member of the White House Task Force on Disadvantaged Youth and the White House Domestic Violence Working Group, working closely with the National Institute on Drug Abuse to define the scope of its Health Services Research portfolio. From June 2000 through January 2002, Dr. Barthwell served as Executive Vice President and Chief Clinical Officer of Human Resources Development Institute drug treatment center, where she served as Deputy Executive Director and Medical Director from 1985 through 1987. From 1999 through January 2002, she served as President and CEO of BRASS Foundation drug treatment center, where she was Medical Director since 1995. From 1996 through January 2002, Dr. Barthwell served as President of Encounter Medical Group (an affiliate of EMGlobal). From 1987 through 1996 she served as Medical Director of Interventions. in Chicago, Illinois. She was a founding member of the Chicago Area AIDS Task Force, hosted



a weekly local cable show on AIDS, and is a past president of the American Society of Addiction Medicine. In 2003, Dr. Barthwell received the Betty Ford Award, given by the Association for Medical Education and Research in Substance Abuse. In 1997, Dr. Barthwell's peers named her one of the "Best Doctors in America" in addiction medicine. Dr. Barthwell received a B.A. in Psychology from Wesleyan University, an M.D. from University of Michigan Medical School, and post-graduate training at University of Chicago and Northwestern University Medical Center.

Organization of Company

Hythiam, Inc. was formed and incorporated in New York on February 13, 2003, by Reserva, LLC, a non operating company wholly owned by the company's chief executive officer. The registrant, which was formerly known as Alaska Freightways, Inc. (Alaska), was incorporated in the state of Nevada on June 1, 2000, and previously provided transportation and freight brokerage services in the state of Alaska. In September and October 2003, Alaska sold substantially all of its operating assets and liabilities, merged with the Company, changed its name to Hythiam, Inc. and reincorporated in Delaware on September 29, 2003. Following merger, reincorporation and consolidation transactions, the registrant is now the sole surviving entity. Because the Company was the sole operating company at the time of the merger with Alaska, the merger was accounted for as a reverse acquisition, with the Company deemed the acquirer for accounting purposes.

Available Information

We make our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K, and all amendments to these reports available free of charge on our corporate website as soon as reasonably practicable after such reports are filed with, or furnished to, the SEC. Our corporate website is located at www.Hythiam.com. The information contained on our website is not part of this report or incorporated by reference herein.

ITEM 1A. RISK FACTORS

You should carefully consider and evaluate all of the information in this report, including the risk factors listed below. Risks and uncertainties in addition to those we describe below, that may not be presently known to us, or that we currently believe are immaterial, may also harm our business and operations. If any of these risks occurs, our business, results of operations and financial condition could be harmed, the price of our common stock could decline, and future events and circumstances could differ significantly from those anticipated in the forward-looking statements contained in this report.

Risks Related to Our Business

We have a limited operating history, making it difficult to evaluate our future performance

We have a limited history of operations. We were formed in February 2003 and commenced operations in June 2003. Investors have limited substantive financial information on prior operations to evaluate the company as an investment. Our potential must be viewed in light of the problems, expenses, difficulties, delays and complications often encountered in the operation of a new business. We will be subject to the risks inherent in the ownership and operation of a company with a limited operating history such as regulatory setbacks and delays, fluctuations in expenses, competition, the general strength of regional and national economies, and governmental regulation. Any failure to successfully address these risks and uncertainties would seriously harm our business and prospects.



We expect to continue to incur operating losses, and if we are not able to raise necessary additional funds we may have to reduce or stop operations

We have not generated significant revenues or become profitable, may never do so, and may not generate sufficient working capital to cover the cost of operations. Our revenues since commencement of operations in June 2003 were \$1.4 million through December 31, 2005. Our accumulated deficit through December 31, 2005 was \$39.4 million. We anticipate that operating deficits will continue for at least the next twelve months of our operations. Because many of our costs generally will increase, the cost of operating the company will exceed the income therefrom during this period. No party has guaranteed to advance additional funds to us to provide for any such operating deficits. Our cash and marketable securities totaled approximately \$47 million as of December 31, 2005. Our fourth quarter 2005 net cash burn rate was approximately \$2.6 million per month. We expect to increase our monthly expenditures over the next twelve months as we increase staff, commence marketing activities, expand the number of licensees and provide funding for research studies. If our revenues do not meet expectations and our expenses continue to increase, our cash reserves will be exhausted in fifteen to eighteen months, and we will be required to seek additional funds.

We may seek additional funding through public or private financings or collaborative arrangements. If we obtain additional capital through collaborative arrangements, these arrangements may require us to relinquish greater rights to our technologies and protocols than we might otherwise have done. If we raise additional capital through the sale of equity, or securities convertible into equity, further dilution to our then existing stockholders will result. If we raise additional capital through the incurrence of debt, our business may be affected by the amount of leverage we incur, and our borrowings may subject us to restrictive covenants. Additional funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing on a timely basis, we may be required to delay, reduce or stop operations, any of which would have a material adverse effect on our business.

We are dependent on third party healthcare providers licensing and using our protocols, and if they delay or fail to do so our revenues and earnings could be adversely affected

Only a physician may treat or supervise the treatment of patients using the PROMETA™ protocols, which requires us to enter into licenses with physicians, hospitals, properly equipped outpatient settings or other treatment facilities in order to provide convenient treatment access points for patients. Our revenues are therefore dependent to a significant degree upon the relationships we can establish with physicians, hospitals and other healthcare facilities to license our protocols for treating their patients. In 2005, approximately 63% of our revenues were derived from only three licensees. As of December 31, 2005, we had entered into licensing agreements for 32 sites throughout the United States, of which 25 were added in 2005. The number of patients who were treated by our licensees in 2005 was approximately 215, and in the last six months of 2005 was approximately 135. Additional rollout is anticipated to be dependent on our ability to negotiate and conclude licensing agreements with such healthcare providers across the country and their ability to generate patients. If we are unable to enter into similar arrangements with these additional healthcare providers for any reason, that would significantly limit our growth potential and negatively impact our business prospects. In addition, if physicians, hospitals and healthcare providers do not attract sufficient patient volume and revenue they may not be willing to continue to offer our protocols.

The success of our protocols is largely dependent upon referrals of patients to facilities that license our technology and upon the use of our protocols by physicians in treating their patients. There is no requirement for physicians to refer their patients to facilities that license our protocols, or to use our protocols in treating their patients. They are free to refer patients to any other substance dependence treatment service, program or facility, and to treat their patients using whatever method they determine to be in the patients' best interests. The failure of physicians to treat a sufficient number of patients using our protocols, or to refer patients to facilities that use our protocols, or the loss of physicians that use our protocols would have a material adverse effect on our operations and could adversely affect our revenues and earnings.

We may fail to successfully manage and maintain the growth of our business, which could adversely affect our results of operations

As we continue expanding our operations, sales and marketing activities, this expansion could put significant strain on our management, operational and financial resources. To manage future growth, we will need to continue to hire, train and manage additional employees, particularly a specially-trained sales force to market our protocols. Concurrent with expanding our operational and marketing activities, we will also be increasing our research and development activities, including the development of protocols for other types of addictions, with the expectation of ultimately commercializing those products. We have maintained a small financial and accounting staff, and our reporting obligations as a public company, as well as our need to comply with the requirements of the Sarbanes-Oxley Act of 2002, the rules and regulations of the SEC and The Nasdaq National Market, will continue to place significant demands on our financial and accounting staff, on our financial, accounting and information systems and on our internal controls. As we grow, we will need to add additional accounting staff and continue to improve our financial, accounting and information systems and internal controls in order to fulfill our reporting responsibilities and to support expected growth in our business. Our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth or management may not be able to effectively hire, train, retain, motivate and manage required personnel. Our failure to manage growth effectively could limit our ability to achieve our marketing and commercialization goals or to satisfy our reporting and other obligations as a public company.

Our treatment protocols may not be as effective as we believe them to be, which could limit or prevent us from maintaining revenues

Our belief in the efficacy of our treatment protocols is based on a limited number of unpublished studies, primarily in Spain, and our limited initial experience with a small number of patients in the United States. Such results may not be statistically significant, have not been subjected to close scientific scrutiny, and may not be indicative of the long-term future performance and safety of our protocols. Controlled scientific studies, including those that have been announced and planned for the future, may yield results that are unfavorable or demonstrate that our protocols are not clinically effective or safe. While we have not experienced such problems to date, if the initially indicated results cannot be successfully replicated or maintained over time, utilization of our protocols could decline substantially.

Our marketing efforts may not result in acceptance of our protocols in the marketplace, which could adversely affect our revenues and earnings

While we have been able to generate initial interest in our protocols among a limited number of healthcare providers, there can be no assurance that our efforts or the efforts of others will be successful in fostering acceptance of our protocols in the target markets. If our marketing and promotional efforts are not as successful as we expect them to be, the likelihood of expending all of our funds prior to reaching a level of profitability will be increased.

Marketplace acceptance of our protocols may largely depend upon healthcare providers' interpretation of our limited data, the results of pending studies, or upon reviews and reports that may be given by independent researchers. We have awarded and are in the process of awarding additional unrestricted grants to academic and affiliated research institutions and other research organizations interested in conducting research studies of our PROMETA protocols. As of December 31, 2005, we have committed to spending approximately \$4.4 million over the next twenty-four months to fund unrestricted grants. In the event such research does not give our treatment technology high approval ratings, it is unlikely we will be able to achieve significant market acceptance.

Our industry is highly competitive, and we may not be able to compete successfully

The healthcare business in general, and the substance dependence treatment business in particular, are highly competitive. Hospitals and healthcare providers that treat substance dependence are highly competitive, and we must convince them that they will benefit by use of our protocols. We will compete with many types of substance dependence treatment methods, treatment facilities and other service providers, many of whom are more established and better funded than we are. Many of these other treatment methods—most of which involve only a single drug—and facilities are well established in the same markets we will target, have substantial sales volume, and are provided and marketed by companies with much greater financial resources, facilities, organization, reputation and experience than we have.

There are a number of companies developing or marketing medications for reducing craving in the treatment of alcoholism. These include:

- The addiction medication naltrexone, an opiate receptor antagonist, is marketed by a number of generic pharmaceutical companies as well as under the trade name ReVia® by Bristol Myers Squibb, for treatment of alcohol dependence. However, naltrexone must be administered on a chronic or continuing basis and is associated with relatively high rates of side effects, including nausea. U.S. sales are estimated to be just under \$25 million per year for this treatment.
- Alkermes is developing a long-acting injectable form of naltrexone, VIVITROL™, intended to be administered by a physician via monthly injections. The company reported results from a phase III clinical study indicating that in the overall study population, patients treated with VIVITROL 380 mg experienced approximately a 25% reduction in the rate of heavy drinking relative to placebo. Alkermes, in partnership with Cephalon, reports it intends to launch VIVITROL in the second quarter of 2006, pending final FDA approval.
- Forest Laboratories holds the license in the U.S. to market Campral® Delayed-Release Tablets (acamprosate calcium), approved by the FDA in 2004. Acamprosate is an NMDA receptor antagonist. The product must be taken two to three times per day on a chronic or long-term basis. Clinical studies supported the effectiveness in the maintenance of abstinence for alcohol-dependent patients who had undergone inpatient detoxification and were already abstinent from alcohol, but the product was not effective for patients who had not undergone detoxification and who were not abstinent prior to treatment.

We see these products as being potentially useful during the continuing care phase of treatment following treatment using the PROMETA protocols, but not being directly competitive. To the best of our knowledge, there are no treatment protocols or medications approved, marketed or in development within the U.S. that reduce the cravings for cocaine, methamphetamine or other addictive prescription psychostimulants. However, our competitors may develop and introduce new processes and products that are equal or superior to our protocols in treating substance dependencies. Accordingly, we may be adversely affected by any new processes and technology developed by our competitors.

There are approximately 13,000 facilities reporting to the Substance Abuse and Mental Health Services Administration that provide substance abuse treatment on an inpatient or outpatient basis. Well known examples of residential treatment programs include the Betty Ford Center, Caron Foundation, Hazelden and Sierra Tucson. In addition, individual physicians may provide substance dependence treatment in the course of their practices. There are several points of resistance to penetrating the substance dependence treatment market. First, there is the historical focus on the use of psychological or behavioral therapies as opposed to medical or physiological treatments for substance dependence. Healthcare providers and potential patients may be resistant to the transition of treating substance dependence as a disease rather than as a behavioral aberration. Second, healthcare providers may



be reluctant to use our protocols due to the absence of published clinical studies supporting their efficacy. Research studies of the PROMETA protocols may not lead to acceptable results or the results may not be published. If we are unable to penetrate these substantial barriers to entry we may not be able to successfully implement our business plan.

We depend on key personnel, the loss of which could impact the ability to manage our business

Our future success depends on the performance of our senior management and our key professional personnel. It therefore depends to a significant extent on retaining the services of our key executive officers, in particular our Chairman and Chief Executive Officer, Terren S. Peizer, our Director and Chief Administrative Officer, Richard Anderson, our Director and Chief Operating Officer, Anthony M. LaMacchia, and our Chief Financial Officer, Chuck Timpe. Each of these key executives is party to an employment agreement which, subject to termination for cause or good reason, has a remaining term of two to three years. While we believe our relationships with our executives are good and do not anticipate any of them leaving in the near future, the loss of the services of Mr. Peizer or any other key member of management could have a material adverse effect on our ability to manage our business. While we have not experienced any problems in attracting and retaining desirable employees, our success is dependent upon our ability to continue to attract and retain qualified management, professional, administrative and sales personnel to support our future growth.

We are subject to personal injury claims, which could result in substantial liabilities that may exceed our insurance coverage

All significant medical treatments and procedures, including treatment utilizing our protocols, involve the risk of serious injury or death. Even under proper medical supervision, withdrawal from alcohol may cause severe physical reactions. While we do not treat patients or determine whether treatment using our protocols is appropriate for any particular patient, and have not been the subject of any personal injury claims for patients treated by providers using our protocols, our business entails an inherent risk of claims for personal injuries, which are subject to the attendant risk of substantial damage awards. We cannot control whether individual physicians will properly select patients, apply the appropriate standard of care, or conform to our protocols in determining how to treat their patients. A significant source of potential liability is negligence or alleged negligence by physicians treating patients using our protocols. While our agreements typically require them to indemnify us for their negligence, there can be no assurance they will be willing and financially able to do so if claims are made. In addition, our license agreements require us to indemnify physicians, hospitals or their affiliates for losses resulting from our negligence. There can be no assurance that a future claim or claims will not be successful or, including the cost of legal defense, will not exceed the limits of available insurance coverage.

We currently have insurance coverage for up to \$5 million per year for personal injury claims. We may not be able to maintain adequate liability insurance, in accordance with standard industry practice, with appropriate coverage based on the nature and risks of our business, at acceptable costs and on favorable terms. Insurance carriers are often reluctant to provide liability insurance for new healthcare services companies and products due to the limited claims history for such companies and products. In addition, based on current insurance markets, we expect that liability insurance will be more difficult to obtain and that premiums will increase over time and as the volume of patients treated with our protocols increases. In the event of litigation, regardless of its merit or eventual outcome, or an award against us during a time when we have no available insurance or insufficient insurance, we may sustain significant losses of our operating capital which may substantially impair or destroy the investments of stockholders.



If government and third-party payors fail to provide coverage and adequate payment rates for treatment using our protocols, our revenue and prospects for profitability will be harmed

Our future revenue growth will depend in part upon the availability of reimbursement from third-party payors for treatment providers using our protocols. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly attempting to contain healthcare costs by demanding price discounts or rebates and limiting both coverage on which procedures they will pay for and the amounts that they will pay for new procedures. As a result, they may not cover or provide adequate payment for treatment using our protocols. We might need to conduct studies in order to demonstrate the cost-effectiveness of treatment using our protocols to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Adequate third-party reimbursement might not be available to enable us to realize an appropriate return on investment in research and product development, and the lack of such reimbursement could have a material adverse effect on our operations and could adversely affect our revenues and earnings.

Our planned international operations may be subject to foreign regulation, and the success of our foreign operations will depend on many factors.

While we will establish policies and procedures that we believe will be sufficient to ensure that we operate in substantial compliance with applicable foreign laws, regulations and requirements, the criteria are often vague and subject to change and interpretation. Our international operations may become the subject of foreign regulatory, civil, criminal or other investigations or proceedings, and our interpretations of applicable laws and regulations may be challenged. The defense of any such challenge could result in substantial cost and a diversion of management's time and attention. Thus, any such challenge could have a material adverse effect on our international business and our plan to expand our international operations, regardless of whether it ultimately is successful. If we fail to comply with any applicable international laws, or a determination is made that we have failed to comply with these laws, our financial condition and results of operations, including our domestic operations, could be adversely affected.

In addition private pay healthcare system in Europe is not as developed as in the US and as a result it may be more difficult to convince patients in these countries to pay or to pay substantial amounts for treatment. We will be reliant on relationships that we establish with local companies, thought leaders and governments. There can be no assurance we will be able to establish these relationships, maintain them or that the partners will retain their influence in the market. It may take longer than we expect to commence operations or to operate our business at profitable levels as we do not have the established relationships and knowledge of the regulations and business practices in the markets we are entering.

Risks Related to our Intellectual Property

We may not be able to adequately protect the proprietary treatment protocols which are the core of our business

We consider the protection of our proprietary treatment protocols to be critical to our business prospects. We obtained the rights to some of our most significant patent-pending technologies through a license agreement which is subject to a number of conditions and restrictions, and a breach or termination of that agreement could significantly impact our ability to use and develop our technologies. We currently have no issued U.S. patents covering our PROMETA protocols. In addition, the patent applications we have filed and licensed may not issue as patents, and any issued patents may be too narrow in scope to provide us with a competitive advantage. Our patent position is uncertain and includes complex factual and legal issues, including the existence of prior art that may preclude or limit the scope of patent protection. Other inventors may have filed earlier patent applications of which we are unaware and which may prevent our applications from being granted. Patent examiners and third parties may



object to the validity or scope of some or all of our claims. Any of the patents that may be issued to us will expire twenty years after they were first filed.

Competitors or others may institute challenges against the validity or enforceability of any patent owned by us, and if successful our patents may be denied, rendered unenforceable, or invalidated. The cost of litigation to uphold the validity of patents, and to protect and prevent infringement of patents can be substantial. Maintaining, prosecuting, and enforcing a patent portfolio might require funds that may not be available.

We may not be able to adequately protect the aspects of our treatment protocols that are not subject to patent protection, or are subject to only limited patent protection. Furthermore, competitors and others may independently develop similar or more advanced treatment protocols and technologies, may design around aspects of our technology, or may discover or duplicate our trade secrets and proprietary methods.

To the extent we utilize processes and technology that constitute trade secrets under applicable laws, we must implement appropriate levels of security for those trade secrets to secure the protection of such laws, which we may not do effectively. For some of our proprietary rights, we may need to secure assignments of rights from independent contractors and third parties to perfect our rights, and if we fail to do so they may retain ownership rights in the intellectual property upon which our business is based. Policing compliance with our confidentiality agreements and unauthorized use of our technology is difficult, and we may be unable to determine whether piracy of our technology has occurred. In addition, the laws of many foreign countries do not protect proprietary rights as fully as the laws of the United States.

While we have not had any significant issues to date, the loss of any of our trade secrets or proprietary rights which may be protected under the foregoing intellectual property safeguards may result in the loss of our competitive advantage over present and potential competitors.

Confidentiality agreements with employees, licensees and others may not adequately prevent disclosure of trade secrets and other proprietary information

In order to protect our proprietary technology and processes, we rely in part on confidentiality provisions in our agreements with employees, licensees, treating physicians and others. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. To date we have had one instance, in February 2004, in which it was necessary to send a formal demand to cease and desist using our protocols to treat patients to a consultant who had signed a confidentiality agreement. He subsequently complied with the demand and signed an innovation, proprietary information and confidentiality agreement, and an intellectual property assignment agreement.

We may not be able to adequately protect our other intellectual property rights, which could limit our ability to compete

While we believe we have proprietary ownership, assigned or licensed rights in intellectual property which is capable of protection under federal trademark, copyright and/or patent laws, and under state laws regarding trade secrets, we may not have taken, or in the future may not take, appropriate legal measures, and may not be able to adequately secure the necessary protections for our intellectual property. We currently have no issued U.S. patents protecting our PROMETA protocols, and have not yet registered all of our trademarks or copyrights and, until we do so, we must rely on various state and common law rights for enforcement of the rights to exclusive use of our trade secrets, trademark and copyrights.



Although Hythiam® is a registered trademark, our trademark applications for our PROMETA™ trademarks are pending before the U.S. Patent and Trademark Office, and we have not yet been granted registration for these marks. If our trademark registrations are objected to or denied that may impact our ability to use and protect our brand names and company and product identity.

Although we have applied for trademarks for some of our brand names, and patents on some of our technology, in the future we may decide not to secure federal protection of certain copyrights, trademarks or patents to which we may be entitled. Failure to do so, in the case of copyrights and trademarks, may reduce our access to the courts, and to certain remedies of statutory damages and attorneys' fees, to which we may be entitled in the event of a violation of our proprietary and intellectual rights by third parties. Similarly, the failure to seek issuance of any patents to which we may be entitled may result in loss of patent protection should a third party copy the patentable technology. The loss of any proprietary rights which are protectable under any of the foregoing intellectual property safeguards may result in the loss of a competitive advantage over present or potential competitors, with a resulting decrease in revenues and profitability for us. There is no guarantee that such a loss of competitive advantage could be remedied or overcome by us at a price which we would be willing or able to pay, which could have a material adverse effect on our operations and could adversely affect our revenues and earnings.

We may be subject to claims that we infringe the intellectual property rights of others, and unfavorable outcomes could harm our business

Our future operations may be subject to claims, and potential litigation, arising from our alleged infringement of patents, trade secrets or copyrights owned by other third parties. We intend to fully comply with the law in avoiding such infringements. However, within the healthcare, drug and bio-technology industry, established companies have actively pursued such infringements, and have initiated such claims and litigation, which has made the entry of competitive products more difficult. We may experience such claims or litigation initiated by existing, better-funded competitors. Court-ordered injunctions may prevent us from bringing new products to market, and the outcome of litigation and any resulting loss of revenues and expenses of litigation may substantially affect our ability to meet our expenses and continue operations.

Risks Related to our Industry

The healthcare industry in which we operate is subject to substantial regulation by state and federal authorities, which could hinder, delay or prevent us from commercializing our protocols

The healthcare industry is highly regulated and continues to undergo significant changes as third-party payors, such as Medicare and Medicaid, traditional indemnity insurers, managed care organizations and other private payors increase efforts to control cost, utilization and delivery of healthcare services. Although our licensees do not currently bill or seek reimbursement from Medicare, Medicaid or other governmental organizations for the treatment of patients using the PROMETA protocols, we are nevertheless subject to the overall effect of the changes created by increased cost control and financial pressures on the industry.

Healthcare companies are subject to extensive and complex federal, state and local laws, regulations and judicial decisions governing various matters such as the licensing and certification of facilities and personnel, the conduct of operations, billing policies and practices, policies and practices with regard to patient privacy and confidentiality, and prohibitions on payments for the referral of business and self-referrals. There are federal and state laws, regulations and judicial decisions that govern patient referrals, physician financial relationships, submission of healthcare claims and inducement to beneficiaries of federal healthcare programs. Many states prohibit business corporations from practicing medicine, employing or maintaining control over physicians who practice medicine, or engaging in certain business practices, such as splitting fees with healthcare providers. Many



healthcare laws and regulations applicable to our business are complex, applied broadly and subject to interpretation by courts and government agencies. Our failure, or the failure of our licensees, to comply with these healthcare laws and regulations could create liability for us and negatively impact our business.

In addition, the Food and Drug Administration (FDA), regulates development, testing, labeling, manufacturing, marketing, promotion, distribution, record-keeping and reporting requirements for prescription drugs, medical devices and biologics. Other regulatory requirements apply to dietary supplements (including vitamins). Compliance with laws and regulations enforced by the FDA and other regulatory agencies may be required relative to our protocols or any other medical products or services developed or used by us. Failure to comply with applicable laws and regulations may result in various adverse consequences, including withdrawal of our protocols from the market, the imposition of civil or criminal sanctions, or the required modification or redesign of our protocols. We may not have the financial resources to modify our protocols or implement new techniques. Accordingly, our ability to market our protocols in compliance with applicable laws and regulations may be a threshold test for our survival.

We believe that this industry will continue to be subject to increasing regulation, political and legal action and pricing pressures, the scope and effect of which we cannot predict. Legislation is continuously being proposed, enacted and interpreted at the federal, state and local levels to regulate healthcare delivery and relationships between and among participants in the healthcare industry. Any such changes could prevent us from marketing some or all of our products and services for a period of time or permanently.

We may be subject to regulatory and investigative proceedings, which may find that our policies and procedures do not fully comply with complex and changing healthcare regulations

While we have established policies and procedures that we believe will be sufficient to ensure that we operate in substantial compliance with applicable laws, regulations and requirements, the criteria are often vague and subject to change and interpretation. We may become the subject of regulatory or other investigations or proceedings, and our interpretations of applicable laws and regulations may be challenged. The defense of any such challenge could result in substantial cost and a diversion of management's time and attention. Thus, any such challenge could have a material adverse effect on our business, regardless of whether it ultimately is successful. If we fail to comply with any applicable laws, or a determination is made that we have failed to comply with these laws, our financial condition and results of operations could be adversely affected.

The promotion of our protocols may be found to violate federal law concerning "off-label" uses of prescription drugs, which could prevent us from marketing our protocols

The Food Drug & Cosmetic (FDC) Act, requires that prescription drugs be approved for a specific medical indication by the FDA prior to their marketing in interstate commerce. In addition, promotion of dietary supplements for uses beyond those permitted by law may be treated as the unlawful promotion of drugs absent FDA approval. Violations of the FDC Act may result in either civil (seizure or injunction) or criminal penalties. Our procedural medical protocols call for the use of prescription drugs for the treatment of chemical dependence and drug addiction, conditions not approved for use in the drugs' official labeling, and physicians prescribe and use these drugs when treating patients using our protocols. In addition, our protocols include the use of nutritional supplements. While the FDA generally does not regulate licensed physicians who prescribe approved drugs for non-approved or "off-label" uses in the independent practice of medicine, our promotion of our protocols through advertising and other means may be found to violate FDA regulations or the FDC Act. The FDA has broad discretion in interpreting those regulations. If the FDA determines that our promotion of our medical treatment protocols violates the FDC Act or brings an enforcement action against us for violating the FDC Act or FDA regulations that is successful, our promotion of our protocols will have to stop and we may be unable to continue operating under our current business



model. Even if we defeat any FDA challenge, the expenses associated with defending the claim or negative publicity concerning the off-label use of drugs in our protocols could adversely affect our business and results of operation.

Treatment using our protocols may be found to require review or approval, which could delay or prevent the study or use of our protocols

The FDA asserts jurisdiction over many clinical trials, or experiments, in which a drug is administered to human subjects. Hospitals and clinics have established Institutional Review Boards, or IRBs, to review and approve clinical trials using investigational treatments in their facilities. Certain investigations involving new drugs or off-label uses for approved drugs must be the subject of an FDA investigational New Drug exemption (IND). Use of our treatment protocol by individual physicians in treating their patients may be found to constitute a clinical trial or investigation that requires IRB review or an IND. FDA has broad authority in interpreting and applying its regulations, so it may find that use of our protocols by our licensees or collection of outcomes data on that use constitutes a clinical investigation subject to IRB and FDA jurisdiction and may take enforcement action against us. Individual hospitals and physicians may also submit their use of our protocols in treatment to their IRBs and individual IRBs may find that use to be a clinical trial that requires FDA approval or they may prohibit or place restrictions on that use. Any of these results may adversely affect our business and the ability of our customers to use our protocols.

Failure to comply with the Federal Trade Commission Act or similar state laws could result in sanctions or limit the claims we can make

The company's promotional activities and materials, including advertising to consumers and physicians, and materials provided to licensees for their use in promoting our protocols, are regulated by the Federal Trade Commission (FTC) under the FTC Act, which prohibits unfair and deceptive acts and practices, including claims which are false, misleading or inadequately substantiated. The FTC typically requires competent and reliable scientific tests or studies to substantiate express or implied claims that a product or service is effective. If the FTC were to interpret our promotional materials as making express or implied claims that our protocols are effective for the treatment of alcohol, cocaine or methamphetamine addiction, it may find that we do not have adequate substantiation for such claims. Failure to comply with the FTC Act or similar laws enforced by state attorneys general and other state and local officials could result in administrative or judicial orders limiting or eliminating the claims we can make about our protocols, and other sanctions including fines.

Our business practices may be found to constitute illegal fee-splitting or corporate practice of medicine, which may lead to penalties and adversely affect our business

Many states, including California in which our principal executive offices are located, have laws that prohibit business corporations, such as us, from practicing medicine, exercising control over medical judgments or decisions of physicians, or engaging in certain arrangements, such as employment or fee-splitting, with physicians. Courts, regulatory authorities or other parties, including physicians, may assert that we are engaged in the unlawful corporate practice of medicine by providing administrative and ancillary services in connection with our protocols, or that licensing our technology for a portion of the patient fees, or subleasing space and providing turn-key business management to affiliated medical groups in exchange for management and licensing fees, constitute improper fee-splitting, in which case we could be subject to civil and criminal penalties, our contracts could be found legally invalid and unenforceable, in whole or in part, or we could be required to restructure our contractual arrangements. There can be no assurance that this will not occur or, if it does, that we would be able to restructure our contractual arrangements on favorable terms.

Our business practices may be found to violate anti-kickback, self-referral or false claims laws, which may lead to penalties and adversely affect our business

The healthcare industry is subject to extensive federal and state regulation with respect to financial relationships and “kickbacks” involving healthcare providers, physician self-referral arrangements, filing of false claims and other fraud and abuse issues. Federal anti-kickback laws and regulations prohibit certain offers, payments or receipts of remuneration in return for (i) referring patients covered by Medicare, Medicaid or other federal health care program, or (ii) purchasing, leasing, ordering or arranging for or recommending any service, good, item or facility for which payment may be made by a federal health care program. In addition, federal physician self-referral legislation, commonly known as the Stark law, generally prohibits a physician from ordering certain services reimbursable by Medicare, Medicaid or other federal healthcare program from any entity with which the physician has a financial relationship. While providers who license our protocols currently do not seek such third party reimbursement for treatment using our protocols, we anticipate they may do so in the future. In addition, many states have similar laws, some of which are not limited to services reimbursed by federal healthcare programs. Other federal and state laws govern the submission of claims for reimbursement, or false claims laws. One of the most prominent of these laws is the federal False Claims Act, and violations of other laws, such as the anti-kickback laws or the FDA prohibitions against promotion of off-label uses of drugs, may also be prosecuted as violations of the False Claims Act.

While we believe we have structured our relationships to comply with all applicable requirements, federal or state authorities may claim that our fee arrangements, agreements and relationships with contractors, hospitals and physicians violate these anti-kickback, self-referral or false claims laws and regulations. These laws are broadly worded and have been broadly interpreted by courts. It is often difficult to predict how these laws will be applied, and they potentially subject many typical business arrangements to government investigation and prosecution, which can be costly and time consuming. Violations of these laws are punishable by monetary fines, civil and criminal penalties, exclusion from participation in government-sponsored health care programs and forfeiture of amounts collected in violation of such laws. Some states also have similar anti-kickback and self-referral laws, imposing substantial penalties for violations. If our business practices are found to violate any of these provisions, we may be unable to continue with our relationships or implement our business plans, which would have an adverse effect on our business and results of operations.

We may be subject to healthcare anti-fraud initiatives, which may lead to penalties and adversely affect our business

State and federal governments are devoting increased attention and resources to anti-fraud initiatives against healthcare providers, taking an expansive definition of fraud that includes receiving fees in connection with a healthcare business that is found to violate any of the complex regulations described above. While to our knowledge we have not been the subject of any anti-fraud investigations, if such a claim were made defending our business practices could be time consuming and expensive, and an adverse finding could result in substantial penalties or require us to restructure our operations, which we may not be able to do successfully.

Our use and disclosure of patient information is subject to privacy and security regulations, which may result in increased costs

In conducting research or providing administrative services to healthcare providers in connection with the use of our protocols, we may collect, use, maintain and transmit patient information in ways that will be subject to many of the numerous state, federal and international laws and regulations governing the collection, dissemination, use and confidentiality of patient-identifiable health information, including the federal Health Insurance Portability and Accountability Act (HIPAA) and related rules. The three rules that were promulgated pursuant to HIPAA that could most significantly affect our business are the Standards for Electronic Transactions, or Transactions Rule; the



Standards for Privacy of Individually Identifiable Health Information, or Privacy Rule; and the Health Insurance Reform: Security Standards, or Security Rule. HIPAA applies to covered entities, which include most healthcare facilities and health plans that will contract for the use of our protocols and our services. The HIPAA rules require covered entities to bind contractors like us to compliance with certain burdensome HIPAA rule requirements. Other federal and state laws restricting the use and protecting the privacy of patient information also apply to our licensees directly and to us, either directly or indirectly.

The HIPAA Transactions Rule establishes format and data content standards for eight of the most common healthcare transactions. When we perform billing and collection services on behalf of our licensees we may be engaging in one of more of these standard transactions and will be required to conduct those transactions in compliance with the required standards. The HIPAA Privacy Rule restricts the use and disclosure of patient information, requires entities to safeguard that information and to provide certain rights to individuals with respect to that information. The HIPAA Security Rule establishes elaborate requirements for safeguarding patient information transmitted or stored electronically. We may be required to make costly system purchases and modifications to comply with the HIPAA rule requirements that are imposed on us and our failure to comply may result in liability and adversely affect our business.

Federal and state consumer protection laws are being applied increasingly by the FTC and state attorneys general to regulate the collection, use and disclosure of personal or patient information, through web sites or otherwise, and to regulate the presentation of web site content. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access.

Numerous other federal and state laws protect the confidentiality of personal and patient information. These laws in many cases are not preempted by the HIPAA rules and may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our licensees and potentially exposing us to additional expense, adverse publicity and liability. Other countries also have, or are developing, laws governing the collection, use and transmission of personal or patient information and these laws could create liability for us or increase our cost of doing business.

We may not be able to profitably adapt to the changing healthcare and substance dependence treatment industry, which may reduce or eliminate our commercial opportunity

Healthcare organizations, public and private, continue to change the manner in which they operate and pay for services. In recent years, the healthcare industry has been subject to increasing levels of government regulation of reimbursement rates and capital expenditures, among other things. We cannot predict the likelihood of all future changes in the healthcare industry in general, or the substance dependence treatment industry in particular, or what impact they may have on our earnings, financial condition or business.

Risks Related to our Common Stock

Our stock price may be subject to substantial volatility, and you may lose all or a substantial part of your investment

Our common stock is traded on The Nasdaq National Market. Over the last year, it traded between \$4.26 and \$9.30 per share on limited and sporadic volume ranging from approximately 14,900 to 1,449,400 shares per day. As a result, the current price for our common stock on the Nasdaq is not necessarily a reliable indicator of our fair market value. The price at which our common stock will trade may be highly volatile and may fluctuate as a result of a number of factors, including the number of shares available for sale in the market, quarterly variations in our operating results, actual or anticipated announcements of new data, studies, products or services by us or competitors, regulatory investigations or determinations, acquisitions or strategic alliances by us or our competitors, recruitment or departures of key personnel, the gain or loss of significant customers, changes in the estimates of our operating performance, market conditions in our industry and the economy as a whole.



Over one-third of our stock is controlled by a single stockholder who has the ability to substantially influence the election of directors and the outcome of matters submitted to stockholders

As of December 31, 2005, Reserva Capital, LLC, a limited liability company whose sole managing member is Terren S. Peizer, our chairman and chief executive officer, directly owned 13,700,000 shares, which represent approximately 35% of our 39,504,330 shares of outstanding common stock. As a result, Mr. Peizer presently and is expected to continue to have the ability to substantially influence the election of our board of directors and the outcome of all other issues submitted to our stockholders. The interests of this stockholder may not always coincide with our interests or the interests of other stockholders, and it may act in a manner that advances its best interests and not necessarily those of other stockholders. One consequence to this substantial stockholder's interest is that it may be difficult for investors to remove management of the company. It could also deter unsolicited takeovers, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices.

Provisions in our certificate of incorporation, bylaws and Delaware law could discourage a change in control, and adversely affect existing stockholders

Our certificate of incorporation and the Delaware General Corporation Law contain provisions that may have the effect of making more difficult or delaying attempts by others to obtain control of our company, even when these attempts may be in the best interests of stockholders. Our certificate of incorporation also authorizes our board of directors, without stockholder approval, to issue one or more series of preferred stock, which could have voting and conversion rights that adversely affect or dilute the voting power of the holders of common stock. Delaware law also imposes conditions on certain business combination transactions with "interested stockholders."

These provisions and others that could be adopted in the future could deter unsolicited takeovers or delay or prevent changes in our control or management, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices. These provisions may also limit the ability of stockholders to approve transactions that they may deem to be in their best interests.

We have never paid cash dividends and do not intend to do so

We have never declared or paid cash dividends on our common stock. We currently plan to retain any earnings to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends in the future will depend on our financial condition, results of operations and capital requirements, as well as other factors deemed relevant by our board of directors.



ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTY

Our principal executive offices, including substantially all of our sales, marketing and administrative functions, are located in leased office space of a total of approximately 15,000 square feet in Los Angeles, California. The lease commenced in December 2003, and was amended in May 2005, to increase the space by approximately 4,200 square feet. The base rent is currently approximately \$46,000 per month, subject to annual adjustment over the remaining original seven-year term. We are currently negotiating an amendment to the lease to add an additional 5,000 square feet to accommodate our continued expansion of our executive offices and additional staffing requirements. As we expand in the future, we may lease additional regional office facilities, as necessary, to service our customer base. We believe that the current office space is adequate to meet our current needs, and that additional facilities will be available for lease to meet our future needs.

In April 2005 we entered into a five year lease for approximately 5,400 square feet of medical office space at an initial base rent of approximately \$19,000 per month commencing in August 2005. The space is occupied by The PROMETA Center, an affiliated medical practice, under a full service management agreement. We believe that the space is adequate to meet our current and future needs for this practice.

ITEM 3. LEGAL PROCEEDINGS

Not applicable.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is listed for trading on The NASDAQ National Market under the symbol "HYTM." Prior to March 8, 2005, the stock traded on the American Stock Exchange under the symbol "HTM." Prior to December 15, 2003, the stock was quoted on the OTC Bulletin Board. As of March 1, 2006, there were approximately 105 record holders representing approximately 3,679 beneficial owners of our common stock. Following is a list by fiscal quarters of the closing sales prices of our stock:

	Closing Sales Prices	
2005	High	Low
4th Quarter	\$ 6.85	\$ 4.45
3rd Quarter	\$ 7.30	\$ 5.12
2nd Quarter	\$ 8.54	\$ 4.95
1st Quarter	\$ 9.02	\$ 5.24
2004		
2004	High	Low
4th Quarter	\$ 6.51	\$ 3.39
3rd Quarter	\$ 4.47	\$ 2.00
2nd Quarter	\$ 6.45	\$ 3.00
1st Quarter	\$ 8.40	\$ 5.56

We have never declared or paid any dividends. We may, as our board of directors deems appropriate, continue to retain all earnings for use in our business or may consider paying dividends in the future.

Information regarding securities authorized for issuance under equity compensation plans is incorporated by reference to Part III of this report.



ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth selected financial data that is qualified by reference to, and should be read in conjunction with, Item 7. Management's Discussion and Analysis of Results of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data included elsewhere in this report.

(In thousands, except per share amounts)	Year Ended December 31,		Period from February 13, 2003 (Inception) to December 31,
	2005	2004	2003
Revenues	\$ 1,164	\$ 192	\$ 75
Operating expenses			
General and administrative			
Salaries and benefits	9,247	5,117	1,617
Research and development	2,646	177	-
Other expenses	13,264	6,173	1,928
Depreciation and amortization	879	670	75
Total operating expenses	26,036	12,137	3,620
Loss from operations	(24,872)	(11,945)	(3,545)
Interest income	834	171	41
Loss before provision for income taxes	(24,038)	(11,774)	(3,504)
Provision for income taxes	-	1	-
Net loss	\$ (24,038)	\$ (11,775)	\$ (3,504)
Basic and diluted net loss per share	\$ (0.77)	\$ (0.47)	\$ (0.21)
Weighted average shares outstanding	31,173	24,877	16,888
CASH FLOW DATA			
Net cash used in operating activities	\$ (18,789)	\$ (10,248)	\$ (1,374)
Net cash used in investing activities	(22,236)	(10,612)	(16,527)
Net cash provided by financing activities	40,442	21,416	21,345
BALANCE SHEET DATA			
	As of December 31,		
	2005	2004	2003
Cash, cash equivalents and marketable securities	\$ 47,000	\$ 27,479	\$ 16,640
Total current assets	47,720	28,093	17,344
Total assets	54,462	33,962	22,580
Total liabilities	4,723	2,128	2,092
Stockholders' equity	49,739	31,834	20,488

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

The forward-looking comments contained in the following discussion involve risks and uncertainties. Our actual results may differ materially from those discussed here due to factors such as, among others, limited operating history, difficulty in developing, exploiting and protecting proprietary technologies, intense competition and substantial regulation in the healthcare industry. Additional factors that could cause or contribute to such differences can be found in the following discussion, as well as under Item 1.A Risks Factors above.

Overview

We research, develop, license and commercialize innovative physiological treatment protocols designed for use by healthcare providers to treat individuals diagnosed with dependencies to alcohol, cocaine and methamphetamine, as well as combinations of these drugs. We have been unprofitable since our inception and may incur substantial additional operating losses for at least the next twelve months as we incur expenditures on research and development, continue to implement commercial operations and allocate significant and increasing resources to sales, marketing and other start-up activities. Accordingly, our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and our historical operations and financial information are not necessarily indicative of the future operating results or financial condition or ability to operate profitably as a commercial enterprise. In 2005 we transitioned from a development stage company to an operational company, increasing our number of licensed sites from seven to 32 as of December 31, 2005, and reporting over \$1 million in revenues.

Operations

We commenced operations in July 2003 and signed our first licensing agreement in November 2003. Under our licensing agreements, we provide treatment providers access to our PROMETA protocols and marketing support to attract patient referrals. We receive a fee for the licensed technology and related services generally on a per patient basis. Until the fourth quarter 2004, we had signed only two license agreements and had generated a limited amount of revenues from only one hospital. In the fourth quarter 2004, our business development efforts resulted in signing five additional license agreements with hospitals and other healthcare providers. In 2005, through increased efforts to obtain additional licensing agreements with hospitals and healthcare providers in major U.S. markets, we licensed an additional 25 sites, bringing the total number of licensed sites to 32 throughout the United States as of December 31, 2005.

Most new licensees become operational after a two to six month period that is required for training and other site initiation activities, but others may take longer before their programs advance beyond the training phase. We believe that the number of patients treated by our licensees will increase over time as our marketing, advertising and branding activities are implemented and clinical outcomes data from research studies become available.

In December 2005, we commenced management of The PROMETA Center, Inc., a new affiliated medical practice operating in a state-of-the-art outpatient facility located in Santa Monica, California. Under the terms of a full service management agreement, we manage the medical practice in exchange for management and licensing fees. The practice has a primary focus on using the PROMETA protocols for dependencies on alcohol, cocaine and methamphetamines but will also offer medical interventions for other substance dependencies. The PROMETA Center is the first location solely dedicated to the treatment of alcohol, cocaine and methamphetamine dependencies with the PROMETA protocols. The revenues and expenses of the PROMETA center are included in our consolidated financial statements under accounting standards applicable to variable interest entities.



Research and Development

In 2005 we announced a number of clinical research studies by preeminent researchers in the field of substance dependence, to evaluate the efficacy of PROMETA in treating alcohol and stimulant dependence. We anticipate that these studies will be the basis for publication in scientific journals. We expect initial data from the first methamphetamine study to be made available in the first half of 2006. In addition, we have contracted with a contract research organization (CRO) to establish a clinical outcomes registry for the monitoring and evaluation of up to 750 patients undergoing treatment using PROMETA at our commercial licensee sites. We have also announced several pilot studies with state programs and drug court systems to study the efficacy of the PROMETA protocols. In 2005 our expenditures related to research and development was \$2.6 million as compared to \$177,000 in the prior year, and we plan to spend over \$8 million in 2006 and 2007 for research grants, commercial pilots and the patient outcomes registry.

International Licensing

In 2004 and 2005 we established several wholly-owned foreign subsidiaries for the purpose of licensing our intellectual property in foreign markets, and entered into an agreement to acquire protocols for the treatment of nicotine and drug dependence in Europe. Our foreign activities to date have consisted of funding of legal and other consulting services, development and start-up activities for potential business opportunities in Europe. As of December 31, 2005, we had not commenced any foreign operations.

Results of Operations

In 2005, we increased the number of licensed sites from seven to 32 as of December 31, 2005. Eight of our licensees each contributed over 5% of our revenues in 2005, compared to only one in 2004 which contributed 93% of our revenues that year. We expect that an increasing number of our licensees will become operational in 2006, and plan to continue to expand the number of licensees in major metropolitan service areas throughout the country.

Revenues

Our revenues are generated from fees that we charge to hospitals, healthcare facilities and other healthcare providers that license our PROMETA protocols. Our license agreements provide for a combined fee for the licensed technology and related services, set on a per patient basis, and thus our revenues are generally related to the number of patients treated. We also consolidate the revenues and expenses of the PROMETA center under accounting standards applicable to variable interest entities. Key indicators of our financial performance are the number of facilities and healthcare providers that contract with us to license our technology and the number of patients that are treated by those providers using the PROMETA protocols.

Revenues for the 12 months ended December 31, 2005 and 2004 were \$1,164,000 and \$192,000, respectively, and \$75,000 for the period from February 13, 2003 (inception) to December 31, 2003. The total number of patients treated by our licensees was approximately 215 in 2005, 40 in 2004 and 15 in 2003. The increases in revenues each year is directly attributable to the increasing number of patients treated at our licensed sites, with fourteen licensees contributing to revenues at some level in 2005 as compared to three in 2004 and one in 2003. Our average license fees per patient also increased from approximately \$4,800 in 2004 to \$5,400 in 2005 as the relative percentage of patients treated by our licensees who were offered partial or full discounts during the site start-up period or for training purposes declined in 2005 from 2004. There have been no significant changes in our licensing fees charged to our licensees between the periods.



Operating Expenses

Our operating expenses more than doubled from 2004 to 2005 to approximately \$26 million as we commercialized operations, increased our management and support staff, commenced marketing and advertising our PROMETA protocols, funded clinical research studies and invested in development of international opportunities.

Salaries and benefits expenses were \$9.2 million and \$5.1 million for the years ended December 31, 2005 and 2004, respectively, and \$1.6 million for the period from February 13, 2003 (inception) to December 31, 2003. The significant increases in 2005 over 2004 reflect the increase in personnel from 37 to approximately 90 employees in 2005, as we have added managers in the field to support our 32 licensed sites and have increased our corporate staff to support our rapid growth in operations, research, sales and marketing efforts, new business initiatives and general administrative functions.

In 2005 we expensed approximately \$2.6 million for research and development, compared to \$177,000 in 2004, as we funded unrestricted grants for research studies to evaluate our PROMETA protocols, initiated the patient outcomes registry and commenced commercial pilot studies. We plan to spend over \$8 million over the next two years for such studies. We believe the results from these studies will validate PROMETA as a method of care for treating alcoholism and stimulant dependence, as well as serve to accelerate our growth. The first outcomes data from these studies are expected to be published in the first half of 2006.

Other operating expenses were \$13.3 million and \$6.2 million for the years ended December 31, 2005 and 2004, respectively, and \$1.9 million for the period from February 13, 2003 (inception) to December 31, 2003. Included in other operating expenses were non-cash charges for share-based expense of \$1.7 million, \$1.2 million and \$345,000 for the years ended December 31, 2005 and 2004 and for the period from February 13, 2003 (inception) to December 31, 2003, respectively. Other operating expenses include legal, audit, insurance, rent, travel and entertainment, investor relations, marketing, advertising, business development and other professional consulting costs. Most expenditures increased significantly in 2005 from 2004 due to the rapid growth of our business and the resulting increase in our corporate infrastructure to support the increase in staffing in 2005. In addition, beginning in the second half of 2005, we invested significant funds in test piloting local advertising campaigns and the development of corporate advertising and marketing programs to increase public awareness of our PROMETA treatment, as well as development of a consumer website. We also incurred over \$400,000 in 2005 for consultants and additional audit fees to meet the new internal control reporting requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

Interest Income

The increase in interest income from \$171,000 in 2004 to \$834,000 in 2005 is primarily due to additional proceeds from our equity offerings of \$21 million in December 2004 and \$40 million in November 2005, and an increase in the weighted average interest rates during 2005.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the sale of shares of our stock. In September 2003 we received net proceeds of approximately \$21 million from the private placement of our equity securities, and in December 2004 we received net proceeds of approximately \$21 million from a second private placement of our stock. In November 2005, we raised an additional \$40 million in net proceeds from a follow-on underwritten offering of 9.2 million shares of our common stock. As of December 31, 2005 we had a balance of approximately \$47 million in cash, cash equivalents and marketable securities.



Since we are a rapidly growing business, our prior operating costs are not representative of our expected on-going costs. As we continue to implement commercial operations and allocate significant and increasing resources to sales, marketing and other start-up activities, we expect our monthly cash operating expenditures to steadily increase from our current average of approximately \$2.3 million per month to approximately \$3.2 million per month over the next twelve months, excluding research and development costs. We plan to spend approximately \$8 million over the next two years for research and development.

In 2005, we expended approximately \$1.8 million in capital expenditures for the build-out and furnishing of The Prometa Center, the purchase of computers and office equipment for our new staff and expansion of our corporate office facilities, additional investment in the development of our information systems and other equipment needs. In 2006, we expect our capital expenditures to be approximately \$1.5 million.

We will continue to invest in the infrastructure we believe we will need, both in management as well as systems and equipment, to develop, market and implement our business plan. Our future capital requirements will depend upon many factors, including progress with marketing our technologies, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, the necessity of, and time and costs involved in obtaining, regulatory approvals, competing technological and market developments, and our ability to establish collaborative arrangements, effective commercialization, marketing activities and other arrangements.

We expect to continue to incur negative cash flows and net losses for at least the next twelve months. Based upon our current plans, including anticipated growth in our revenues, we believe that our existing cash reserves totaling approximately \$47 million as of December 31, 2005 will be sufficient to meet our operating expenses and capital requirements until we achieve profitability. However, changes in our business strategy, technology development or marketing plans or other events affecting our operating plans and expenses may result in the expenditure of existing cash before that time. If this occurs, our ability to meet our cash obligations as they become due and payable will depend on our ability to sell securities, borrow funds or some combination thereof. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners. We may also seek to raise additional capital through public or private financing in order to increase the amount of our cash reserves on hand. We may not be successful in raising necessary funds on acceptable terms, or at all.

Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. As of the date of this report, we are not currently involved in any legal proceeding that we believe would have a material adverse effect on our business, financial condition or operating results.

Contractual Obligations and Commercial Commitments

The following table sets forth a summary of our material contractual obligations and commercial commitments as of December 31, 2005:

Contractual Obligations	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating lease obligations (1)	\$ 4,024,000	\$ 783,000	\$ 1,636,000	\$ 1,605,000	-
Contractual commitments for clinical studies	\$ 4,387,000	\$ 2,408,000	\$ 1,979,000	-	-
	<u>\$ 8,411,000</u>	<u>\$ 3,191,000</u>	<u>\$ 3,615,000</u>	<u>\$ 1,605,000</u>	<u>-</u>

(1) Operating lease commitment for our corporate office facilities and the PROMETA Center, including deferred rent liability.

Off-Balance Sheet Arrangements

As of December 31, 2005 we had no off-balance sheet arrangements.

Effects of Inflation

Our most liquid assets are cash, cash equivalents and marketable securities. Because of their liquidity, these assets are not directly affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. Generally accepted accounting principles require management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. We base our estimates on experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that may not be readily apparent from other sources. Our actual results may differ from those estimates.

We consider our critical accounting estimates to be those that (1) involve significant judgments and uncertainties, (2) require estimates that are more difficult for management to determine, and (3) may produce materially different results when using different assumptions. Management has discussed these critical accounting estimates, the basis for their underlying assumptions and estimates and the nature of our related disclosures herein with the Audit Committee of the Board of Directors. Our critical accounting estimates cover the following areas:

Share-based Expense

We account for the issuance of options and warrants for services from non-employees in accordance with Statement of Financial Accounting Standards (SFAS) 123, "Accounting for Stock-Based Compensation," by estimating the fair value of options and warrants issued using the Black-Scholes pricing model. This model's calculations include the exercise price, the market price of shares on grant date, weighted average assumptions for risk-free interest rates, expected life of the option or warrant, expected volatility of our stock and expected dividend yield. The amounts recorded in the financial statements for share-based expense could vary significantly if we were to use different assumptions. For example, the assumptions we have made for the expected volatility of our stock price have been made using volatility averages of other public healthcare companies, since we have a limited history as a public company and our actual stock price volatility would not be meaningful. If we were to use the actual volatility of our stock price, there may be a significant variance in the amounts of share-based expense from the amounts reported. Based on the 2005 assumptions used for the Black-Scholes pricing model, a 50% increase in stock price volatility would have increased the fair values of options by approximately 25%.

Commencing January 1, 2006, we implemented the accounting provisions of SFAS 123R on a modified-prospective basis to recognize stock-based compensation for employee stock option awards in our statements of operations for future periods. See "Recent Accounting Pronouncements" below for a discussion of SFAS 123R.

Impairment of Intangible Assets

We have capitalized significant costs, and plan to capitalize additional costs, for acquiring patents and other intellectual property directly related to our products and services. We will continue to evaluate our intangible assets for impairment on an ongoing basis by assessing the future recoverability of such capitalized costs based on estimates of our future revenues less estimated costs. Since we have not recognized significant revenues to date, our estimates of future revenues may not be realized and the net realizable value of our capitalized costs of intellectual property may become impaired. In December 2005, we recorded an impairment charge of \$272,000 to write off the capitalized costs of intellectual property relating to an acquired patent for a treatment method for opiate addiction that we have determined would not likely be utilized in our current business plan.

Segment Reporting

We currently operate in one reportable segment. Substantially all of our services are provided within the United States, and substantially all of our assets are located within the United States.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS 123R, "Share-Based Payment," which addresses the accounting for employee stock options. SFAS 123R revises the disclosure provisions of SFAS 123 and supersedes APB 25. SFAS 123R requires that the cost of all employee stock options be reflected in the financial statements based on the estimated fair value of the awards at date of grant. Share-based compensation for non-employees is accounted for in accordance with FASB Emerging Issues Task Force (EITF) No. 96-18 "Accounting For Equity Instruments That Are Issued To Other Than Employees For Acquiring Or In Conjunction With Selling Goods Or Services." In April 2005, the Securities and Exchange Commission (SEC) amended Rule 4-01(a) of Regulation S-X to defer the required date for compliance with SFAS 123R to the first interim or annual reporting period of the registrant's first fiscal year beginning on or after June 15, 2005. We have adopted SFAS 123R on January 1, 2006, which complies with the amended Rule 4-01(a). Under SFAS 123R, we will transition to the fair-value-based method using a modified prospective application. Under that transition method, compensation cost will be recognized commencing in 2006 for the portion of outstanding awards for which the requisite service has not yet been rendered. We do not expect the provisions of SFAS 123R to result in a significant change in the compensation expense we currently disclose on a pro forma basis under SFAS 123. Through December 31, 2005, we accounted for share-based payments to employees using the intrinsic value method under APB 25 and, as such, generally recognized no compensation cost for employee stock options. Accordingly, the adoption of fair value method under SFAS 123R will increase our operating costs, but will not have a material impact on our overall financial position. The specific magnitude of the impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based incentive awards granted in the future. However, had we adopted SFAS 123R in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss and loss per share in the footnotes to our financial statements.

In May 2005, the FASB issued SFAS 154, "Accounting Changes and Error Corrections." SFAS 154 replaces Accounting Principals Board (APB) Opinion No. 20, "Accounting Changes" and SFAS 3, "Reporting Accounting Changes in Interim Financial Statements" and establishes retrospective application as the required method for reporting a change in accounting principle. SFAS 154 provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The reporting of a correction of an error by restating previously issued financial statements is also addressed. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not expect the adoption of this statement to have a material impact on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest our cash in short term commercial paper, certificates of deposit, money market accounts and marketable securities. We consider any liquid investment with an original maturity of three months or less when purchased to be cash equivalents. We classify investments with maturity dates greater than three months when purchased as marketable securities, which have readily determined fair values as available-for-sale securities. Our investment policy requires that all investments be investment grade quality and no more than ten percent of our portfolio may be invested in any one security or with one institution. At December 31, 2005, our investment portfolio consisted of investments in highly liquid, high grade commercial paper, variable rate securities and certificates of deposit. The weighted average interest rate of cash equivalents and marketable securities held at December 31, 2005 was 4.2%.

Investments in both fixed rate and floating rate interest earning instruments carry a degree of interest rate risk. Fixed rate securities may have their fair market value adversely impacted due to a rise in interest rates, while floating rate securities with shorter maturities may produce less income if interest rates fall. The market risk associated with our investments in debt securities is substantially mitigated by the frequent turnover of our portfolio.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and related financial information required to be filed hereunder are indexed under Item 15 of this report and are incorporated herein by reference.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls

We have evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our system of disclosure controls and procedures as of the end of the period covered by this report. Based on this evaluation our Chief Executive Officer and our Chief Financial Officer have determined that they are effective in connection with the preparation of this report.

There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) and for assessing the effectiveness of our internal control over financial reporting. Our internal control system is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements in accordance with United States' generally accepted accounting principles.



Our internal control over financial reporting is supported by written policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and that our receipts and expenditures are being made only in accordance with authorizations of our management and our Board of Directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2005 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in *Internal Control-Integrated Framework*. Management’s assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on this assessment, our management concluded that, as of December 31, 2005, our internal control over financial reporting was effective.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions and that the degree of compliance with the policies or procedures may deteriorate.

BDO Seidman, LLP, the independent registered public accounting firm that audited the financial statements included in this Annual Report on Form 10-K, was engaged to attest to and report on management’s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005. A copy of this report is included at page F-3 of this Annual Report on Form 10-K.

ITEM 9B. OTHER INFORMATION

Not applicable.



PART III

The information required by Items 10 through 14 of Part III is incorporated by reference from Item 1 of this report and from registrants' proxy statement that will be mailed to stockholders in connection with the registrant's 2006 annual meeting of stockholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1),(2) Financial Statements

The Financial Statements and Financial Statement Schedules listed on page F-1 of this document are filed as part of this filing.

(a)(3) Exhibits

The following exhibits are filed as part of this report:

Exhibit No.	Description
3.1	Certificate of Incorporation of Hythiam, Inc., a Delaware corporation, filed with the Secretary of State of Delaware on September 29, 2003 ⁽¹⁾
3.2	By-Laws of Hythiam, Inc., a Delaware corporation ⁽¹⁾
4.1	Specimen Common Stock Certificate
10.1*	2003 Stock Incentive Plan ⁽¹⁾
10.2*	Employment Agreement of Terren S. Peizer
10.3*	Employment Agreement of Richard Anderson
10.4*	Employment Agreement of Anthony LaMacchia
10.5*	Employment Agreement of Chuck Timpe
10.6*	Employment Agreement of David E. Smith, M.D.
10.7*	Consulting Services Agreement between Hythiam, Inc. and David E. Smith & Associates
10.8*	Management and Support Services Agreement between Hythiam, Inc. and David E. Smith, M.D. Medical Group, Inc.
14.1	Code of Conduct and Ethics ⁽²⁾
14.2	Code of Ethics for CEO and Senior Financial Officers ⁽²⁾
21.1	Subsidiaries of the Company
23.1	Consent of Independent Registered Public Accounting Firm – BDO Seidman, LLP
31.1	Certification by the Chief Executive Officer, pursuant to Rule 13-a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification by the Chief Financial Officer, pursuant to Rule 13-a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification by the Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification by the Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

⁽¹⁾ Incorporated by reference to exhibit of the same number to the registrant's Form 8-K filed September 30, 2003.

⁽²⁾ Incorporated by reference to exhibit of the same number to the registrant's annual report on Form 10-K for the year ended December 31, 2003.

* Management contract or compensatory plan or arrangement.

Hythiam will furnish without charge to requesting security holders copies of any exhibits not contained herein.



SIGNATURES

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

HYTHIAM, INC.

Date: March 16, 2006

By: /s/ TERREN S. PEIZER

Terren S. Peizer

POWER OF ATTORNEY

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

<u>/s/ TERREN S. PEIZER</u> Terren S. Peizer	Chairman of the Board of Directors and Chief Executive Officer (Principal Executive Officer)	March 16, 2006
<u>/s/ CHUCK TIMPE</u> Chuck Timpe	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2006
<u>/s/ RICHARD A. ANDERSON</u> Richard A. Anderson	Director and Chief Administrative Officer	March 16, 2006
<u>/s/ ANTHONY M. LAMACCHIA</u> Anthony M. LaMacchia	Director and Chief Operating Officer	March 16, 2006
<u>/s/ LESLIE F. BELL</u> Leslie F. Bell	Director	March 16, 2006
<u>/s/ HERVÉ DE KERGROHEN</u> Hervé de Kergrohen	Director	March 16, 2006
<u>/s/ IVAN M. LIEBERBURG</u> Ivan M. Lieberburg	Director	March 16, 2006
<u>/s/ MARC G. CUMMINS</u> Marc G. Cummins	Director	March 16, 2006
<u>/s/ ANDREA GRUBB BARTHWELL</u> Andrea Grubb Barthwell	Director	March 16, 2006



HYTHIAM, INC. AND SUBSIDIARIES
Index to Financial Statements and Financial Statement Schedules

Financial Statements

Report of Independent Registered Public Accounting Firm	F-2
Report of Independent Registered Public Accounting Firm	F-3
Consolidated Balance Sheets as of December 31, 2005 and 2004	F-4
Consolidated Statements of Operations for the Years Ended December 31, 2005, 2004, and the Period from February 13, 2003 (Inception) to December 31, 2003	F-5
Consolidated Statement of Stockholders' Equity for the Period from February 13, 2003 (Inception) to December 31, 2005	F-6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2005, 2004 and the Period from February 13, 2003 (Inception) to December 31, 2003	F-7
Notes to Consolidated Financial Statements	F-8

Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable, not required, or the information is shown in the Financial Statements or Notes thereto.



Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Hythiam, Inc.
Los Angeles, California

We have audited the accompanying consolidated balance sheets of Hythiam, Inc. and subsidiaries (the "Company") as of December 31, 2005 and 2004 and the related consolidated statements of operations, stockholders' equity and cash flows for the years ended December 31, 2005 and 2004 and the period from February 13, 2003 (inception) to December 31, 2003. 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 in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits 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, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Hythiam, Inc. and subsidiaries as of December 31, 2005 and 2004 and the consolidated results of its operations and its cash flows for the years ended December 31, 2005 and 2004 and the period from inception to December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2005, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2006 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Los Angeles, California
March 15, 2006



Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Hythiam, Inc.
Los Angeles, California

We have audited management's assessment, included in *Management's Report on Internal Control over Financial Reporting* appearing in Item 9A of the accompanying Annual Report on Form 10-K, that Hythiam, Inc. and subsidiaries (the "Company") maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2005 is fairly stated, in all material respects, based on the criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of December 31, 2005 and 2004 and the related statements of operations, stockholders' equity and cash flows for the years ended December 31, 2005 and 2004 and the period from February 13, 2003 (inception) to December 31, 2003, and our report dated March 15, 2006 expressed an unqualified opinion on those financial statements.

/s/ BDO Seidman, LLP
Los Angeles, California
March 15, 2006



HYTHIAM, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

(Dollars in thousands, except share data)

	December 31,	
	2005	2004
ASSETS		
Current assets		
Cash and cash equivalents	\$ 3,417	\$ 4,000
Marketable securities	43,583	23,479
Restricted cash and marketable securities	44	-
Receivables, net	249	168
Prepays and other current assets	427	446
Total current assets	47,720	28,093
Long-term assets		
Property and equipment, net	3,498	2,424
Intellectual property, net	2,733	3,080
Deposits and other assets	511	365
	\$ 54,462	\$ 33,962
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,652	\$ 609
Accrued compensation and benefits	1,285	826
Other accrued liabilities	298	329
Total current liabilities	4,235	1,764
Long-term liabilities		
Deferred rent liability	488	364
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.0001 par value; 50,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, \$.0001 par value; 200,000,000 shares authorized; 39,504,000 and 30,111,000 shares issued and 39,144,000 and 29,751,000 shares outstanding at December 31, 2005 and December 31, 2004, respectively	4	3
Additional paid-in-capital	89,176	47,234
Accumulated deficit	(39,441)	(15,403)
	49,739	31,834
	\$ 54,462	\$ 33,962

See accompanying notes to consolidated financial statements.



HYTHIAM, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)	Year Ended December 31,		Period from February 13, 2003 (Inception) to December 31, 2003
	2005	2004	
Revenues	\$ 1,164	\$ 192	\$ 75
Operating Expenses			
General and administrative			
Salaries and benefits	9,247	5,117	1,617
Research and development	2,646	177	-
Other operating expenses	13,264	6,173	1,928
Depreciation and amortization	879	670	75
Total operating expenses	26,036	12,137	3,620
Loss from operations	(24,872)	(11,945)	(3,545)
Interest income	834	171	41
Loss before provision for income taxes	(24,038)	(11,774)	(3,504)
Provision for income taxes	-	1	-
Net loss	\$ (24,038)	\$ (11,775)	\$ (3,504)
Basic and diluted net loss per share	\$ (0.77)	\$ (0.47)	\$ (0.21)

See accompanying notes to consolidated financial statements.



HYTHIAM, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
Period from February, 13, 2003 (Inception) to December 31, 2005

(In thousands)	Preferred Stock		Common Stock		Additional Paid- in-Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Common stock issued at inception	-	\$ -	13,740	\$ -	\$ 1	\$ -	\$ 1
Common stock issued in merger transaction	-	-	1,120	1	(1)	-	-
Preferred stock and warrants issued for cash	1,876	2	-	-	4,688	-	4,690
Beneficial conversion feature of preferred stock	-	-	-	-	124	(124)	-
Common stock issued in private placement offering, net of expenses	-	-	7,035	7	16,647	-	16,654
Conversion of preferred stock to common stock	(1,876)	(2)	1,876	2	-	-	-
Par value change from \$0.001 to \$0.0001	-	-	-	(8)	8	-	-
Common stock and warrants issued for intellectual property acquired	-	-	836	1	2,280	-	2,281
Stock options and warrants issued for outside services	-	-	-	-	366	-	366
Net loss	-	-	-	-	-	(3,504)	(3,504)
Balance at December 31, 2003	-	-	24,607	3	24,113	(3,628)	20,488
Common stock and warrants issued for outside services	-	-	17	-	1,351	-	1,351
Common stock issued in private placement offering, net of expenses	-	-	5,017	-	21,349	-	21,349
Common stock issued for intellectual property acquired	-	-	83	-	354	-	354
Exercise of warrants	-	-	27	-	67	-	67
Net loss	-	-	-	-	-	(11,775)	(11,775)
Balance at December 31, 2004	-	-	29,751	3	47,234	(15,403)	31,834
Common stock, options and warrants issued for outside services	-	-	23	-	1,501	-	1,501
Exercise of options and warrants	-	-	170	-	265	-	265
Issuance of shares in connection with public offering, net of expenses	-	-	9,200	1	40,176	-	40,177
Net loss	-	-	-	-	-	(24,038)	(24,038)
Balance at December 31, 2005	-	\$ -	39,144	\$ 4	\$ 89,176	\$ (39,441)	\$ 49,739



HYTHIAM, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Year Ended December 31,		Period from February 13, 2003 (Inception) to December 31,
	2005	2004	2003
Operating activities			
Net loss	\$ (24,038)	\$ (11,775)	\$ (3,504)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	879	670	75
Deferred rent	124	(17)	64
Share-based expense	1,701	1,172	345
Asset impairment	272	-	-
Loss on disposition of fixed assets	64	-	-
Changes in current assets and liabilities:			
Receivables	(81)	(14)	(154)
Prepays and other current assets	(181)	(20)	(228)
Accounts payable	2,043	(650)	1,259
Accrued compensation and benefits	459	508	318
Other accrued liabilities	(31)	(122)	451
Net cash used in operating activities	(18,789)	(10,248)	(1,374)
Investing activities			
Purchase of marketable securities	(80,704)	(31,914)	(18,240)
Proceeds from sales and maturities of marketable securities	60,600	21,631	5,044
Restricted cash	(44)	-	-
Purchases of property and equipment	(1,803)	(205)	(2,443)
Intellectual property costs	(139)	(126)	(538)
Deposits and other assets	(146)	2	(350)
Net cash used in investing activities	(22,236)	(10,612)	(16,527)
Financing activities			
Net proceeds from sale of common and preferred stock and warrants	40,177	21,349	21,345
Exercises of stock options and warrants	265	67	-
Net cash provided by financing activities	40,442	21,416	21,345
Net (decrease) increase in cash and cash equivalents	(583)	556	3,444
Cash and cash equivalents at beginning of period	4,000	3,444	-
Cash and cash equivalents at end of period	\$ 3,417	\$ 4,000	\$ 3,444
Supplemental disclosure of non-cash activity			
Common stock and warrants issued for intellectual property	\$ -	\$ 354	\$ 2,280
Common stock, options and warrants issued for outside services	200	1,351	139
Common stock and warrants issued as commissions on private placement	-	-	265

See accompanying notes to consolidated financial statements.



HYTHIAM, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

Note 1. Summary of Significant Accounting Policies

Organization

Hythiam, Inc., (“the Company”), was formed and incorporated in New York on February 13, 2003, by Reserva, LLC, a non operating company wholly owned by the company’s chief executive officer. The Company was formed to research, develop, license and commercialize innovative physiological treatment protocols for substance dependence. The registrant, which was formerly known as Alaska Freightways, Inc. (“Alaska”), was incorporated in the state of Nevada on June 1, 2000, and previously provided transportation and freight brokerage services in the state of Alaska. In September and October 2003, Alaska sold substantially all of its operating assets and liabilities, merged with the Company, changed its name to Hythiam, Inc. and reincorporated in Delaware. Following merger, reincorporation and consolidation transactions, the registrant is now the sole surviving entity. Because the Company was the sole operating company at the time of the merger with Alaska, the merger was accounted for as a reverse acquisition, with the Company deemed the acquirer for accounting purposes.

References to “Hythiam,” the “Company,” “we” and “us,” and the discussion and analysis of financial condition and results of operations set forth in this report, are based upon the financial condition and operations of Hythiam, Inc. prior to the merger and of the newly-constituted registrant following the merger, together with its wholly-owned subsidiaries.

In December 2004, we established a wholly-owned foreign subsidiary for the purpose of licensing our proprietary intellectual property in foreign markets, and in 2005, we established additional foreign subsidiaries in Europe for this purpose.

Basis of Presentation

The consolidated financial statements include the accounts of the Company, our wholly-owned subsidiaries and the accounts of The PROMETA Center, Inc., a California professional corporation, which is beneficially owned and controlled by our senior vice president of medical affairs. Under the terms of a management services agreement with the PROMETA Center, we provide and perform all nonmedical management and administrative services for the medical group. We also agreed to provide a working capital loan to the PROMETA Center up to a maximum of \$500,000 to allow for the medical group to pay for its obligations. Payment of our management fee is subordinate to payments of the obligations of the medical group, and repayment of the working capital loan is not guaranteed by the shareholder or other third party. Based on the provisions of these agreements, we have determined that the PROMETA Center is a variable interest entity, and that we are the primary beneficiary as defined in FASB Interpretation 46, “Consolidation of Variable Interest Entities,” an Interpretation of ARB No. 51 (FIN 46). As a variable interest entity, we are required to consolidate the revenues and expenses of the PROMETA Center.

All intercompany transactions and balances have been eliminated in consolidation. Certain reclassifications have been made in the prior period to be consistent with current period presentation.

In 2005 we transitioned from a development stage company to an operational company, increasing our number of licensed sites from seven to 32 as of December 31, 2005, and reporting over \$1 million in revenues.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and the reported amounts of expenses. Actual results could differ from those estimates.

Cash Equivalents and Marketable Securities

We invest available cash in short-term commercial paper, certificates of deposit and high grade variable rate securities. Liquid investments with an original maturity of three months or less when purchased are considered to be cash equivalents.

Investments, including auction rate securities and certificates of deposit, with maturity dates greater than three months when purchased which have readily determined fair values are classified as available-for-sale investments and reflected in current assets as marketable securities at fair market value. Auction rate securities are recorded at par value, which equals fair market value, as the rate on such securities resets generally every 7, 28 or 35 days. Our marketable securities at December 31 consisted of the following investments with the following maturities:

	Fair Market Value	Less than 1 Year	1-5 Years	5-10 Years	More than 10 Years
December 31, 2005					
Variable auction rate taxable municipal securities	\$ 43,241,000	\$ -	\$ -	\$ -	\$ 43,241,000
Certificates of deposits	342,000	342,000	-	-	-
	<u>\$ 43,583,000</u>	<u>\$ 342,000</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 43,241,000</u>
December 31, 2004					
Variable auction rate taxable municipal securities	\$ 22,474,000	\$ -	\$ -	\$ -	\$ 22,474,000
U.S. government agency securities	1,005,000	1,005,000	-	-	-
	<u>\$ 23,479,000</u>	<u>\$ 1,005,000</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 22,474,000</u>

The cost of the above securities approximated fair market value at December 31.

Restricted cash and marketable securities represent deposits secured as collateral for a bank credit card program.

Fair Value of Financial Instruments and Concentration of Credit Risk

The carrying amounts reported in the balance sheet for cash, cash equivalents, marketable securities, accounts receivable, accounts payable and accrued liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments. At December 31, 2005, all of our cash equivalents and marketable securities were invested in highly liquid, high grade auction rate securities and certificates of deposit. At December 31, 2005, all cash equivalents and marketable securities were recorded at fair market value and no single investment represented more than 9% of the investment portfolio.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Additions and improvements to property and equipment are capitalized at cost. Expenditures for maintenance and repairs are charged to expense as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, which range from two to seven years for furniture and equipment. Leasehold improvements are amortized over the lesser of the estimated useful lives of the assets or the related lease term, principally five to seven years.

Intellectual Property and Other Intangibles

Intellectual property consists primarily of certain technology, patents, patents pending, know-how and related intangible assets with respect to protocols for treatment of dependence to alcohol, cocaine, methamphetamine, and other addictive stimulants. These assets are stated at cost and are being amortized on a straight-line basis from the date costs are incurred over the remaining life of the respective patents, which range from twelve to sixteen years.



Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," long-lived assets such as property, equipment and intangibles subject to amortization are reviewed for impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. In reviewing for impairment, we compare the carrying value of such assets to the estimated undiscounted future cash flows expected from the use of the assets and their eventual disposition. When the estimated undiscounted future cash flows are less than their carrying amount, an impairment loss is recognized equal to the difference between the assets' fair value and their carrying value. In December 2005, we recorded an impairment charge of \$272,000 in other operating expense to write off the capitalized costs of intellectual property relating to an acquired patent for a treatment method for opiate addiction that we have determined would not likely be utilized in our current business plan.

Revenue Recognition

Our revenues are derived from licensing our treatment protocols and providing administrative services to hospitals, treatment facilities and other healthcare providers. We determine revenues earned based on the terms of these contracts, which determination requires the use of judgment, including the assessment of the collectibility of receivables. Licensing agreements typically provide for a fixed fee on a per-patient basis, payable to us following commencement of the patient's initial treatment using our protocol. For revenue recognition purposes, we treat the protocol licensing and related administrative services as one unit of accounting. We record the fees owed to us under the terms of the agreements at the time we have performed substantially all required services for each patient's treatment, which for the significant majority of our license agreements to date is in the period in which the patient's medically supervised treatment has commenced, and, in other cases, is at the time the medical treatment has been completed.

In 2005, three of our licensees accounted for over 10% of our revenues each, representing 25%, 20% and 18% of our revenues. In 2004 and 2003, one licensee accounted for 93% and 100%, respectively.

The revenues of the PROMETA Center, which we include in our consolidated financial statements, are derived from charging fees directly to patients for treatments using the PROMETA protocols. Revenues from patients treated at the PROMETA Center, which were approximately \$59,000 in 2005, are recorded based on the number of days of treatment completed during the period as a percentage of the total number treatment days for the protocols. Revenues relating to the aftercare portion of the treatment are deferred and recorded over the period that the aftercare services are provided.

Advertising Costs

Costs incurred for advertising, including production costs, are generally expensed when incurred or on a straight-line basis over the periods that advertisements are run. Our advertising costs were approximately \$1.1 million in 2005. We had no direct advertising costs in 2004 or 2003.

Foreign Currency

Assets and liabilities of foreign subsidiaries are translated into U.S. dollars at year-end exchange rates. Income and expense items are translated at average exchange rates prevailing during the year. The local currency is the functional currency. Foreign currency transaction gains of approximately \$21,000 for the year ended December 31, 2005, are primarily related to intercompany receivables and payables for which settlement is planned in the foreseeable future, and are included in the Consolidated Statements of Operations. There were no foreign currency translation adjustments recorded in the Consolidated Statements of Comprehensive Income because the amounts were immaterial.



Income Taxes

We account for income taxes pursuant to SFAS 109, "Accounting for Income Taxes," which uses the liability method to calculate deferred income taxes. To date, we have not recorded any income tax liability due to our accumulated losses. Also, no income tax benefit has been recorded due to the uncertainty of our ability to realize the net operating loss carryforwards.

Basic and Diluted Loss per Share

In accordance with SFAS 128, "Computation of Earnings Per Share," basic loss per share is computed by dividing the net loss to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted loss per share is computed by dividing the net loss for the period by the weighted average number of common and dilutive common equivalent shares outstanding during the period.

Common equivalent shares, consisting of approximately 6,901,000, 6,379,000 and 5,174,000 of incremental common shares as of December 31, 2005, 2004 and 2003, respectively, issuable upon the exercise of stock options and warrants have been excluded from the diluted earnings per share calculation because their effect is anti-dilutive.

A summary of the net loss and shares used to compute net loss per share is as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss	\$ (24,038,000)	\$ (11,775,000)	\$ (3,504,000)
Less: Beneficial conversion feature of preferred stock	-	-	\$ (124,000)
Net loss to common stockholders	<u>\$ (24,038,000)</u>	<u>\$ (11,775,000)</u>	<u>\$ (3,628,000)</u>
Basic and diluted loss per share	<u>\$ (0.77)</u>	<u>\$ (0.47)</u>	<u>\$ (0.21)</u>
Weighted average common shares used to compute basic and diluted loss per share	<u>31,173,000</u>	<u>24,877,000</u>	<u>16,888,000</u>

All share and per share data have been restated to reflect a stock split of 100 to 1 declared on July 1, 2003.

Accounting for Share-Based Compensation

We account for the issuance of employee stock options using the intrinsic value method under Accounting Principles Board Opinion (APB) No. 25, "Accounting for Stock Issued to Employees". In 1995, the Financial Accounting Standards Board (FASB) issued SFAS 123, "Accounting for Stock-Based Compensation", which defines fair-value-based method of accounting for stock compensation plans. However, it also allows a company to continue to measure compensation costs for options issued to employees and directors using APB 25. Had we determined compensation cost based on the fair value at the grant date for such stock options under SFAS 123, the pro forma effect on net loss and net loss per share would have been as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss as reported	\$ (24,038,000)	\$ (11,775,000)	\$ (3,504,000)
Add: Stock-based compensation expense	20,000	-	-
Less: Stock-based expense determined under fair value based method	<u>(901,000)</u>	<u>(463,000)</u>	<u>(73,000)</u>
Pro forma net loss	<u>(24,919,000)</u>	<u>(12,238,000)</u>	<u>(3,577,000)</u>
Less: Beneficial conversion feature of preferred stock	-	-	(124,000)
Net loss to common stockholders	<u>\$ (24,919,000)</u>	<u>\$ (12,238,000)</u>	<u>\$ (3,701,000)</u>
Net loss per share:			
As reported – basic and diluted	\$ (0.77)	\$ (0.47)	\$ (0.21)
Pro forma – basic and diluted	\$ (0.80)	\$ (0.49)	\$ (0.22)



The estimated weighted average fair values of options granted during 2005, 2004 and 2003 were \$4.83, \$3.10 and \$0.83 per share, respectively, calculated using the Black-Scholes pricing model with the following assumptions:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Expected volatility	58%	61%	0%
Risk-free interest rate	4.18%	4.24%	4.09%
Weighted average expected lives	10 years	10 years	10 years
Expected dividend yield	0%	0%	0%

The volatility in 2003 was assumed to be zero, since all options were granted prior to the date our stock was first publicly traded.

See “Recent Accounting Pronouncements” below for a discussion of SFAS 123R, which requires changes to our accounting for share-based compensation effective January 1, 2006.

We account for the issuance of warrants for services from non-employees in accordance with SFAS 123, “Accounting for Stock-Based Compensation”, by estimating the fair value of warrants issued using the Black-Scholes pricing model. This model’s calculations include the warrant exercise price, the market price of shares on grant date, the weighted average information for risk-free interest, expected life of warrant, expected volatility of our stock and expected dividends.

For warrants issued as compensation to non-employees for services that are fully vested and non-forfeitable at the time of issuance, the estimated value is recorded in equity and expensed when the services are performed and benefit is received as provided by Financial Accounting Standards Board Emerging Issues Task Force (EITF) No. 96-18 “Accounting For Equity Instruments That Are Issued To Other Than Employees For Acquiring Or In Conjunction With Selling Goods Or Services.”

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS 123R, “Share-Based Payment,” which addresses the accounting for employee stock options. SFAS 123R revises the disclosure provisions of SFAS 123 and supersedes APB 25. SFAS 123R requires that the cost of all employee stock options be reflected in the financial statements based on the estimated fair value of the awards at date of grant. Share-based compensation for non-employees is accounted for in accordance with EITF No. 96-18. In April 2005, the Securities and Exchange Commission (SEC) amended Rule 4-01(a) of Regulation S-X to defer the required date for compliance with SFAS 123(R) to the first interim or annual reporting period of the registrant’s first fiscal year beginning on or after June 15, 2005. We have adopted SFAS 123R on January 1, 2006, which complies with the amended Rule 4-01(a). Under SFAS 123R, we will transition to the fair-value-based method using a modified prospective application. Under that transition method, compensation cost will be recognized commencing in 2006 for the portion of outstanding awards for which the requisite service has not yet been rendered. We do not expect the provisions of SFAS 123R to result in a significant change in the compensation expense we currently disclose on a pro forma basis under SFAS 123. Through December 31, 2005, we accounted for share-based payments to employees using the intrinsic value method under APB 25 and, as such, generally recognized no compensation cost for employee stock options. Accordingly, the adoption of fair value method under SFAS 123R will increase our operating expenses, but will not have a material impact on our overall financial position. The specific magnitude of the impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based incentive awards granted in the future. However, had we adopted SFAS 123R in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss and loss per share as noted above.



In May 2005, the FASB issued SFAS 154, "Accounting Changes and Error Corrections." SFAS 154 replaces APB 20, "Accounting Changes" and SFAS 3, "Reporting Accounting Changes in Interim Financial Statements" and establishes retrospective application as the required method for reporting a change in accounting principle. SFAS 154 provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The reporting of a correction of an error by restating previously issued financial statements is also addressed. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not expect the adoption of this statement to have a material impact on our financial statements.

Note 2. Management Services Agreement

In November 2005, we executed a management services agreement with David E. Smith, M.D. Medical Group, Inc., a California professional corporation, d.b.a. The PROMETA Center, Inc., which is beneficially owned and controlled by our senior vice president of medical affairs. The term of the agreement is one year, and will continue on a month-to-month basis thereafter, unless terminated for cause.

We licensed the medical group the right to use our proprietary treatment protocols and related trademarks and agreed to provide the medical group all required day-to-day management services, including general administrative support services, information systems, recordkeeping, scheduling, billing, collection, marketing and local business development, and assistance in obtaining and maintaining all federal, state and local licenses, certifications and regulatory permits required for, or in connection with, the medical group's operation and equipment located at any of its offices. The medical group retains the sole right and obligation to provide medical services to its patients.

We provide medical office space to the medical group located in Santa Monica, California, on a non-exclusive basis, and we are responsible for all costs associated with rent and utilities. The medical group will pay us a monthly fee equal to the aggregate amount of (a) our costs of providing management services (including reasonable overhead allocable to the delivery of our services and including start-up costs such as pre-operating salaries, rent, equipment, and tenant improvements incurred for the benefit of the medical group, provided that any capitalized costs, including all start-up expense, will be amortized over a five year period), (b) 10% of the foregoing costs, and (c) any performance bonus amount, as determined by the medical group in its sole discretion. The medical group's payment of our fee is subordinate to payment of the medical group's obligations, including physician fees and medical group employee compensation.

We also agreed to provide a credit facility to the PROMETA Center to be available as a working capital loan up to a maximum of \$500,000 to allow for the medical group to pay for its obligations, pursuant to a revolving credit note. Funds will be advanced pursuant to the terms of the management services agreement described above. We will earn interest at the rate of 2% over the prime rate. The note will become due on demand, or upon termination of the management services agreement.



Note 3. Receivables

Receivables consisted of the following as of December 31:

	<u>2005</u>	<u>2004</u>
License fees receivable	\$ 168,000	\$ 124,000
Tenant improvement allowance (1)	68,000	-
Other receivables	32,000	54,000
	<u>268,000</u>	<u>178,000</u>
Less-allowance for doubtful accounts	(19,000)	(10,000)
	<u>\$ 249,000</u>	<u>\$ 168,000</u>

(1) Amounts receivable from landlord upon completion of lease build-out of new office space

We use the specific identification method for recording the provision for doubtful accounts, which was \$25,000 and \$7,000 for the years ended December 31, 2005 and 2004, respectively, and \$14,000 for the period from February 13, 2003 (inception) to December 31, 2003. Accounts written off against the allowance for doubtful accounts was \$16,000 and \$11,000 for the years ended December 31, 2005 and 2004, respectively.

Note 4. Property and Equipment

Property and equipment consisted of the following as of December 31:

	<u>2005</u>	<u>2004</u>
Furniture and equipment	\$ 2,154,000	\$ 1,501,000
Leasehold improvements	2,516,000	1,439,000
	<u>4,670,000</u>	<u>2,940,000</u>
Less-accumulated depreciation	(1,172,000)	(516,000)
	<u>\$ 3,498,000</u>	<u>\$ 2,424,000</u>

Depreciation expense was \$665,000 and \$499,000 for the years ended December 31, 2005 and 2004, respectively, and \$ 28,000 for the period from February 13 (inception) to December 31, 2003.

Note 5. Intellectual Property

PROMETA Protocols

In March 2003, we entered into a Technology Purchase and License Agreement (Technology Agreement) with Tratamientos Avanzados de la Adicción S.L., a Spanish corporation (Seller), to acquire, on an exclusive basis, all of the rights, title and interest to use and or sell the products and services and license the intellectual property owned by Seller with respect to a method for the treatment of alcohol and cocaine dependence, known as the PROMETA protocols, on a worldwide basis except in Spain (as amended in September 2003). We have granted Seller a security interest in the intellectual property to secure the payments and performance obligations under the Technology Agreement. As consideration for the intellectual property acquired, we issued to Seller approximately 836,000 shares of our common stock in September 2003 at a fair market value of \$2.50 per share, plus warrants to purchase approximately 532,000 shares of our common stock at an exercise price of \$2.50 per share, valued at approximately \$192,000. Warrants for 160,000 shares are exercisable at any time through September 29, 2008, and the remaining warrants for 372,000 shares become exercisable equally over five years and expire ten years from date of grant.



In addition to the purchase price for the above intellectual property, we agreed to pay a royalty fee to Seller equal to three percent (3%) of gross revenues from the PROMETA protocols using the acquired intellectual property for so long as we (or any licensee) use the acquired intellectual property. For purposes of the royalty calculations, gross revenue is defined as all payments made by patients for the treatment, including payments made to our licensees. Royalty fees, which totaled \$71,000 and \$18,000 for the years ended December 31, 2005 and 2004, respectively, and \$3,000 for the period from February 13, 2003 (inception) to December 31, 2003, are reflected in operating expense as revenues are recognized.

In October 2004, the Technology Agreement was amended (Amendment) to expand the definition of “Processes”, limited to alcohol and cocaine in the original agreement dated March 2003, to also include crack cocaine and methamphetamine treatment processes, and the term “Intellectual Property” was expanded to include all improvements through September 14, 2004. As consideration for the Amendment, we agreed to pay \$75,000 and issue 83,221 shares of our common stock, valued at \$354,000.

Under the Technology Agreement, we are obligated to allocate each year a minimum of 50% of the funds we expend on sales, marketing, research and development to such activities relating to the use of the intellectual property acquired. If we do not expend at least the requisite percentage on such activities, the Seller has the right to have the intellectual property revert to the Seller. We may terminate Seller’s reversion rights by making an additional payment of an amount which, taken together with previously paid royalties and additional payments, would aggregate \$1,000,000. In 2003, 2004 and 2005 we met our obligations with respect to this requirement.

The total cost of the assets acquired, plus additional costs incurred by us related to filing patent applications on such assets have been reflected in long-term assets as intellectual property. Amortization is being recorded on a straight-line basis over the remaining 16.5 year life of the pending patents, commencing July 1, 2003.

Patent for Opiate Addiction Treatment

In August 2003, we acquired a patent for a treatment method for opiate addiction at a foreclosure sale held by Reserva Capital, LLC, a company owned and controlled by our chief executive officer and substantial shareholder, through a foreclosure sale in satisfaction of debt owed to Reserva by a medical technology development company. We paid approximately \$314,000 in cash and agreed to issue 360,000 shares of our common stock to the technology development company at a future date conditional upon the occurrence of certain events, including a full release of claims by all of the technology development company’s creditors. As of December 31, 2005, such contingencies had not been satisfied, and we have not recorded any value for the shares that may be issued as additional consideration.

In December 2005, we evaluated our potential use of this patent and determined that it would not likely be utilized in our current business plan. Accordingly, we recorded an impairment charge of \$272,000 to write off the remaining capitalized costs of intellectual property relating to this patent. If and when it becomes probable that we will release all or a portion of the 360,000 contingent shares, which are currently subject to a stock pledge agreement, the fair market value of the shares released will be recorded as an additional non-cash impairment charge. Based on our closing stock price of \$6.15 per share on December 31, 2005, the fair market value of the 360,000 contingent shares was approximately \$2.2 million.



Treatment for Nicotine Dependence

In June 2005, we and a wholly-owned foreign subsidiary entered into an asset purchase agreement with Dr. Jacob Hiller to obtain the worldwide rights to his trade secret protocols for the treatment of nicotine and drug dependence, in exchange for a percentage of future net profits from exploitation of the protocols. We have engaged Dr. Hiller as a consultant to explore opportunities in Europe to open treatment clinics for the treatment of nicotine dependence using these protocols.

Amortization

Amortization expense for intellectual property was \$214,000 and \$171,000 for the year ended December 31, 2005 and 2004, respectively, and \$47,000 for the period from February 13, 2003 (inception) to December 31, 2003, and is estimated to be \$200,000 for each of the next five years. The accumulated amortization as of December 31, 2005 and 2004 was \$374,000 and \$218,000, respectively.

Note 6. Income Taxes

As of December 31, 2005, we had net federal operating loss carry forwards and net state operating loss carry forwards of approximately \$33,317,000 and \$31,644,000, respectively. The net federal operating loss carry forwards expire in 2025 and net state operating loss carry forwards begin expiring in 2013. Foreign net operating loss carryforwards were approximately \$1,140,000, of which \$970,000 will expire in 7 years and \$170,000 will carry forward indefinitely.

The primary components of temporary differences which give rise to our net deferred tax are as follows:

Deferred tax asset	2005	2004
Federal and foreign net operating losses	\$ 13,281,000	\$ 5,996,000
Stock-based compensation	1,283,000	979,000
Accrued liabilities	425,000	-
Other temporary differences	248,000	(7,000)
Valuation allowance	(15,237,000)	(6,968,000)
	\$ -	\$ -

As of December 31, 2003, our valuation allowance on deferred tax assets was \$1,241,000.

We have provided a valuation allowance in full on our net deferred tax assets in accordance with SFAS 109, "Accounting for Income Taxes". Because of our continued losses, management has assessed the realizability of our net deferred tax assets as being less than the more-likely-than-not criteria set forth for SFAS 109. Furthermore, certain portions of our net operating loss carryforwards were acquired, and therefore subject to further limitation set forth under the Federal tax code which could further limit our ability to realize our deferred tax assets and provides that if there is a change in control for tax purposes the use of the net operating loss carryforwards is limited per year.

The difference between our effective tax rate and that computed under the federal statutory rate is as follows:

	2005	2004
Federal statutory rate	-34.0%	-34.0%
State taxes	-5.3%	-6.0%
Other	-1.5%	0.0%
Change in valuation allowance	40.8%	40.0%
	0.0%	0.0%



Note 7. Equity Financings

In September 2003, we completed a private placement offering (2003 Offering) for a total of \$21,927,500 in proceeds from private investors. We raised \$4,690,000 of these proceeds during the period July through September 2003 in a bridge financing through the issuance of 1,876,000 shares of convertible preferred stock at a price of \$2.50 per share, plus warrants for 385,000 shares of common stock at an exercise price of \$2.50 per share. The remaining proceeds from the 2003 Offering were raised through the issuance of 6,895,000 restricted shares of our common stock at a price of \$2.50 per share. The preferred stock was converted into restricted shares of common stock on a one-to-one basis upon the completion of the 2003 Offering. The warrants have a fair market value using the Black-Scholes pricing model of \$124,000, which has been reflected as a beneficial conversion feature in the financial statements. The warrants expire from three to five years after issuance.

In connection with the 2003 Offering, we paid commissions to registered broker-dealers aggregating approximately \$321,000 in cash, issued 100,000 shares of common stock valued at \$2.50 per share and issued approximately 209,000 warrants for the purchase of common stock at exercise prices of \$2.50 to \$3.00 per share. We also paid approximately \$70,000 in cash, issued 40,000 shares of common stock valued at \$2.50 per share and issued approximately 28,000 warrants for the purchase of common stock at a price of \$2.50 per share to financial consultants for services rendered in connection with the 2003 Offering. The warrants expire from three to four years from date of issue and have a combined fair market value of approximately \$26,000 using the Black-Scholes pricing model.

In December, 2004, we issued 5,017,331 shares of common stock at a price of \$4.50 per share in a private placement offering (2004 Offering) for a total of \$22,578,000 in proceeds from private investors, including two Company board members who invested a total of \$1,200,000. We paid \$1,229,000 in commissions to placement agents in connection with the transaction.

In November 2005, we completed an underwritten equity offering of 9,200,000 shares at a price of \$4.75 per share for a total of \$43,700,000 in proceeds. We paid \$3,059,000 in commissions to the underwriters in connection with the transaction.

Note 8. Stock, Stock Options and Warrants

Common Stock

In July 2003, we effected a stock split of 100 to 1, thereby increasing our shares then outstanding from 137,400 to 13,740,000. In September 2003, in connection with the reverse acquisition, we reincorporated in Delaware and issued newly authorized common stock to all stockholders. The accompanying financial statements and loss per share have been adjusted retroactively to reflect the stock split.

We issued 23,400 and 16,644 shares of our common stock in 2005 and 2004, respectively, for services relating to investor relations. The stock-based expense relating to such shares amounted to \$134,000 and \$86,000 for the years ended December 31, 2005 and 2004, respectively.

Preferred Stock

In July 2003, 15,000,000 shares of preferred stock, \$.001 par value, were authorized. During the third quarter, 2003, we issued 1,876,000 preferred shares in connection with the 2003 Offering. Upon completion of the 2003 Offering, all of the outstanding preferred shares were exchanged for common shares on a one-to-one basis. In September 2003, we reincorporated in Delaware and increased the authorized number of preferred shares to 50,000,000 at a \$.0001 par value.



Stock Options

In September 2003, our directors and shareholders approved the 2003 Stock Incentive Plan (Plan) to reserve 5.0 million shares of common stock for issuance to employees, officers, directors and consultants of the Company. The board of directors determines the terms of stock option agreements, including vesting requirements. The exercise price of incentive stock options must be no less than the fair market value on the date of grant. The options expire not later than ten years from the date of grant.

In June 2004, our directors and shareholders approved an amendment to the Plan to increase the total number of shares issuable under the Plan from 5.0 million to 6.0 million shares.

In June 2005, our directors and shareholders approved an amendment to the Plan to increase the total number of shares issuable under the Plan from 6.0 million to 7.0 million shares.

In 2003, we granted options for 4.0 million shares to employees, officers, directors and consultants, at exercise prices ranging from \$2.50 to \$2.75 per share and with vesting over periods from three to five years from the date of grant. In 2004, we granted options under the Plan at exercise prices ranging from \$2.80 to \$7.50 per share and with vesting over periods from three to five years. In 2005, we granted options under the Plan at exercise prices ranging from \$5.72 to \$7.34 per share and with vesting over periods from zero to five years.

Stock option activity under the Plan is summarized as follows:

	Shares	Weighted Avg Exercise Price
2003		
Granted	4,000,000	\$ 2.56
Exercised	-	-
Cancelled	(60,000)	2.50
Balance, December 31, 2003	<u>3,940,000</u>	<u>2.56</u>
2004		
Granted	1,479,000	4.31
Exercised	-	-
Cancelled	(542,000)	3.69
Balance, December 31, 2004	<u>4,877,000</u>	<u>2.98</u>
2005		
Granted	1,382,000	6.45
Exercised	(54,000)	3.29
Cancelled	(677,000)	4.35
Balance, December 31, 2005	<u>5,528,000</u>	<u>\$ 3.71</u>



The weighted average remaining contractual life and weighted average exercise price of options outstanding as of December 31, 2005 were as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares	Weighted Average Remaining Life (yrs)	Weighted Average Price	Shares	Weighted Average Price
As of December 31, 2005					
\$2.50 to \$3.50	3,847,000	6.2	\$ 2.60	1,621,000	\$ 2.58
\$3.51 to \$5.50	224,000	7.8	\$ 4.51	35,000	\$ 4.25
\$5.51 to \$6.50	762,000	8.4	\$ 5.73	97,000	\$ 5.62
\$6.51 to \$7.50	695,000	9.1	\$ 7.36	20,000	\$ 7.50
	<u>5,528,000</u>			<u>1,773,000</u>	

As of December 31, 2004 and the period from February 13, 2003 (inception) to December 31, 2003, options exercisable were 864,000 and 25,000, respectively.

Included in the table above, at December 31, 2005 and 2004, were options outstanding for 495,000 and 520,000 shares, respectively, granted to consultants and directors providing outside services. These options vest over periods ranging from three to five years and are expensed when the services are performed and benefit is received as provided by EITF 96-18. During the years ended December 31, 2005, 2004, and the period from February 13, 2003 (inception) to December 31, 2003, stock-based expense relating to such stock options amounted \$1,230,000, \$600,000 and \$337,000, respectively. Non-vested options had an estimated fair value of approximately \$992,000 and \$1,666,000, respectively, as of December 31, 2005 and 2004, using the Black-Scholes pricing model. During the years ended December 31, 2005, 2004 and the period from February 13, 2003 (inception) to December 31, 2003, such options granted to consultants were 65,000, 75,000 and 445,000, respectively, at weighted average exercise prices of \$5.49, \$5.56 and \$2.50 per share, respectively, the fair market values at the dates of grant.

Warrants

In addition to the warrants issued in 2003 in connection with the Technology Agreement and the 2003 Offering, in September 2003, we issued an immediately-exercisable, five-year warrant to purchase 80,000 shares of common stock at \$2.50 per share, to a management advisor for investment relation services to be performed over a one-year period. The warrant had an estimated value of approximately \$29,000 using the Black-Scholes pricing model and was capitalized as a prepaid asset and amortized over the one-year service period.

In January 2004, we issued a warrant to purchase 150,000 shares of common stock at \$7.00 per share to a management advisor for investor relations services, with vesting over one year and an expiration date three years from date of issue. In July 2004, we issued a warrant to purchase 20,000 shares of common stock at \$2.80 per share to a consultant for legal services, with vesting over a 36-month period and an expiration date five years from date of issue. In October 2004, we issued a warrant to purchase 100,000 shares of common stock at \$2.50 per share to a management advisor for investor relations services with immediate vesting and an expiration date three years from date of issue. In December 2004, we issued a warrant to purchase 25,000 shares of common stock at \$3.75 per share to a management advisor for investor relations services with immediate vesting and an expiration date three years from date of issue.

In January 2005, we issued a warrant to purchase 25,000 shares of common stock at \$5.72 per share to a management advisor for investor relations services. The warrant vested immediately and expires three years from



date of grant. We also issued warrants to purchase 20,000 shares of common stock to a management consultant, of which a warrant for 10,000 shares was issued at \$2.80 per share, with immediate vesting and expires in 2014, and a warrant for the remaining 10,000 shares was issued at \$5.80 per share, with immediate vesting and expires in 2006.

Warrant activity is summarized as follows:

	Shares	Weighted Average Exercise Price
2003		
Granted	1,234,000	\$ 2.54
Exercised	-	-
Cancelled	-	-
Balance, December 31, 2003	1,234,000	2.54
2004		
Granted	295,000	5.04
Exercised	(27,000)	2.50
Cancelled	-	-
Balance, December 31, 2004	1,502,000	3.03
2005		
Granted	45,000	5.09
Exercised	(174,000)	2.50
Cancelled	-	-
Balance, December 31, 2005	1,373,000	\$ 3.14

Warrants outstanding at December 31, 2005 are summarized as follows:

Description	Shares	Weighted Average Remaining Contractual Life (yrs)	Weighted Average Exercise Price
Warrants issued for intellectual property	532,000	6.2	\$ 2.50
Warrants issued to preferred stockholders	352,000	2.1	2.50
Warrants issued in connection with equity offering	166,000	1.3	2.76
Warrants issued to consultants	323,000	2.8	5.06
	1,373,000	3.8	\$ 3.14

At December 31, 2005, unvested warrants had an estimated value of approximately \$44,000 using the Black-Scholes pricing model.

Stock-based expense relating to warrants amounted to \$337,000, \$486,000 and \$8,000 for the years ended December 31, 2005, 2004 and the period from February 13, 2003 (inception) to December 31, 2003, respectively.

Note 9. Commitments and Contingencies

Lease Commitments

We incurred rent expense of approximately \$600,992 and \$378,000 for the years ended December 31, 2005, and 2004, respectively, and \$82,000 for the period from February 13, 2003 (inception) to December 31, 2003. In September 2003, we signed a lease agreement for our corporate offices at an initial lease cost of approximately \$33,000 per month, with increases scheduled annually over the lease term. The term of the lease is seven years beginning on the lease commencement date, December 15, 2003, with a right to extend the lease for an additional five years. In April, 2005 we amended the lease to expand our corporate office facilities at an additional base rent of approximately \$11,000 per month, subject to annual adjustment over the remaining initial six-year term. As a condition to signing the original lease, we secured a \$350,000 letter of credit for the landlord as a form of security deposit. The letter of credit is collateralized by a certificate of deposit in the amount of \$350,000.

In April 2005 we entered into a five year lease for approximately 4,600 square feet of medical office space at an initial base rent of approximately \$19,000 per month commencing in August 2005. The space is occupied by The PROMETA Center, an affiliated medical practice, under a full service management agreement. As a condition to signing the lease, we secured a \$90,000 letter of credit for the landlord as a form of security deposit. The letter of credit is collateralized by a certificate of deposit in the amount of \$90,000.

Rent expense is calculated using the straight-line method based on the total minimum lease payments over the initial term of the lease. Unamortized landlord tenant improvement allowances and rent expense exceeding actual rent payments are accounted for as deferred rent liability in the balance sheet.

Future minimum lease payments on the non-cancelable lease are as follows:

<u>Year Ending December 31,</u>	<u>Base Rental Payments</u>
2006	\$ 783,000
2007	806,000
2008	830,000
2009	854,000
2010	751,000
Thereafter	-
Total	<u>\$ 4,024,000</u>

Legal Proceedings

We are subject to claims and lawsuits in our normal course of business. As of December 31, 2005, we were not involved in any legal proceeding that would have a material adverse effect on the business, financial condition or operating results.

Note 10. Related Party Transactions

Andrea Grubb Barthwell, M.D., a director, is the founder and chief executive officer of a healthcare and policy consulting firm providing consulting services to us. In 2005, we paid or accrued approximately \$83,000 in fees to the consulting firm. There were no other material related party transactions in 2005, 2004 or 2003.



Note 11. Interim Financial Information (Unaudited)

Summarized quarterly supplemental financial information is as follows:

	Quarter Ended				Total Year
	March	June	September	December	
	(In thousands, except per share amounts)				
Year Ended December, 31, 2005					
Net revenues	\$ 203	\$ 230	\$ 361	\$ 370	\$ 1,164
Operating loss	(4,480)	(4,866)	(6,756)	(8,770)	(24,872)
Net loss	(4,319)	(4,692)	(6,604)	(8,423)	(24,038)
Basic and diluted loss per share	(0.15)	(0.16)	(0.22)	(0.24)	(0.77)
Year Ended December, 31, 2004					
Net revenues	\$ 67	\$ 5	\$ 41	\$ 79	\$ 192
Operating loss	(3,050)	(2,542)	(3,020)	(3,333)	(11,945)
Net loss	(3,012)	(2,505)	(2,980)	(3,278)	(11,775)
Basic and diluted loss per share	(0.12)	(0.10)	(0.12)	(0.13)	(0.47)