# Curaxis Pharmaceutical Corp Initiation | USA | Healthcare May-2011



Rating: Speculative Buy Target Price: \$2.00 Current Price: \$0.51 Upside: 300%

#### Price Chart



Stock Information Symbol: CURX Country: USA Sector: Healthcare Market-Cap: \$25.4 million 52 Weeks H/L: \$1.90 - \$0.26

#### CURAXIS PHARMACEUTICAL CORP

Curaxis Pharmaceutical Corporation, a develop-stage specialty pharmaceutical company, focuses on developing a hormone drug product candidate (Memryte, VP4896) for the treatment of Alzheimer's disease and various cancers. Its therapeutic platform is based on the hypothesis that various diseases of aging might be caused by age-related changes in the function of the hypothalamic-pituitary-gonadal (HPG) axis. The HPG axis is a hormonal endocrine feedback loop that controls development, reproduction, and aging in animals. The company was founded in 2001 and is based in Durham, North Carolina

Analysts: Cathy Reese Michelle Boone

#### INTRODUCTION

In this report, the CURX ticker symbol is used to refer to Curaxis Pharmaceutical (previously known as Voyager Pharmaceutical Corp) both before and after this company merged with Auto Search Cars, Inc. and Auto Search Cars Acquisition Corp. in 2010.

Our valuation suggests a 12 month price target for Curaxis Pharmaceutical Corporation (OTC: CURX.PK) stock of \$2.00 and we rate the company as a BUY.

## CAPITAL RAISING ACTIVITIES

CURX is in the process of raising approximately \$20 million to fund a Phase IIb trial for its lead drug product, Memryte. CURX's management has stated that due to its recent meetings with investors, it expects to be capable of raising sufficient funding for this next clinical phase for Memryte by mid-2011.

#### RECENT MERGER

CURX was initially incorporated on February 27, 2001 as Voyager Pharmaceutical Corporation. On February 8, 2010, CURX entered into a merger agreement with Auto Search Cars, Inc., Auto Search Cars Acquisition Corp and became Auto Search. On July 29, 2010, CURX' common stock was retired, and on July 30, 2010, the new merged corporation went through a process to change the corporate name to Curaxis Pharmaceutical Corporation.

#### MEMRYTE (VP4896)

Leuprolide acetate is an analogue of a naturally occurring gonadotropin-releasing hormone. CURX has conducted pre-clinical and clinical trials using leuprolide acetate to treat Alzheimer's disease in mild-to-moderate patients. Results have been promising for leuprolide acetate to be a potential therapy for women with Alzheimer's disease.

Memryte is a proprietary biodegradable implant composed of leuprolide acetate and a biodegradable polymer. The implant measures about 1.5 millimeters in diameter and 3.0 centimeters in length and delivers a slow release of leuprolide acetate. The implant can be inserted in about 10 minutes in a physician's office using a local anesthetic. In a Phase I (ALADDIN 105) clinical trial, Memryte demonstrated the ability to provide a long-term steady level of leuprolide acetate.

On May 5, 2011, CURX announced that Memryte was chosen by the editors of *R&D Directions* magazine as one of today's top "100 Great Investigational Drugs in Development. We believe this acknowledgment indicates a renewed interest by the science and medical communities in Memryte's clinical program and potential

## UPCOMING EVENT

CURX's next step in its clinical development of the Memryte implant is the initiation of a planned Phase IIb clinical trial. CURX believes this study's protocol will be a 12-month, double-blind, placebo-controlled study with 1 active treatment arm and 1 placebo arm, with a 60/40 split between the active arm and the placebo arm. The trial will enroll approximately 200-250 women. There is some conjecture that this Phase IIb trial could be considered by the U.S. Food and Drug Administration (FDA) as a pivotal trial for marketing approval. There is also corporate consideration by CURX to include an interim data "look" for this trial's results, but CURX management is very cognizant that this action may prove to be a double-edged sword if inadequate time has passed to demonstrate efficacy. We estimate a late-2014 FDA marketing approval for Memryte.

Curaxis Pharmaceuticals Corp: Key Financial Data

\$ thousands	2010	2011e	2012e	2013e	2014e	2015e
Revenue					20,000	80,000
Operating income	(1,937)	(4,789)	(9,789)	(3,789)	3,409	24,000
Net Income (loss)	(2,244)	(4,789)	(9,789)	(3,789)	3,409	24,000
EPS, \$	(0.03)	(0.05)	(0.09)	(0.03)	0.03	0.19
WA shares outstanding	67,323	90,000	115,000	125,000	125,000	125,000

Source: OPUS



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#### **EXECUTIVE SUMMARY**

A product approval with revenue generation will be very meaningful for CURX's future. We do not expect this to occur prior to 2014. The primary value of CURX, in our opinion, resides in the potential of its lead product candidate, Memryte, and the ability of this product's intrinsic delivery system to set it apart from other leuprolide acetate products. Specialty pharmaceutical companies, such as Neurocrine Biosciences Inc. (Nasdaq.NBIX. Not Rated), NuPathe Inc (Nasdaq.PATH.Not Rated) and NeuroLogix Inc (OTC BB.NRGX.OB-Not Rated) have next year Price/Earnings of about 15X (avg. for comparison categories: Yahoo Finance). Due to CURX's Phase I and Phase II clinical data that indicates the potential for success in its planned Phase IIb's patient cohort (women with mild to moderate Alzheimer's disease) and Memryte's mid-stage development status, we believe a 15X earnings multiple is appropriate. By using our 2015 earnings estimate (first full year of Memryte sales data), we believe that we provide CURX with adequate time to demonstrate its capability to meet both development and corporate goals. We also apply a 35% discount due to the risks related to Memryte's mechanism of action, the known difficulties in developing Alzheimer's disease therapies and CURX's past history of financial insecurity.

We initiate Curaxis Pharmaceutical (OTC: CURX.PK) with a BUY recommendation and a price target of \$2.00 per share. We arrive at our \$2.00 12-month price target by applying a 15X multiple to our 2015 earnings estimate of \$0.19 discounted back at 35%.

CURX is a development-stage specialty pharmaceutical company developing its lead pipeline candidate, Memryte, for the treatment of Alzheimer's disease and oncology. CURX's current therapeutic programs are based on the hypothesis that a number of age related diseases are caused by changes in the hypothalamic-pituitary-gonadal axis. This axis is a hormonal endocrine feedback loop that controls development, reproduction and aging. CURX has detected a similar hormonal signaling feedback loop in Alzheimer's patients' brain cells and also in some tumors.

CURX Management includes two founders of Curaxis Pharmaceutical, Patrick S. Smith and David J. Corcoran. The commitment of the entire current upper management team seems apparent from the length of time that most of these individuals have remained with the company despite its lack of financial security. CURX's upper management has also stated that the company needs to strengthen its Board of Directors, which it has plans to accomplish in the foreseeable future.

CURX's lead pipeline product, Memryte (VP4896), is a small implant composed of leuprolide acetate encased in a biodegradable material. The Memryte implant slowly releases the leuprolide acetate into the body over an extended period. The leuprolide acetate is intended to significantly decrease luteinizing hormone in blood and brain tissue. In CURX's Phase I Memryte trial, it demonstrated that this slow delivery of leuprolide acetate significantly suppressed or eliminated luteinizing hormone levels in healthy male and female subject's serum.

On May 5, 2011, CURX announced that Memryte was chosen by the editors of *R&D Directions* magazine as one of today's top "100 Great Investigational Drugs in Development. "This is *R&D Direction's* tenth annual list of promising clinical compounds. Memryte was chosen due to it's promising ability to treat Alzhiemer's disease through multiple pathways (beta amyloid, tau phosphorylation, inflammation and abnormal cell division). We believe this recent acknowledgment indicative renewed interest by the science and medical communities in Memryte's clinical program and potential success.

CURX owns an issued United States patent (US 6,242,421) with claims directed at treating Alzheimer's disease by administering any agent, including leuprolide acetate, which decreases or eliminates blood serum levels of luteinizing hormone. This patent and Hatch Waxman extensions are expected to protect Memryte from competition through about 2023.

**Business Model** 

Leadership

Memryte (VP4896)

Intellectual Property Position



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Phase IIb

Additional Pipeline

Losses expected for the Foreseeable future

Substantial additional Funding will be required

Dependent on the success of Lead drug candidate, Memryte (VP4896)

Clinical trials for Memryte For mild to moderate Alzheimer's disease may not Be successful

LH Hypothesis is not Viewed as the predominant Hypothesis for Alzheimer's

Use third parties contractors To manufacture its product candidates CURX's plans to initiate a planned Phase IIb study in approximately 200-250 women with mild to moderate Alzheimer's disease. The purpose of this new trial is to support the findings of the ALADDIN I and ALADDIN 301 Phase II clinical results and help in the protocol design of Memryte's Phase III program. CURX management believes it will need to raise about \$20 million to cover the expenses of this study and any associated administrative expenses. CURX has not been able to advance its clinical development of Memryte beyond Phase II since 2006 due to a lack of financial resources.

CURX has completed pre-clinical research for leuprolide acetate use in the treatment of certain cancers, such as hormone refractory prostate cancer, brain cancers, kidney cancer, pancreatic cancer and non-small-cell lung cancer. CURX does not intend to begin any additional oncology studies until the Phase IIb trial of Memryte therapy for mild to moderate Alzheimer's disease in women is completed.

#### INVESTMENT RISKS

CURX is in a situation that requires it to successfully develop a product with considerable commercialization promise. CURX is in mid-stage development of its lead product, Memryte. There also may be unknown issues that could hinder CURX's ability to obtain regulatory approvals, manufacturing capability and marketing competence.

CURX has conducted Memryte clinical trials in Alzheimer's disease patients through Phase II. The most recent trial was initially designed as a Phase III clinical trial, but it was terminated in 2006 due to lack of financial resources. CURX believes that it will be capable of raising the necessary funds to resume Memryte's clinical development, but there can be no guarantee that this will occur. CURX's research and development expenses are expected to noticeably increase once Memryte's clinical trials in mild to moderate Alzheimer's disease are restarted.

If CURX is unable to commercialize Memryte for Alzheimer's disease or if there is a significant delay in Memryte's clinical development, CURX would be materially harmed. CURX has spent the majority of its resources on developing Memryte for mild to moderate Alzheimer's disease.

CURX's Phase II clinical trial (ALADDIN I) for women with mild to moderate Alzheimer's disease utilized an injectable formulation of leuprolide acetate. In this trial, CURX discovered a positive trend that favored the cohort using the highest leuprolide acetate dose versus placebo, but statistical significance was not achieved for the primary efficacy endpoints or for any of the secondary efficacy endpoints.

The luteinizing hormone hypothesis (LH Hypothesis) proposes that Alzheimer's disease neurological and biochemical changes are due to increased amounts of the pituitary hormone, luteinizing hormone. This hypothesis supports that levels in the body of luteinizing hormone increase as a person gets older and Alzheimer's disease neurological changes result. Another hypothesis, the beta amyloid hypothesis, states that the amyloid beta protein that makes up Alzheimer's disease brain plaques is toxic and causes Alzheimer's disease. The beta amyloid hypothesis is the predominant medical perspective.

CURX's has used and is expected to continue to use third parties to manufacture its products. This situation may create a negative circumstance of not having sufficient amounts of its products or that a product would not be available at a suitable cost. These risks may delay or prevent clinical development and commercialization programs.



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Rely on Durect Corporation, As sole source of Memryte CURX depends on Durect Corporation (Nasdaq.DRRX-Not Rated) as its only supplier of Memryte. Memryte requires precise, high quality manufacturing, so a failure by DRRX to have and maintain proper standards may cause patient injury or death, product recalls or withdrawals, delays or failures in Memryte testing or delivery, cost overruns or other issues that could materially affect CURX.

Reliance on third parties to conduct their clinical trials

CURX does not directly conduct its clinical trials for the development of its pipeline. It depends on third parties, such as contract research organizations (CRO), clinical data management organizations, medical institutions, and clinical investigators, to perform these studies. CURX's dependence on third parties for the majority of its clinical development activities reduces its control over this part of its business.

May be unable to obtain and enforce patent protection CURX's issued patent and its potential patents may not be broad enough to protect it against third parties with similar technologies or products. Additionally, its patent(s) may also not provide it with a competitive advantage. CURX believes its claimed methods for Alzheimer's disease therapy are "patentably" distinct and should be found valid and enforceable.

#### CURAXIS PHARMACEUTICAL CORPORATION: COMPANY OVERVIEW

CURX is a development-stage pharmaceutical company. Its lead pipeline product, Memryte, is being clinically advanced as a new potential therapy for Alzheimer's disease and various cancers. CURX's therapeutic platform supporting Memryte's development is founded on the hypothesis that many diseases of aging may be caused by age-related changes in the function of the hypothalamic-pituitary-gonadal axis. The hypothalamic-pituitary-gonadal axis is a hormonal endocrine feedback loop that controls development, reproduction and aging. CURX's asserts that the hormones associated with this feedback loop are useful in youth when they support growth and development but may be damaging in older persons because the feedback system becomes impaired enough to bring about diseases, such as Alzheimer's disease and certain cancers. CURX believes its discovery of similar hormonal signaling mechanisms in Alzheimer's patients' brain tissue (at the cellular level) and in various tumors provides a potential opportunity to develop a therapy with a new mechanism of action for these conditions.

#### **Corporate History**

February 27, 2001:

 CURX (Voyager Pharmaceutical Corp) was incorporated under the laws of the state of Delaware.

February 8, 2010:

 CURX entered into a merger agreement with Auto Search Cars, Inc., Auto Search Cars Acquisition Corp.

July 29, 2010:

- CURX common stock was retired.
- Each holder of CURX Common Stock received one share of Auto Search common stock for
  each share of CURX Common Stock Each share of the Auto Search Common Stock issued
  was restricted from trading or resale for a period of one year Restriction did not apply to Auto
  Search Common Stock issued in exchange for shares of CURX Common Stock issued in
  CURX's' Bridge Financing Auto Search stockholders continued to own their existing shares.

July 30, 2010:

Changed its name to Curaxis Pharmaceutical Corporation.





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#### **TECHNOLOGY**

#### Alzheimer's Disease Background

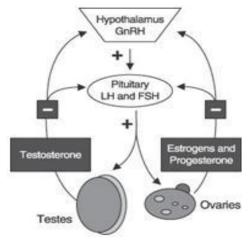
Alzheimer's Disease was first described in 1906 by Dr. Alois Alzheimer, a German physician. This brain disease is progressive, degenerative and ultimately terminal. It destroys memory and the ability to learn, reason, make judgments, communicate and carry out daily activities. People with Alzheimer's disease also experience personality and behavior changes (e.g., anxiety, suspiciousness and agitation, delusions, hallucinations). Alzheimer's disease is believed to be caused by a loss of connections between neurons as well as by beta amyloid protein plaques and neurofibrillary tau protein in a person's brain. Approved therapies only treat symptoms by temporarily increasing cognitive abilities and general behavior. No available therapies slow or halt this disease's progression. Alzheimer's disease causes a person to become debilitated and eventually will result in death. The disease is age-related with about 13% of people 65 years of age and 50% of people 85 years and older suffering from it. An estimate for 2009 indicated there were 35 million people worldwide suffering from Alzheimer's disease (5.3 million in the U.S.). The amount of people with Alzheimer's disease is expected to nearly double every 20 years to 65.7 million in 2030 and 115.4 million in 2050. The Alzheimer's Association believes that about 450,000 new U.S. cases are diagnosed annually. Women suffer from Alzheimer's disease at a higher rate than men.

#### **CURX's Alzheimer's Disease Program**

Leuprolide acetate is an analogue of a naturally occurring gonadotropin-releasing hormone. It has been prescribed for more than 20 years for the treatment of certain hormone-related diagnoses. (e.g., prostate cancer; endometriosis; precocious puberty). Leuprolide acetate has an established safety profile. Leuprolide acetate, a gonadotropin releasing hormone agonist, acts as a potent inhibitor of gonadotropin secretion.

Women represent nearly two-thirds of Alzheimer's patients. Leuprolide acetate suppresses men's production of testosterone so supplemental testosterone may required when men are treated with Leuprolide acetate. Men present more of a challenge for Alzheimer's disease leuprolide acetate therapy due to this need for testosterone supplementation. CURX plans to initially focus on developing leuprolide acetate (Memryte implant) as an Alzheimer's disease therapy for women.

Human biochemical processes are regulated by both positive and negative feedback. Positive feedback usually supports a reaction (e.g., hormone production) and negative feedback obstructs a reaction. Concentrations of hypothalamic (referring to this region of the brain), pituitary gland and gonadal hormones are regulated by positive and negative feedback. The feedback begins when the hypothalamus releases gonadotropin-releasing hormone that stimulates the pituitary gland to secrete luteinizing hormone and follicular stimulating hormone (two gonadotropins). These gonadotropins attach to receptors on a female's ovaries or on a male's testicles and stimulate the production of estrogen and testosterone.







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After the hypothalamus senses that either estrogen or testosterone are at an acceptable level, it reduces the release of gonadotropin-releasing hormone that eventually reduces the secretion of estrogen and testosterone. This feedback continually recurs.

#### **Assessment of Alzheimer's Patients**

- The Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-co):
  - A memory and cognition test designed to measure changes in Alzheimer's disease
    patients that may occur in response to a drug. An increasing score in this scale (over
    time, compared to the baseline score) indicates cognitive decline, while a decreasing
    score (over time, compared to the baseline score) indicates cognitive improvement
- The Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC)
  - A global measure of the change in condition from baseline in Alzheimer's disease based on information gained from interviews with both the patient and the caregiver
- Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory (ADCS-ADL)
  - A comprehensive rating scale measuring a person's ability to perform daily living activities (e.g., eating, dressing, bathing, shopping). Score is based on caregiver interviews. An increasing score (over time, compared to the baseline score) indicates improved capacity to perform activities, while a decreasing score indicates less capacity

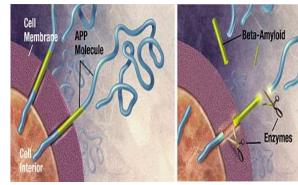
These assessments are recognized by the Food and Drug Administration (FDA) and foreign regulatory agencies.

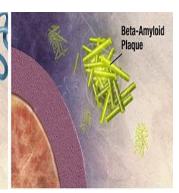
#### **Additional Hypotheses**

There are several hypotheses regarding the cause of Alzheimer's disease, the predominant one being the beta amyloid hypothesis.

## **Beta Amyloid Hypotheses**

The rationale for the beta amyloid hypothesis is that beta amyloid protein that is the main component in plaques found in the brains of Alzheimer's disease patients is toxic. It is commonly believed that by inhibiting production and eliminating amyloid beta protein, a reduction in the formation (and potential elimination) of the plaques would be accomplished. A variety of companies have attempted to develop therapies to suppress or eliminate amyloid beta protein, and this research has been ongoing for two decades without resulting in an approved treatment. CURX's Memryte program does not directly target amyloid beta elimination, but there is supporting pre-clinical evidence that leuprolide acetate reduces amyloid beta concentrations.







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Current knowledge does not prove nor disprove the amyloid hypothesis, but points to a need for its reassessment. A view that amyloid beta is a factor, versus the factor, that causes Alzheimer's disease is more uniform with present data, and is more likely to endorse comprehensive and effective therapeutic strategies

In March 2011, at the 10th International Conference on Alzheimer's and Parkinson's Diseases in Barcelona, Spain, Professor Korczyn (Sieratzki Professor of Neurology at Tel-Aviv University) stated that because Alzheimer's disease is "multifactorial," development of therapies should not be targeted only at beta amyloid, but rather development should target the numerous causes involved in this disease, such as inflammation and vascular risk factors (e.g, high blood pressure).

In spite of Prof. Korczyn's forthright statement, much of the science presented at the meeting was still aimed at amyloid species (e.g., amyloid precursor protein, beta amyloid oligomers, aggregates and plaques). The attitude still exists that the beta amyloid hypothesis has not yet sufficiently been tested. There were amyloid beta related presentations at this meeting aimed at gamma secretase despite LLY's semagacestat failure. The next related compound expected to provide data is Bristol-Myers Squibb's BMS-708163 in Phase II. There are implications that inhibiting gamma secretase effects other pathways and may cause associated toxicities. Dr Koo (University of California at San Diego) believes that gamma secretase remains a viable drug target for Alzheimer's disease, but seems unconvinced as to the future of gamma secretase inhibitors. Koo has implied that the cognitive decline rate in an ongoing BMS-708163 Phase II study may not favor drug treatment. Roche and AstraZeneca (NYSE.AZN-Not Rated), despite LLY's semagacesta failure, are not disregarding gamma secretase as an Alzheimer's disease

drug target, but Elan's (NYSE.ELN - Not Rated) and Wyeth's (NYSE.PFE-Not Rated) Bapineuzumab faces uncertainty about its ability to neutralize soluble beta amyloid and clear fibrillar amyloid. Bapineuzumab's pivotal Phase III program is anticipated to provide data to support an FDA New Drug Application (NDA) in 2012. In an industry sponsored symposium, ELN's chief scientific officer, Dr Schenk, spoke out about how data still supports anti-amyloid approaches.

The Beta Amyloid Hypotheses seems to now be accruing more professional skepticism rather than more professional support.

## Tau Hypothesis

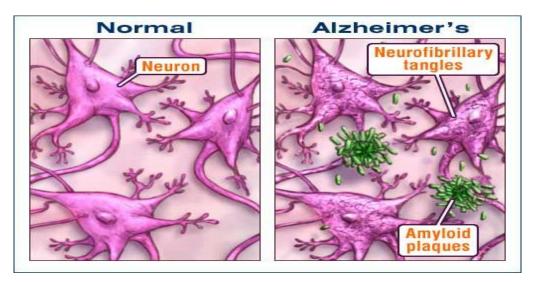
Tau proteins contribute to the internal structural of neurons. In Alzheimer's disease, tau proteins have high amounts of phosphorylation that causes a part of the protein to split off and generate protein fragments. These fragments are not functional and clump together (neurofibrillary tangles) inside a neuron (nerve cell) and are considered toxic. These tangles and beta amyloid plaques are primary characteristics of Alzheimer's disease.

CURX's leuprolide acetate program does not target tau-related neurofibrillary tangles, but there is support that luteinizing hormone (suppressed by Memryte) is a cause of tau proteins phosphorylation so could contribute to tangle formation. CURX has pre-clinical results that luteinizing hormone treatment of neuroblastoma cell lines increased phosphorylation of tau protein, but leuprolide acetate reduced phosphorylation.





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#### **Abnormal Cell Division Hypothesis**

The cell cycle hypothesis purports that Alzheimer's disease's neurological and biochemical changes are due to brain cells abnormal re-entry into the cell division cycle. The cell division cycle is a cell duplicating into two cells. It is commonly believed the brain cells in adults do not have the capability to divide, so this hypothesis focuses on adult brain cells that seem to divide. This hypothesis indicates that these dividing adult brain cells die, and cause the Alzheimer's disease clinical deficits. CURX's preclinical data for luteinizing hormone treatment of glioblastoma and neuroblastoma cells displayed an increased cell division that may be prevented by leuprolide acetate treatment.

#### **Oxidative Stress**

Oxidative stress can result from chemical by-products produced in normal cellular metabolism. These by-products may be capable of damaging cells or causing genetic changes. Treating a nerve cell line with luteinizing hormone produced early data indicating that luteinizing hormone may inhibit enzymes necessary to control oxidative stress. Therefore, by eliminating luteinizing hormone by treatment with leuprolide acetate may decrease the oxidative effect.

#### Inflammation

Autoimmune diseases such as rheumatoid arthritis and multiple sclerosis are examples of uncontrolled inflammation. Inflammation has also been considered as a potential cause of Alzheimer's disease. Anti-inflammatory drugs have not been successful in treating Alzheimer's disease. Pre-clinical studies indicate that luteinizing hormone promotes production of cytokines that increase the inflammatory response so luteinizing hormone may exacerbate Alzheimer's disease and reducing it with leuprolide acetate (Memryte) may be beneficial.

#### **LH Hypothesis**

Based upon CURX's pre-clinical and clinical studies, its management believes that highly elevated pituitary hormone levels that are often produced as a result of normal aging may be important in Alzheimer's disease development. When estrogen levels are lowered during menopause, luteinizing hormone and follicle-stimulating hormone (both are gonadotropins) increase. In males, testosterone production decreases about 1% per year so gonadotropins increase more gradually in males. CURX's management believes its early research indicates that increased luteinizing hormone contributes to Alzheimer's disease pathological changes. CURX management refers to this hypothesis as the LH Hypothesis.

CURX's lead developmental drug product, Memryte (VP4896), is intended to significantly reduce luteinizing hormone in blood and brain tissue by delivering a controlled release dose of leuprolide acetate to suppress the luteinizing hormone production.

# OPUS GROUP FINANCIAL

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CURX's Phase I trial demonstrated dramatic suppression of luteinizing hormone amounts in the healthy male and female participants' serum.

In the Journal of Biological Chemistry in May 2004, CURX published an article indicating that leuprolide treatment of normal mice significantly reduced the concentrations of two different segments of brain amyloid beta (71% after four weeks; 40% after eight weeks).

• J Biol Chem 279(19):20539-20545).

In Biochemica Biphysica Acta in April 2006, CURX published an article that demonstrated leuprolide acetate treatment, when given to mice with Alzheimer's-like disease, significantly reduced concentrations of brain amyloid beta, and resulted in stabilized, and in certain instances, enhanced cognition when leuprolide treated mice were compared to the mice receiving a placebo.

 Luteinizing hormone modulates cognition and amyloid-β deposition in Alzheimer APP transgenic mice. Bioch Biophys Acta 1762(4)447-452).

In summary, CURX's management believes that the gonadotropin, luteinizing hormone, is an important and pivotal contributing factor to the development of Alzheimer's disease.

- Luteinizing hormone may
  - Lead to increased amyloid beta protein production
  - o Direct tau protein changes that may lead to neurofibrillary tangles
  - o Impact other aspects (e.g., oxidative stress and inflammation)

#### CLINICAL DEVELOPMENT PIPELINE

Prior to completing its development of the Memryte implant, CURX dosed an intra-muscular injectable leuprolide acetate formulation in two Phase II dose-ranging clinical trials for Alzheimer's disease treatment. The safety profile of leuprolide acetate has been well established over many years with the most common side effects being hot flashes and osteoporosis. Most women who have or will enter CURX's trials are post-menopausal, so these side effects should present acceptable difficulties.

## CLINICAL TRIALS

#### ALADDIN 301 / Phase II

In August 2006, CURX completed enrollment in this Phase II trial that was initially designed as the first of two planned Phase III randomized, double-blind, placebo-controlled, 56-week, Phase III clinical trials of Memryte for treatment of mild to moderate Alzheimer's disease. In this trial, Memryte was combined with acetyl cholinesterase inhibitors

Men and women aged 60 years or older with mild to moderate Alzheimer's disease were randomly assigned to Memryte or placebo in a 3:2 ratio. Memryte or placebo was dosed every 8 weeks with each patient given two Memryte implants on each visit. The dosage of the two Memryte implants was similar to the leuprolide acetate high dose administered in ALADDIN II (see below) and 150% of the ALADDIN I high dose. ALADDIN I and ALADDIN II clinical trials dosed leuprolide acetate as an intra-muscular injection every 12 weeks over 48 weeks

The primary efficacy endpoint was measured by the difference from placebo in ADAS-cog and ADCS-CGIC scores versus baseline. Secondary efficacy endpoints were change from baseline in a variety of other commonly used Alzheimer's disease measurements, including ADCS-ADL, at 50 weeks.

The study was discontinued in October 2006 due to financial constraints. The Phase III study protocol was converted to a Phase II protocol. At the time of the Phase III termination, there were about 625 patients enrolled at 62 sites in the U.S. and Canada; 369 patients had received a 24 week assessment, about 193 patients had received a 32/34 week assessment, and about 89 patients had received a 40 week assessment.

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In May 2007, CURX performed an analysis of ALADDIN 301 results for two patient groups:

- Men and women
  - Demonstrated no differences that favored Memryte therapy. This was in part contributed to some of the men on placebo performing better than expected on the placebo.
- Women only
  - An efficacy signal was noted.

Analysis was performed on the patients who completed the 24, 32/34 or 40 week assessments.

#### ALADDIN I / 103 Phase II

A randomized, double-blind, placebo-controlled, dose-ranging, 48-week, Phase II clinical study assessing efficacy and safety of an injectable leuprolide acetate on cognitive and global function in women aged 65 years or older with mild to moderate Alzheimer's disease. The patients from 5 U.S. clinical sites were allowed to use AChEIs during the trial. A 109 women were enrolled; 108 were included in the intent-to-treat population and assigned to one of three groups (36 patients in each cohort)

- Low dose leuprolide acetate group; 11.25 mg of leuprolide every 12 weeks
- High dose leuprolide acetate group; 22.5 mg of leuprolide every 12 weeks
- Placebo

An injection of leuprolide acetate or placebo injection was dosed once every 12 weeks. Primary efficacy endpoints were patient scores on the ADAS-cog and the ADCS-CGIC at 48 weeks versus patients' baseline scores. Secondary efficacy endpoints included other scores, such as the ADCS-ADL at 48 weeks versus baseline. A trend was seen at week 48 that favored the leuprolide acetate high dose arm that seemed to indicate disease stabilization versus the placebo arm. Leuprolide acetate injection did not statistically achieve the primary or secondary endpoints.

An analysis was also performed on 78 patients in three patient groups in the intent-to-treat patient population

- (1) 28 patients treated with acetylcholinesterase inhibitors and a 11.25 mg dose of leuprolide acetate
  - This group was not statistically different from the acytelcholinesterase inhibitor and placebo patient group
- (2) 24 patients treated with acetylcholinesterase inhibitors and a leuprolide acetate 22.5 mg dose (high dose)
  - During the seven patient assessment visits during the 48-week study, this
    group was more statistically favorable than the mean score of the placebo
    plus acetylcholinesterase inhibitors group on each of the ADAS-cog, ADCSCGIC and ADCS-ADL measures
  - SUBGOUP ANALYSIS: The p-values were calculated in two different ways for
    analysis of these intent-to-treat groups. First, the unadjusted p-values were calculated
    as if this they were the primary efficacy endpoint. Second, CURX adjusted the pvalues to account for the multiple statistical comparisons by applying Bonferroni
    correction (uses an estimated statistical penalty).
    - The mean ADAS-cog score worsened by 0.18 points at week 48 from baseline compared to a mean worsening of 3.30 points in the group receiving placebo
      - The p-value for this difference was 0.026 on an unadjusted basis and 0.078 on an adjusted basis
    - In the ADCS-CGIC analysis, 58% of the subgroup receiving the 22.5 mg dose of leuprolide acetate and an acytelcholinesterase inhibitor scored no change or better at week 48 in comparison with baseline versus 38% of the subgroup receiving placebo and an acytelcholinesterase inhibitor.
      - The p-value for this difference was 0.031 on an unadjusted basis and 0.093 on an adjusted basis

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- The mean ADCS-ADL score in the subgroup receiving the 22.5 mg dose of leuprolide acetate and an acytelcholinesterase inhibitor declined 0.54 points at week 48 from baseline compared to a mean decline of 6.85 points in the subgroup receiving placebo and an acytelcholinesterase inhibitor.
  - The p-value for this difference was 0.015 on an unadjusted basis and 0.044 on an adjusted basis
- (3) 26 patients treated with acetylcholinesterase inhibitors and a placebo

#### ALADDIN II / 104 Phase II

A randomized, double-blind, placebo controlled, dose-ranging, 48-week, Phase II clinical trial in men aged 65 years or older with mild to moderate Alzheimer's disease, to assess the efficacy and safety of an injectable formulation of leuprolide acetate on cognitive and global function in men with mild to moderate Alzheimer's disease.

#### Trial Arms:

- 22.5 mg (low dose) of leuprolide per 12 weeks; 39 men
- 33.75 mg (high dose) of leuprolide per 12 weeks; 42 men
- Placebo, 38 men

Patients were given an injection of leuprolide acetate or placebo once every 12 weeks. The primary efficacy endpoints were ADAS-cog and the ADCS-CGIC scores at 48 weeks compared to baseline. Secondary efficacy endpoints included a ADCS-ADL score at 48 weeks versus the baseline score. The low and high doses of leuprolide acetate produced very similar results. Leuprolide acetate did not statistically achieve the primary or secondary efficacy endpoints in this trial. The p-values for the endpoints in this trial were 0.729 for ADAS-cog, 0.530 for ADCS-CGIC and 0.232 for ADCS-ADL. There was a small but not statistically significant signal on the ADAS-cog in favor of both leuprolide acetate treatment groups at week 48.

The safety profile in ALADDIN II was similar to that of ALADDIN I

#### ALADDIN 105 / Phase I

This trial was a single center, randomized, double-blind, placebo-controlled, multiple-dose and formulation comparison study of Memryte. It enrolled 50 healthy post-menopausal women from 45-70 years of age and men between 50-70 years of age. Memryte provided a rather steady systemic dosing of leuprolide acetate over eight-weeks. After the first 24 hours of Memryte dosing, steady concentrations of leuprolide acetate began with a peak at about four weeks and then slowly declined. No serious adverse events noted.

#### Planned Phase IIb Study

CURX's next step in it's clinically development of Memryte is to initiate a Phase IIb study in approximately 200-250 women. The purpose of this study will be to confirm the ALADDIN I and ALADDIN 301 clinical trials' results and provide a foundation for determining the size and duration of Memryte's Phase III program. CURX management has stated that this study will probably be a 12-month, double-blind, placebo-controlled study enrolling 1 active treatment arm and 1 placebo arm, with a 60/40 split between these patient cohorts. CURX management believes it will require approximately \$20 million to cover the costs associated with this trial including associated administrative expenses. Curaxis has not advanced the clinical development of Memryte since 2006 due to inadequate financial resources.

#### ADDITIONAL PIPELINE PROGRAM

CURX has conducted pre-clinical research to evaluate Memryte's potential as a cancer therapy (e.g., hormone refractory prostate cancer, brain cancers, kidney cancer, pancreatic cancer and non-small-cell lung cancer (NSCLC).



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The predicted potential for Memryte to be an oncology therapy is based on scientific data about autocrine (cell produced factors regulating its own functions)-paracrine (cell produced factors that regulate adjacent cells' functions) signaling and cancer cells' involvement in the hypothalamic-pituitary-gonadal hormonal feedback loop (HPG axis). CURX's research indicates there is a mechanism related to the hypothalamic-pituitary-gonadal hormonal feedback loop that helps propel cancer cell growth. So, if gonadotropins are eliminated by leuprolide acetate therapy, this cell growth may be restricted.

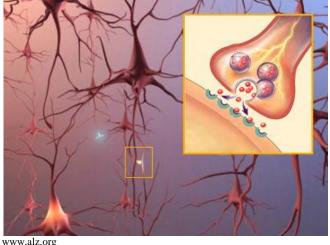
CURX plans to develop Memryte for several cancer. Because CURX has completed Phase I safety trials of Memryte, it should be able to initiate an oncology clinical program with Phase II clinical trial(s). CURX does not intend to begin any additional oncology programs until Memryte's Phase IIb clinical trial for mild-to-moderate Alzheimer's disease in women is completed.

## COMPETITION

The U.S. Food and Drug Administration (FDA) has approved five medications (table below) to treat the symptoms of Alzheimer's disease.

DRUG NAME	BRAND NAME	APPROVED FOR	FDA APPROVED
memantine (Forest Pharmaceuticals, Inc)	Namenda	Moderate to severe	2003
galantamine (Shire Pharmaceuticals; Janssen Pharmaceutical Products, LP)	Razadyne	Mild to moderate	2001
rivastigmine (Novartis AG)	Exelon	Mild to moderate	2000
<b>donepezil</b> (Pfizer, Inc.; Eisai Company, Ltd)	Aricept	All stages	1996
tacrine (Sciele Pharmaceuticals Corp )	Cognex	Mild to moderate	1993

An understanding of the communication network in the brain is helpful to understand how the above listed Alzheimer's drugs work. Neurons (nerve cells) connect and communicate at synapses (junctions between the nerve cells), where tiny bursts of chemicals called neurotransmitters transmit information from one cell to another. Alzheimer's disrupts this process, and eventually destroys the synapses and kills the neurons, damaging a brain's communication system.



www.alz.org
A brain's nerve cells (neurons).

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## Curaxis Pharmaceutical Corp

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Drugs that are FDA approved for Alzheimer's disease support a brain's communication network process through two different means:

- The inhibition of cholinesterase (a drug is called a cholinesterase inhibitor or
  acetylcholinesterase inhibitor) slows the breakdown down of a neurotransmitter so that this
  neurotransmitter can function in the brain for a longer period of time. Donepezil, galantamine,
  rivastigmine and tacrine are cholinesterase inhibitors.
- Memantine is an NMDA (N-methyl-D-aspartate) receptor antagonist. This drug works by regulating glutamate's activity. Glutamate is a chemical messenger involved with learning and memory. Memantine protects a brain cells from excess glutamate that is released in large amounts by Alzheimer's disease damaged cells (and also in other neurological disorders). Glutamate attaches to receptors sites on the cell's surface, which then allows calcium to flow liberally into the cell. This process eventually creates an overexposure to calcium that causes cell damage. Memantine prevents this by partly blocking the NMDA receptors from glutamate attachment.

On average, the approved Alzheimer's drugs in the U.S. are effective for approximately 6-12 months for about 50% of patients who take them.

There are numerous companies and institutional facilities researching and developing prospective Alzheimer's disease treatments. The range in size and resources of these potential competitors is considerable. Presently, there is not a known major corporation or another company developing a drug for Alzheimer's disease with Memryte's mechanism of action.

Development programs for Alzheimer's disease therapies are infamous for their lack of success. Examples of development programs that were discontinued in 2010 are Eli Lilly's (NYSE.LLY - Not Rated) semagacestat. This drug was discontinued in August 2010 because it seemed to make some patients' Alzheimer's disease symptoms worse. Patients' symptoms of memory loss seemed to negatively correlate with the higher the dose of semagacestat they received. Semagacestat, like most Alzheimer's disease drugs in development, was aimed at beta amyloid production. Another drug, Pfizer Inc.'s (NYSE.PFE-Not Rated) and Medivation Inc.'s (NasdaqGM:.MDVN-Not Rated) Dimebon, development was set back due to it not meeting a late-stage clinical trial's primary and secondary endpoints

Eligard is a FDA approved leuprolide acetate injectable suspension product that contains both leuprolide acetate and the Atrigel Delivery system. It is approved for symptom management of advanced prostate cancer. Eligard is administered under the skin with a needle as a liquid. Once it solidifies, it releases leuprolide acetate uniformly throughout the treatment period. This product is supplied as two separate pre-filled syringes whose contents require a seven-step mixing process (Eligard product website) immediately prior to its administration. Administration requires an additional six-step process (corporate website). The Atrigel component is a polymetric (non-gelatin containing) delivery system. Eligard is marketed by Sanofi-Aventis (NYSE: SNY-Not Rated) and there is no indication that it is being developed as a therapy for Alzheimer's disease.

#### PLAN OF OPERATIONS

CURX's strategy is focused on developing Memryte as its lead product candidate. It intends to initially develop Memryte as a treatment for U.S. Alzheimer's disease patients. CURX's management seems to also realize Memryte's potential to generate sales outside the U.S. and from certain oncology indications. Rather than utilize its limited revenues to work on several programs simultaneously, CURX's management plans to initially remain focused only on the development of Memryte as a therapy for Alzheimer's disease. This strategy should help conserve its limited resources while pursuing its most promising prospect to achieve future success.



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#### DISCUSSION OF MODEL AND PRICE TARGET

We do not expect CURX to generate product revenues in the upcoming quarters and that it will acquire necessary revenues through equity offering(s) in the near future. Our CURX revenue expectations in 2014 include the U.S. launch of Memryte during the fourth quarter with associated product stocking orders. We are not relying on, but believe in the possibility, that there is potential for a partnering deal for Memryte's use in Alzheimer's disease and oncology indications. The financial models in this report include a U.S. Memryte launch for Alzheimer's disease, while the potential for a Memryte partnering agreement or an oncology approval is only considered upside to these numbers until we see more momentum in these other areas. Our belief is that CURX will have a full year of Memryte U.S. sales revenues in 2015. After release of late stage Memryte Alzheimer's disease clinical data, CURX could start to receive prospective partnering attention and heighten investors' interest and confidence. Once attention refocuses on CURX's successes and potential and management regularly executes corporate goals, we believe CURX stock price will strongly increase accordingly.

#### INTELLECTUAL PROPERTY

CURX owns the U.S. issued patent, US 6,242,421. This patent's claims are directed at Alzheimer's disease treatment by administering any agent, including leuprolide acetate, which decreases or eliminates blood serum levels of luteinizing hormone. This patent plus Hatch Waxman extensions should protect Memryte from its competition through about 2023.

CURX developed its leuprolide acetate implant, Memryte, with DRXX. Memryte is unique due to its high, sustained release of leuprolide acetate over a two-month time period. DRRX has applied for U.S. and worldwide patent protection on the implant (composition of matter and method of use) and the implant's unique release profile. DRRX's patent would add additional protection to CURX's intellectual property position. CURX holds an exclusive license from DRRX for Memryte's sustained release technology in the treatment of Alzheimer's disease.

Leuprolide acetate, the active pharmaceutical ingredient in Memryte, is off-patent so CURX expects to rely on method of use and formulation patents for product protection.

CURX also has U.S. and worldwide patent applications pending for the concurrent use of leuprolide acetate (and similar compounds) with acetylcholinesterase inhibitors and/or N-Methyl-D-aspartic acid or N-Methyl-D-aspartate (NMDA) receptor antagonists (e.g., memantine; Namenda). If this patent is issued, it is expected to broaden and extend CURX's patent estate that addressing Alzheimer's disease.

## REIMBURSEMENT

CURX's management believes that it will be granted an exclusive permanent Medicare J-Code for Memryte. J-Codes are for injectable drugs that are not self-administered (e.g., chemotherapy, immunosuppressive drugs and inhalation solutions and some orally administered drugs). Prescription and non-prescription drugs and biologicals that are purchased by or dispensed to a patient are not usually covered by J-Codes. A J-code should help prevent payment submission for any similar products to Memryte for the indication of the J-code. This type of a code would be clinically and a financially significant because doctors treating Alzheimer's patients would not be motivated to substitute another product because reimbursement could become complicated.



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#### MANUFACTURING

Leuprolide acetate as a raw material is available from numerous manufacturers.

CURX does not own and does not plan to own a manufacturing facility. It does plan to continue to use third parties to supply its pipeline and approved products.

Memryte implants are manufactured by DRRX using a melt extrusion process that mixes leuprolide acetate with a polymer. A blend is created and sliced into small rod-shaped implants measuring 1.5 millimeters (diameter) and 3.0 centimeters (length)

#### **AGREEMENTS**

## **DRRX** Agreement

- July 2002
  - CURX entered into a Feasibility, Development and Commercialization Agreement with Southern Biosystems, Inc., which afterward merged into DRRX.
    - The agreement is open-ended.
    - DRRX will produce Memryte
      - DRRX may subcontract its responsibilities but remains responsible for its obligations
      - DRRX granted CURX a worldwide, exclusive license to manufacture, market and sell Memryte
    - CURX pays DRRX's costs and milestones for development/regulatory activities
      - CURX has paid \$500,000 in milestones and is obligated to make additional payments of up to a total of \$2,500,000
      - CURX will purchase Memryte at transfer prices equal to specified percentages of DRRX's fully allocated production costs
      - CURX will pay royalties based on Memryte sales
        - o 10% on annual revenues through \$250 million
        - 12% on annual revenues in excess of \$250 million up through \$500 million
        - o 14% on annual revenues in excess of \$500 million

## Covidien/Mallinckrodt Agreement

- January 1, 2009
  - CURX entered into a supply agreement with Mallinckrodt, Inc. a subsidiary of Covidien, Ltd. (NYSE: COV- Not Covered), to purchase 75% of its annual requirements of leuprolide acetate for five years
    - Contract ends December 31, 2013. Agreement will automatically renew for a second five-year period unless Mallinckrodt decides to not renew
    - Mallinckrodt paid CURX the sum of \$500,000 in connection with the execution of this agreement
    - The price of its leuprolide acetate can be adjusted annually upward and downward based on changes in Mallinckrodt's costs and production methods

## **Southridge Agreement**

- May 28, 2009
  - CURX entered into a transaction management agreement with Southridge Business Solutions Group, LLC, of Ridgefield, Connecticut to assist it in restructuring its balance sheet, principally through negotiations with several large trade creditors to reduce their claims, and to assist it in effectuating a merger with a suitable public corporation.



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- Consequently, CURX reduced its trade debt by approximately \$6,000,000 and entered into a merger agreement with Auto Search Cars, Inc.
- CURX issued Southridge warrants of its outstanding stock as of the date of the merger with Auto Search at an exercise price of \$0.001 per share. A total of 2,149,148 warrants have been issued to Southridge under the agreement
- Other terms of this agreement
  - CURX will pay Southridge a management fee of \$10,000 per month, from June 1, 2009 through the first anniversary of the closing of the merger with Auto Search, or July 2011.
  - CURX may terminate the agreement at any time by giving 90 days' advance notice to Southridge.

#### **Canterbury Agreement**

- June 12, 2009
  - CURX entered into a letter agreement with Canterbury Investment Partners, LLC of Hingham, Massachusetts to assist it with the expected merger and negotiations with Southridge.
    - CURX paid Canterbury a retainer of \$50,000 and paid a monthly fee of \$5,833 for twelve months from September 2009 through August 2010.
    - CURX issued a warrant to Canterbury to purchase 854,358 shares of CURX common stock at \$0.22 per share.
    - Following the merger with Auto Search, CURX paid Canterbury \$8,000.00 per month for six months for assistance in CURX's dealings with the financial community.
    - Mark Pompeo (manager of Canterbury) is the brother of Ronald Pompeo, who was elected a director of Curaxis on July 3, 2009

## **GroupMark Agreement**

- September 14, 2009
  - CURX entered into an Investor Development and Corporate Imaging Agreement with GroupMark Financial Services Ltd. of Flemington, New Jersey to assist in developing a new website, blog and public exposure program.
  - CURX paid GroupMark \$50,000 for website and blog development and issued GroupMark a warrant for 100,000 shares of CURX common stock at \$0.30 per share

## SALES AND MARKETING

CURX's management has stated that intends to enter into agreements with corporate partners for the U.S. and potentially other world markets to assist in its Memryte commercialization efforts.

CURX's management also expects that it will be required to subcontract the warehousing/distribution of Memryte and additional management-related activities (e.g., collection of accounts receivables).

## UPPER MANAGEMENT

Patrick S. Smith is CURX's President and Chief Executive Officer and Chairman of the Board. Mr. Smith is a co-founder of CURX and has been its President, Chief Executive Officer and a director since February 2001. In 1981, Mr. Smith founded Critical Care America, an alternative-site healthcare company, and served as Chairman and Chief Executive Officer until November 1992. Mr. Smith has served as a member of the boards of directors of various privately-held corporations including Integrated Care Systems, Cardio-Care America, Women's Care America, Pediatricare America, Infusion Centers America and Naples Community Hospital System, Inc. Mr. Smith is a graduate of John Carroll University and holds an Honorary Doctorate from New York Medical College.



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**David J. Corcoran** is CURX's Vice President of Finance of the Corporation and a director. Mr. Corcoran is a co-founder of CURX and has been CURX's Chief Financial Officer and a director since February 2001. In June 1996, Mr. Corcoran co-founded MedNet Affiliates, a provider of office-based orthopedic services and served as Vice President and a director until August 1999. He has also served as general counsel to Critical Care America from its founding in 1981 through 1992. Mr. Corcoran is a graduate of Bowdoin College and of Northwestern University School of Law.

Judith S. T. Geaslen is CURX's Vice President of Finance. Ms. Geaslen had been CURX's Vice President of Finance and Chief Accounting Officer since January 2010 after serving as Corporate Controller and Accountant since July 2004. From March 1999 to April, 2000, Ms. Geaslen served as Vice President and Corporate Controller at Wilmington Trust Corporation, a financial holding company, and from 1994 to 1999, served as Vice President and Manager of the Asset Review Division. From September 1984 to September 1994, Ms. Geaslen was employed by Ernst & Young, a registered public accounting firm, mostly recently serving as Audit Senior Manager. Ms. Geaslen is a graduate of Saint Mary's College, Notre Dame, Indiana.



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#### FINANCIAL PROJECTIONS

Curaxis Pharmaceutical Corp. **Projections Including Assumptions** (In thousands)

Revenues Cost of services Gross profit Costs and expenses Research and development Selling, general and administrative Income (loss) from operations Other income (expense), net Net income (loss) Income (loss) per share WA shares outstanding

Act	ual				Р	rojected		
Annual		Annual	Annual	Annual		Annual	Annual	Annual
2009		2010	2011	2012		2013	2014	2015
							\$ 20,000 10,000	\$ 80,000 40,000
-		-	-	-		-	10,000	40,000
132 1,077		78 1,859	2,000 2,789	7,000 2,789		1,000 2,789	1,000 5,591	1,000 15,000
(1,209) 6,196		(1,937) (307)	(4,789)	(9,789)		(3,789)	3,409	24,000
\$ 4,987	\$	(2,244)	\$ (4,789)	\$ (9,789)	\$	(3,789)	\$ 3,409	\$ 24,000
\$ 0.08	\$	(0.03)	\$ (0.05)	\$ (0.09)	\$	(0.03)	\$ 0.03	\$ 0.19
60,701		67,323	90,000	115,000		125,000	125,000	125,000

#### <u>Assumptions</u>

Revenues: Q4 2014 sales start, roughly \$20 mill per quarter

Cost of services: 50% of revenues

Costs and expenses

R&D: Q4 2012 goes down to \$1 mill py

2011- double Q3 2011 (hold 2010 constant H1, double H2)

2012- double 2010, then take 75%

2103- Q1 2013 goes up again till Q3 2013: double 2010 for 1H, then 2010 constant in 2H

2014- hold 2013 constant till Q4 when sales start then \$3.5 mill per quarter

2015- \$3.5 million per quarter

Other income (expense), net: assuming the net amount is insignificant

Shares outstanding:

2011- add 40 million shares 2H 2010 (20 mill for year) to the 70 million

2012- add 15 million shares in Q3 2012 (5 mill WA for the year - roughly \$40 mill @ \$3 per share for 1/3 of the year)

Source: Analyst's Estimates



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## **FINANCIALS**

Weighted average shares outstanding - basic Weighted average shares outstanding - diluted Income (loss) per share - diluted Income (loss) per share - basic Net income (loss) Change in fair value of derivative liability Interest from derivative liabilit

Income (loss) from operations Operating Expenses Gain on debt restructuring Interest and other income (expense), net General and administrative Research and development Total operating expenses

Curaxis Pharmaceutical Corp.

Income Statement

(In thousands, excpet per share data)

	60,701		67,323				63,650		63,985		69,408		4
	57,699		67,323		62,336		63,650		63,985		69,408		4
48-	0.08	s	(0.03)	s			(0.01)	₩.	(0.01)	₩.	(0.04)	₩.	)2
es-	0.09	ş	(0.03)	ş	(0.01)	₩.	(0.01)	₩.	(0.01)	₩.	(0.04)	₩.	)2
45	4,987	s	(2,244)	S	(751)	₩.	(380)	₩.	(475)	₩.	(2,786)	₩.	97
			2,250								429		12
			(2,586)								(2,586)		
	(366)		(175)		(67)		(53)		(39)		(41)		2
	6,562		204				204						
	(1,209)		(1,937)		(684)		(531)		(436)		(588)		22
l	1,209		1,937		684		531	l	436		588		22
	1,077		1,859		626		511		413		569		9
-65	132	₩.	78	₩.	58	₩	20	₩	23	₩.	19	₩.	6
	2009	١,	2010		12/31/09		3/31/10	w	6/30/10	6	9/30/10	9	0
			2		2		2		3		3		

**CURX Financials** 

Prepared 4/8/11

12/31/10 10-K Filed 3/31/11

Source: Company Filings

Annual 2008



## Initiation | USA | Healthcare May-2011

## FINANCIALS cont.

local liabilities and stockholders equity	Total stockholders equity	Accumulated deficit	Subscription receivable	Additional paid-in capital	Common stock	Stockholders equity	Total liabilities	Notes payable	Deferred revenue	Deferred purchase credit	Derivative instument	Accrued compensation	Long term liabilities	Total current liabilities	Notes payable	Current portion of capital lease obligation	Accrued expenses	Accounts payable	Current liabilities	Liabilities and stockholders' equity		Total assets	Other assets	mobality and equipments nee
v		_																49			ŀ	₩.		
320	(10,443	(89,804	(104	79,458	- 1		11,366	1,250	1,72	500	1,336	,		6,553	2,52		1,23	2,79				923	61:	

ts ent Assets àsh and cash equivalents
ccounts receivable from related parties repaid assets
ecurity deposit
Total current assets
erty and equipment, net er assets
otal assets
lities and stockholders' equity

Curaxis Pharmaceutical Corp. Balance Sheet (In thousands)

Prepared 4/8/11

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Q2 6/30/10

12/31/10 10-K Filed 3/31/11

Source:	Company	Filings

301 6 309 612 923

98 46 3





## FINANCIALS cont.

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0.2%	22.8%	87.4%
0.0%	0.3%	2.3%
32.6%	27.3%	8,4%
0.7%	0.5%	1.9%
33.5%	50.9%	100.0%
0.2%	0.0%	0.0%
66.3%	49.1%	0.0%
100.0%	100.0%	100.0%
302.6%	215.2%	539.5%
133.4%	100.0%	241.0%
0.4%	0.3%	0.8%
273.6%	224.9%	491,2%
710.0%	540.5%	1272.6%
0.0%	0.0%	0.0%
144.7%	264.2%	0.0%
54.2%	41.8%	104.6%
187.1%	144.5%	361.3%
135,4%	113.0%	366.1%
1231.4%	1104.0%	2104.6%
0.8%	0.6%	13,4%
8608.7%	6642.3%	16377.4%
-11.3%	-15.9%	0.0%
-9729.6%	-7631.0%	-18395.4%
-1131.4%	-1004.0%	-2004.6%
100.0%	100.0%	100.0%
	0.2% 0.0% 32.6% 32.6% 0.2% 66.3% 66.3% 100.0% 133.4% 0.4% 273.6% 710.0% 187.1% 187.1% 187.1% 187.1% 6868.7% 8608.7% 8608.7% 100.0%	11 11 11 11 11 11 11 11 11

5058.5% 1312.9%

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Curaxis Pharmaceutical Corp. Common Size Balance Sheet

Prepared 4/8/11

12/31/10 10-K Fled 3/31/11

Q4 12/31/09 **CURX Financials** 

Source: Company Filings

0.8% 8608.7% -11.3%





## FINANCIALS cont.

Net income EPS	EBI TDA	EBIT	Profitability
(loss			

Cash per WA share
Total cash and investments
Sequential Increase (decrease)

63,985

Depreciation and amortization Cash flows from operating activities

Curaxis Pharmaceutical Corp. (In thou sands)

Prepared 4/8/11

**CURX Financials** 

\J \J \Z

Q1 3/31/10

Annual 2010

Annual 2008

(358)

(252) \*\*

(1,318)

(622)

81 (759)

12/31/10 10-K Fled 3/31/11

Source: Company Filings

# OPUS GROUP FINANCIAL

## Curaxis Pharmaceutical Corp

## Initiation | USA | Healthcare May-2011

#### MEANING OF RATINGS

#### Buv

We believe the company is undervalued relative to its market and peers. We believe its risk reward ratio strongly advocates purchase of the stock relative to other stocks in the marketplace. Remember, with all equities there is always downside risk.

#### Speculative Buy

We believe that the long run prospects of the company are positive. We believe its risk reward ratio advocates purchase of the stock. We feel the investment risk is higher than our typical "buy" recommendation. In the short run, the stock may be subject to high volatility and continue to trade at a discount to its market.

#### Neutral

We will remain neutral pending certain developments.

#### Underperform

We believe that the company may be fairly valued based on its current status. Upside potential is limited relative to investment risk.

#### Sell

We believe that the company is significantly overvalued based on its current status. The future of the company's operations may be questionable and there is an extreme level of investment risk relative to reward.

Some notable Risks within the Microcap Market

Stocks in the Microcap segment of the market have many risks that are not as prevalent in Large-cap, Blue Chips or even Small-cap stocks. Often it is these risks that cause Microcap stocks to trade at discounts to their peers. The most common of these risks is liquidity risk, which is typically caused by small trading floats and very low trading volume which can lead to large spreads and high volatility in stock price. In addition, Microcaps tend to have significant company specific risks that contribute to lower valuations.

Investors need to be aware of the higher probability of financial default and higher degree of financial distress inherent in the microcap segment of the market.



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