

PurAxis, Inc.

Executive Summary

Optically pure drugs at your fingertips

Current needs and problems

According to Alzheimer's Association, an estimated 5.3 million Americans have Alzheimer's disease (AD), of which 5.1 million people aged 65 and older and 200,000 individuals under age 65 have younger-onset Alzheimer's. AD is a progressive and fatal brain disease and is the most common form of dementia. The number of new AD cases is growing and will continue to grow rapidly as the baby boomers age. It is projected by Alzheimer's Association that by mid-century a new case will develop in America every 33 seconds, compared to one per 70 seconds now.

Current solutions

There is no cure for Alzheimer's disease at this point. A number of non-invasive, life-style habits have been suggested for the prevention of Alzheimer's disease, but there is a lack of adequate evidence for a link between these recommendations and reduced degeneration. Despite there being hundreds of compounds in clinical research that aim to cure Alzheimer's, the disease as yet cannot be cured and is degenerative. Stabilizing patients' lives by reducing symptoms is acknowledged as the best solution. Acetylcholinesterase inhibitors such as donepezil are effective in treating the cognitive manifestations of Alzheimer's but can cause nausea, vomiting, muscle cramps, decreased heart rate and abnormal gastric acid production.

Market Analysis

Though no treatment is available to cure Alzheimer's, five drugs are accessible in the market to temporarily slow down worsening of symptoms for about 6 to 12 months. The global AD market was valued at \$5.4 billion and expected to grow to \$6.2 billion with a CAGR of 1.8% by year 2015.

Competitive landscape

The current competition in Alzheimer's disease market is weak, with five FDA approved drugs – Aricept (donepezil), Razadyne (galantamine), Namenda (memantine), Exelon (rivastigimine) and Cognex (tacrine). Of the five, four are active players in the market except for Cognex. The current FDA approved AD treatments cannot stop the underlying destruction of nerve cells; instead, they only slow down the symptoms for about six months or a year, thus, leaving behind a large segment of unmet needs. With 2009 sales of \$3.3 billion, Aricept is the leading drug for Alzheimer's disease, followed by Exelon (Novartis), Namenda (Forest Laboratories) and Razadyne (JNJ).

In contrast to the few approved drugs for the treatment of AD – where just five agents account for an estimated over 95% of drug sales - there are more than 178 candidate drugs or candidate treatments currently in the clinical pipeline. Of these, 82% are at Phases I and II. In addition to drugs aimed at

targeting AD directly, more than 35 other drug classes are being investigated in an effort to develop other strategies for treating AD and its symptoms.

The PurAxis Advantage System

Our pipeline product, optically pure donepezil, is being developed to provide patients with moderate to severe AD with a more effective option to slow the degeneration process of brain cells. There is unmet medical needs for this market segment, requiring more effective medication for symptom relief. Moreover, the side effects of all the approved drugs include gastrointestinal bleeding, ulcers, vomiting, diarrhea and nausea. Their occurrence is usually mitigated by starting the treatment with low doses and escalating it slowly, which might reduce drug effectiveness.

Technology

PurAxis' core technology allows for the production of optically pure chemicals. Specifically, it utilizes a new class of chiral auxiliaries that are incorporated into aldehyde or ketone substrates. The presence of the auxiliary stereochemically biases the outcome of alkylation reactions performed at industrially accessible temperatures (-20°C). PurAxis has the ability to produce single enantiomer chemical building blocks. This proprietary method of production will be used to develop a single enantiomer version of donepezil (Aricept), which is currently sold as a racemate, effectively pursuing a "chiral switch". PurAxis, Inc. plans to price chirally-pure donepezil at an equitable level to Aricept in order to generate a fast rate of market adoption and, as a result, the demand for chirally-pure donepezil.

Management Team

The lead inventor, Dr. Don Coltart, is an Asst. Professor in Duke University's Department of Chemistry and an established researcher in development of new synthetic methodology and other chemically-based processes. PurAxis is also strategically partnered with Southeast TechInvestures, whose mission is rapid conversion of university scientific breakthroughs into products, services and new technology companies. The management team and Board of Directors have extensive experience in business development, commercialization of early-stage technologies and clinical development.

State of Technology

PurAxis, Inc. is currently operating in the product development stage and has funding from an NIH STTR grant and clinical development grant from Duke Translation Research Institute. PureAxis hopes to raise \$15.4 million from investors and is seeking non-dilutive funding for mid-stage technological development through renewal grants from the NIH. The Duke Start-up Challenge funds would contribute to the momentum for commercializing the PurAxis products.