BUSINESS AND ANTICIPATED BUSINESS PLAN

Our Company

Cao Pharmaceuticals Inc., a Texas corporation (“we”, “our”, “us”, “CPI”, or the “Company”), is an early clinical stage oncology drug development company. Our principal place of business is located at 17490 Hwy. 3, Suite B200, Webster, Texas 77598 USA. Our main telephone number is 832-283-7705. General e-mail inquiries may be sent to info@caopharmaceuticals.com.

Our Objectives

We are seeking to develop one or more effective prescription drugs from a natural plant-based extract with relatively low or readily manageable toxicity with a view towards the future treatment of one or more solid tumors in the human body (e.g., colon, lung, breast, prostrate, melanoma, sarcoma, pancreatic, liver, etc., and/or lymphoma). We are also seeking to implement shorter development time frames compared to traditional chemotherapies. We are currently conducting a Phase I clinical trial with our lead drug “CZ48”. If the Phase I clinical trial goes well, we will seek to enter into Phase II trials and beyond with a view towards approval of CZ48 by the U.S. Food and Drug Administration (FDA) for medical treatment. There can be no assurance these objectives will be achieved.

Background and Overview:Camptothecin (CPT)

Camptothecin (CPT) based drugs, derived from a plant extract from the tree Camptotheca acuminata, were discovered in the mid-1960s and shown to have very promising potential as anticancer drugs. Their mechanism of action inhibits the activity of Topoisomerase I, an enzyme necessary for DNA replication in cell division, and leads to cell death by apoptosis.The significance of these compounds was quickly recognized and as a result much work has been done in an attempt to tap their vast potential. The team at Cao Pharmaceuticals have been at the forefront of CPT based drug design. Our view is that the potential of these drugs has just begun to be unlocked. This view stems not only from our knowledge and experience in designing and studying new CPT based drugs in the laboratory, but also from seeing first-hand activity in human use.CPT was discovered during a study conducted by the NIH in testing over 1,000 natural plant extracts gathered from around the world. Of all of these natural extracts, only one had preferential killing of human cancer cells while not harming normal cells. The next step was to study these drugs in humans. Several clinical trials were performed with CPT based drugs. The first trial was with plain CPT (the natural extract). Fifty patients were treated with one complete response (CR) in a Stage 4 lymphoma patient. In the laboratory several new derivatives were designed which demonstrated improved efficacy and lower toxicity. One of these compounds was 9-NitroCamptothecin (9NC). This derivative was then studied in a Phase I trial and there was activity seen in pancreatic cancer. From these results a Phase II trial was initiated treating patients with pancreatic cancer. Even with the best medical care available the average survival is around 6 months.106 patients with advanced pancreatic cancer were treated with survival as an endpoint. Of the evaluable patients approximately one third had no difference in survival, one third lived past 12 months and another third lived past 18 months, with 11 of these surviving 24 months with 2 long term cures. As good as these results were there was a tremendous disconnect between the near cure in treating human cancers in the nude mouse model and these clinical results.From basic laboratory research, it was determined that the last ring in the CPT drug must remain closed in the lactone form to be active. When the ring opens forming the carboxylate the compound loses over 90% of its activity. It was determined that the

reason for the disparity between the mouse data and the pancreatic trial outcome was an albumin species difference between mouse and man.Albumin is a natural protein component of the blood and accounts for over 50% of blood protein. In the mouse blood there is a high concentration of active drug for several hours. Unfortunately Human Serum Albumin (HSA) has an avid affinity to bind to the inactive form of the drug (carboxylate) and causes rapid conversion of the active form of the drug to the inactive form. In humans in just one hour there is less than 10% active drug circulating in the blood. The encouraging news was that the positive outcomes in the Phase II pancreatic study were obtained with just this small fraction of active drug.

CZ48 Overview

Our lead drug candidate “CZ48” has been synthesized to circumvent this binding to HSA, yet retain a high degree of anti-cancer activity.In vitro studies show that when this drug is incubated with Human Serum Albumin (HSA),there is more than a tenfold increase in active drug compared to 9NC.This increase in drug availability should translate into an even higher degree of efficacy. This new drug is currently in a FDA approved Phase I clinical trial.We believe CZ48 is an improved form of the drug 9-NitroCamptothecin (9NC). In clinical trials of 9NC, even with very low blood levels of active drug (< 5%), outcomes showed significant activity and improved survival in patients with advanced pancreatic cancer. CZ48 has been designed to significantly improve blood levels compared to 9NC, yet retain this high degree of anti-cancer activity.In vitro studies show that when CZ48 is incubated with Human Serum Albumin (HSA),blood levels of active drug are increased more than tenfold compared to 9NC.This increase in drug availability should translate into an even higher degree of efficacy.The ongoing Phase I clinical trial of CZ48 is comprised of three dosing steps and is currently in the last (3rd) step. In this 3rd step patient toxicity has been very limited. This is exciting news for us as this was one of the design goals of CZ48. This Phase I trial is scheduled to be completed by the end of 2021. The Phase II trials to evaluate efficacy are schedule to start in Q4 of 2022.

We believe some of the advantages of CZ48 include:

- Oral Administration (i.v. formulations will be available for certain indications)
- Passes the blood brain barrier
- Data suggests killing of cancer stem cells
- Limited and Manageable toxicity
- Good efficacy
- Biomarker development to identify patients sensitive to specific CPT drugs