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## Concert Pharmaceuticals Uses the Naturally-Occurring Element Deuterium to Create First- and Best-In-Class New Medicines That Substantially Reduce the Risks Associated with Current Drug Development Approaches and Increase the Likelihood of Their Commercial Development

Healthcare - Biotechnology  
(Private)

Concert Pharmaceuticals, Inc.

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**Roger Tung, Ph.D.**  
President and CEO

### BIO:

Dr. Roger Tung, President and Chief Executive Officer of Concert Pharmaceuticals, Inc., co-founded the Company in April 2006 based on research he carried out as an independent scientist. Before Concert, Dr. Tung worked in venture-backed start-up and major pharmaceutical companies, including Vertex Pharmaceuticals Inc., where he was a founding scientist, Merck, Sharp & Dohme Research Laboratories, and The Squibb Institute for Medicinal Chemistry. At Vertex, Dr. Tung was most recently Vice President of

Drug Discovery and led their drug discovery programs at its San Diego site. He co-invented and headed discovery of Vertex's two commercial HIV protease inhibitor products, Lexiva® and Agenerase®. He also headed development of Agenerase, in collaboration with Glaxo, through FDA and EMEA approval. Dr. Tung has overseen the discovery of 14 new chemical entities which have been studied in the clinic. He has numerous publications and has been granted 40 U.S. patents. Dr. Tung received his Ph.D. in Medicinal Chemistry at the University of Wisconsin-Madison from Professor Daniel H. Rich.

### Company Profile:

Concert Pharmaceuticals, Inc. is a clinical stage biotechnology company dedicated to creating medically and commercially important new medicines through a novel approach utilizing the naturally-occurring element deuterium. Concert applies its innovative platform to create highly differentiated compounds based on well-understood biological targets and drug molecules, yielding a rich pipeline of new chemical entities (NCEs). By leveraging decades of pharmaceutical experience to design NCEs from proven therapies, Concert's drug candidates have potential for first-in-class use in underserved medical conditions, as well as best-in-class efficacy and safety, while reducing R&D risk, time, and expense. The Company has over 100 patent applications for new drug candidates addressing a broad range of therapeutic areas, including HIV/AIDS, vasomotor symptoms, and renal disease, among others. Since its inception in 2006, Concert has raised more than \$96 million and has

been financed by leading venture capitalists and institutional investors.

Interview by: Lynn Fosse, Sr. Editor

**CEOCFO:** Dr. Tung, what was your vision when you founded Concert Pharmaceuticals and where are you today?

**Dr. Tung:** "I have a long background as an R&D executive in the biotech and pharmaceutical industry. It was clear to me that the paradigm for drug research and development has become increasingly difficult for a number of reasons. The vision behind Concert is to take a different tack at drug discovery that would enable the creation of new chemical entities (NCEs), first-and best-in-class new medicines, in a way that substantially reduces the risks associated with current drug development approaches and increases the likelihood of their successful commercial development."

**CEOCFO:** What is different about the approach of Concert Pharmaceuticals?

**Dr. Tung:** "We generally believe that starting with drugs with proven human pharmacology is the most straight forward way of producing better medicines, by capitalizing on what is known about those compounds and making very directed improvements. Technologically we replace certain hydrogen atoms in successful drugs with deuterium atoms and leave the rest of the molecules generally unchanged. The approach has the advantage that the potency and selectivity of these new chemical entities is, for all intents and purposes, identical to that of the existing drug. However, in some cases, there are very substantial differences in drug metabolism that we believe

can be medically very important.”

**CEO CFO:** What is deuterium?

**Dr. Tung:** “Deuterium is a safe, naturally-occurring element that is related to hydrogen. Deuterium is abundant in nature and we as humans have a couple of grams of deuterium in our bodies. Deuterium has the same shape and size as hydrogen, but it has a greater mass, which results in its forming stronger bonds with other atoms. It is sourced by distillation of water to produce what is called D<sub>2</sub>O, which is the feedstock that we use for deuterium chemistry.”

**CEO CFO:** Where did the idea come from to use deuterium to create new drugs?

**Dr. Tung:** “After spending several decades in the pharmaceutical industry, I thought about technology that might be able to increase the success rate in producing important new medicines. Specifically, I was thinking of approaches to leverage the knowledge around existing medicines and to create better ones. Deuterium has been used quite extensively in human clinical studies, but never as a way of producing a differentiated commercial new entity. I believed using deuterium as a platform approach would allow us to create a pipeline of better medicines while reducing R&D risk, time and expense. With the idea, filing new patent applications and its initial seed capital, Concert was founded in 2006.”

**CEO CFO:** What are you doing at Concert today?

**Dr. Tung:** “We are actually in really good shape as a company both scientifically and financially. We have raised \$96 million since our inception putting us in strong financial position to advance our pipeline and create significant value. We have a very robust pipeline. One compound is in clinical testing and a second is poised to enter the clinic in 2009. We also have a number of exciting research compounds behind that focusing on areas including cancer, cardiovascular disease, and renal disease, among others. We have in many ways an embarrassment of riches, with a lot of opportunities that we could pursue, but we of course are mind-

ful of making sure that we are as focused as possible given the current capital climate. In 2009, we intend to focus our development on CTP-518. CTP-518 is an oral HIV protease inhibitor that we believe eliminates the need for co-administration with a protease inhibitor booster. We believe CTP-518 has the potential to be the best-in-class compound in what has been a very important therapeutic area. This is a therapeutic modality in which we can get very rapid proof-of-concept since the relationship between drug exposure and efficacy are very well understood.”

**CEO CFO:** Why is there a need to eliminate a protease inhibitor booster from HIV treatment regimens?

**Dr. Tung:** “There are happily a lot of therapies that are now available for an HIV infected patient. As a result, those patients are living much longer, and much healthier lives. The emphasis for

**“The vision behind Concert is to take a different tack at drug discovery that would enable the creation of new chemical entities (NCEs), first- and best-in-class new medicines, in a way that substantially reduces the risks associated with current drug development approaches and increases the likelihood of their successful commercial development.” - Roger Tung, Ph.D.**

new medicines are ones that minimize the side effects and make the therapies easier to use. Although there are now many approved HIV drugs, many of them have substantial side effects. Therefore, our focus has been to further the field by simplifying the dosing regimen and by what we believe will be a reduction in side effects of an important existing drug, an HIV protease inhibitor. It’s important to understand that in the HIV protease class, the current standard of care is to give those drugs co-dosed with an entity called ritonavir. The function of ritonavir is to increase the biological half-life of the HIV protease inhibitors resulting in increased trough concentrations in the blood - that’s the lowest concentration that is in the bloodstream before taking the next pill. It works quite well, but unfortunately, there are a lot of side effect issues with ritonavir, in particular nausea. There are also potential cardiovascular safety issues due to the fact that ri-

tonavir increases triglyceride levels and LDL cholesterol. In addition, it is another pill to take, another co-pay and is inconvenient to patients because the formulation for that drug requires refrigeration when temperatures are above 78 degrees Fahrenheit. So, as you can see, there are many things that make ritonavir not ideal. What we have done through the use of our technology is to start with one of the leading protease inhibitors, currently on the market, and to change the metabolism in a way that would enable dosing the compound, we believe, without ritonavir as part of the combination. So it will have all of the benefits of a potent, market leading agent, but with the further advantage of reducing the number of pills that the patient has to take and enhancing the tolerability of the therapy.”

**CEO CFO:** Where are you in the process of developing of the HIV protease inhibitor?

**Dr. Tung:** “We expect to enter clinical evaluation of CTP-518 in the second half of 2009.”

**CEO CFO:** You have 100 patent applications; tell us about some of the other compounds that you have in your pipeline.

**Dr. Tung:** “We have quite a few compounds that we have covered, in terms of filing applications for deuterium-modified versions of those compounds.

The initial compound that we took into the clinic, CTP-347, is a compound that we remain quite interested in as a potential first-in-class non-hormonal treatment for vasomotor symptoms or hot-flashes. This is an indication, which is very wide spread. In addition to the peri- and post-menopausal population, it is experienced by many patients undergoing cancer chemotherapy, particularly for breast cancer, prostate cancer and other hormone related cancers. Therefore, there is a very large patient population that could benefit from a treatment for vasomotor symptoms that in particular are contraindicated from taking hormone replacement therapy. We think that there is a great market for it and we have a compound that we believe may significantly improve upon the safety profile of the existing agent by changing the metabolic

fate of the compound.”

**CEO CFO:** Tell me about CTP-347 and why you believe you have developed a better drug?

**Dr. Tung:** “The hydrogen analog of CTP-347 is a serotonin modulator that has the effect of producing a metabolite which is quite reactive and inactivates irreversibly one of the important liver metabolic enzymes. It therefore creates a lot of drug-drug interactions. By using our technology, we have changed the metabolic fate of the compound so it no longer produces, at least to the extent we can detect, that reactive metabolite. As far as we are aware, we are the first to demonstrate the ability to do that with deuterium substitution.”

**CEO CFO:** What would you say to investors who are putting companies on their radar screen as to why should they consider Concert Pharmaceuticals?

**Dr. Tung:** “We are pioneering what we believe is a very important and powerful approach to creating differentiated, first-in-class and best-in-class medicines. We have demonstrated as an organization that we can execute very quickly. We have great experience in the company. As a management team, we have put five drugs onto the market between us, so we understand the issues with the process of drug R&D unusually well. We also have a very interesting product platform opportunity and that is very rare in the small molecule space. There are areas in large molecule therapeutics, such as antibodies, for example, and RNAi that have that potential to be a platform, but in the small molecule space, there are very few cases of a technology that allows you to broadly access a wide range of therapeutic areas and to do so rapidly and with an enhanced likelihood of success. Therefore, Concert is a pretty unique organization.”

**CEO CFO:** Final thoughts, what should people reading about Concert Pharmaceuticals remember most?

**Dr. Tung:** “We have the pieces to be a truly successful organization. As I indicated, Concert has the personnel and the technology platform, where we are the pioneers and the most advanced company working in this area. In addition, we have the cash to be able to execute on our plans and to ride out the current market situation. We also have a strong intellectual property position for many different molecules. On top of all that, we have received our first notice of allowance for one of our patent applications, so this is an area that is being recognized by the Patent and Trademark Office as novel and inventive. Concert is putting all of those pieces together to create what we think will be one of the winning organizations.”

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