SECTOR — PHARMACEUTICALS

TWST: Let’s start with Concert Pharmaceuticals’ background, its historical beginnings and what led up to its IPO in 2014.

Dr. Tung: Concert’s history is that it came out of an intent to create a broad platform that could create interesting, important and novel new drugs in a way that reduced the drug development risk, the lengthy time lines and the investment that was typically necessary to bring a new drug to market. I conceptualized the use of deuterium very broadly in modifying biologically active molecules to retain their intrinsic activity, potency and selectivity, but potentially change some of the properties that could affect safety, efficacy and tolerability of compounds.

On that basis, I put together a series of initial patent applications that formed the basis of our DCE Platform — Deuterated Chemical Entity Platform — and then I worked with some colleagues, Co-Founders Rich Aldrich and Christoph Westphal, to initially fund the company. Our team has executed very well to advance the technology and create a broad pipeline of clinical entities. This has resulted in some very valuable partnerships and formed the basis of the pipeline that allowed us to IPO the company in 2014.

TWST: What would you add in terms of where your focus is today in terms of research and the application of that?

Dr. Tung: We want to continue broadening the platform. We have a very productive way of creating potentially high-value new medicines, with a sweet spot in bringing deuterium-modified versions of approved drugs into initial human studies very quickly and with low capital investment. This allows us to get important early insight with our compounds, showing the effect that deuterium modification has on human absorption, distribution, metabolism and excretion characteristics. It’s really those changes that lead to the potentially superior clinical properties of the deuterium-modified compounds. We can get to an important proof of concept in a relatively fast and low-cost approach, and so we’ll continue to work on that.

We believe that our technology has the potential to produce not only differentiated and improved versions of existing drugs but also novel and potentially high-value compounds, such as CTP-499. And overall, the technology has gotten to the point where the approach is highly validated, both in terms of the demonstration of differentiated clinical properties of deuterium-modified compounds as well as a number of very substantial high-value transactions around acquisition of companies whose main assets were deuterium-modified compounds.

Right now we are in a strong financial position, we’re well-capitalized after a recent secondary financing. That puts us in a position to execute on our platform and continue to grow our pipeline. Overall, we’re very excited by the breadth of the clear evidence supporting our technology.

TWST: Please describe your assets in terms of human capital, patents and intellectual property. What would you want investors to know in terms of what, in some cases, may not be easily tangible?

Dr. Tung: The human capital is absolutely critical. You don’t get anywhere with technology without having the right people, the depth of experience, the passion and the teamwork to make things happen. We have a very strong team, which we continue to grow. Our team has real depth of experience in the biotech and pharmaceutical industry, which reflects that we’re in a stage of maturity now in biotech where it’s possible to put together a great team of people with a diverse range of experiences
that help to inform the way that new companies like ours move forward. We have people who have been instrumental, either as founders or key personnel, at companies like Vertex, Millennium, Biogen, Genzyme and other very large successful companies, and this expertise will help us to build the next very important biotech company.

In terms of intellectual property, we’re clearly the leaders in investing and attaining intellectual property in the deuterium-modification field. We have had over 60 U.S. patents issued and approximately 150 worldwide patents that have been issued to us, to give a sense of the scale in which we’ve operated in that area, and that includes important territories like the European Union, Japan, China, Canada, Australia and many other countries. So we’re taking a worldwide approach to deploying the technology and gaining intellectual property.

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In terms of know-how and capability, that’s really the core of the company, our DCE Platform. That involves the know-how and experience of identifying compounds for deuterium modification, for synthesizing the analogs and choosing from among deuterium-modified analogs the ones that we will then take forward into clinical evaluation. Then, there are some specific aspects of manufacturing them, of the way in which we run early clinical trials, and all of those things require a lot of expertise and experience to do efficiently and to do well. It’s not a range of capabilities that you can quickly pick up and create, which is why we think we are the only real deuterium platform company in existence.

TWST: What is the potential market demand for the drugs and treatments that you have, and at what stage are they?

Dr. Tung: The compounds that we have in the clinic right now and intend to bring into the clinic have the potential to address multiple multibillion-dollar markets. For example, AVP-786 is a deuterium-modified version of dextromethorphan combined with ultra-low-dose quinidine, which we believe will go into Phase III this year for the treatment of agitation in patients with Alzheimer’s disease. There are no approved drugs for Alzheimer’s agitation, and it’s widely believed to be a very important and large market. It certainly was one of the key factors in the acquisition of our partner Avanir Pharmaceuticals, who is developing that compound. Avanir was acquired by Otsuka earlier this year for north of $3 billion.

We also have compounds that we’re developing for cystic fibrosis, narcolepsy, inflammatory diseases and chronic kidney disease. And we have a substantial preclinical pipeline that we will be deploying in the coming years. Each of these has very substantial medical utility and market potential, so we are at the very early stages of, I think, a very broad, important new technology, which is deuterium-modified pharmaceutical agents.

TWST: Would you tell us more about your relationships with strategic partners and collaborators?

Dr. Tung: We have collaborations with Celgene, Jazz Pharmaceuticals and Avanir Pharmaceuticals. Each collaboration is important and unique. What we do is understand that the partnership is around creating mutual benefit, and that’s best served if we have a shared perspective on how to progress and develop the compounds.

TWST: How would you describe the investment market’s reception to your IPO?

Dr. Tung: We had a great reception to the IPO. There was significant investor demand at the time that we went out with the public offering, resulting in a highly oversubscribed offering at the top of our pricing range. One of the things that really made a difference for us was the initial demonstration that dextromethorphan had very positive Phase II results in the treatment of agitation in Alzheimer’s disease, Avanir’s strong stance that 786 was the candidate that they intend to take into Phase III, and then, as I mentioned, the subsequent acquisition of Avanir by Otsuka helped the investment community recognize that 786 and perhaps by extension other things that we’re working on have very substantial tangible value as new clinical agents and as valuable entities.

So based on that, I think we’ve gotten a lot more recognition, and that and continued expansions in our pipeline and clinical progression led to a secondary offering that we recently completed. I believe we have a growing breadth of investors who are recognizing that what we have is something valuable and special.

TWST: You mentioned the secondary offering. What are the plans for the proceeds? And generally, do you feel you have the ability to tap the capital markets again as you need to?

Dr. Tung: At this time, we are very well-capitalized, and I think we’re in a very strong position to continue deploying our technology to advance our compounds through the clinic. Our deuterium-modified compounds retain the activity and selectivity of the pre-existing drug or other biologically active compound, and we think this provides validation that our deuterated compounds will be important and that our Phase I studies will drive real optionality for our compounds, for either potential licensing or for our understanding their position to take forward into further clinical evaluation and, potentially, commercialization ourselves. So what the financing did was put us in a position of increased strength to be able to deploy our technology.

TWST: You were recently added to the Nasdaq Biotech Index. What’s the importance or impact of that?

Dr. Tung: It was great. It’s a nice recognition that we’re one of the contributors in the biotech field overall, nationally, and it certainly increased the distribution of our shares into a wider range of investors. So we welcome that, and we’re pleased to be part of the index.

TWST: What were the key points from your most recent quarterly earnings results?

Dr. Tung: What we informed the community of is that we were and, even more so, are now in a strong financial position, that we will have continued progression of our clinical pipeline with a lot of events occurring during this year. We also highlighted the expansion of our pipeline with a new compound for the treatment of cystic fibrosis, and we emphasized that what we have is a very well-proven, well-validated technology that we are the leaders in terms of deploying.
TWST: To wrap up, how would you summarize Concert’s goals and strategy in the foreseeable future?

Dr. Tung: I think the company is doing great work right now. The increased financial strength that we have will allow us to increase the breadth of possibilities that we bring into and through the clinic toward becoming important new medicines. We are going to continue supporting our work through the partnerships, and increasingly, the partnerships that we have struck are moving closer and closer to having a very positive financial effect for us, and so I think doing deals is something we would consider in the future. Our eventual goal is to become a fully commercial company, and we’re choosing our spots for the products that we want to take to the market ourselves. We’re going to continue to work to increase the recognition of our brand, our technology and our capabilities, and it’s through discussions like this one that we appreciate the opportunity to reach out and make further contacts with the investment community.

TWST: Thank you. (MN)