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Raymond K. Houck

Aclipse Therapeutics applying Precision Medicine to ALS and CNS Diseases

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CEOCFO: Mr. Houck, what is the vision behind Aclipse Therapeutics?
Mr. Houck: Aclipse's vision is to apply precision medicine to orphan diseases with high unmet medical needs. We are developing therapeutics that we can match with the genetics of specific patients. Thus, delivering drugs to those patients who would benefit the most from the drug.

CEOCFO: I am guessing that there are many potential diseases to consider?
Mr. Houck: Certainly, from a high level, that is true. Our lead product is M102 to treat amyotrophic lateral sclerosis, also called ALS or Lou Gehrig's disease, a devastating neurodegenerative disease. However, M102 may also treat Friedreich's Ataxia, Huntington's disease and Parkinson's disease, all central nervous system (CNS) diseases with patients in dire need for improved therapies.

CEOCFO: Why did you start with those diseases?
Mr. Houck: Aclipse Therapeutics has a team of experienced orphan drug developers and our business model is to in-license drug candidates and then develop those drugs through to U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) approval. Through our research and networks, we were introduced to Dame Pamela Shaw MD, who has led the discovery of M102.

Dr. Shaw is a physician at the University of Sheffield in the UK and she is a world-leading expert in ALS. Dr. Shaw has over two hundred scientists at the Sheffield Institute of Translational Neuroscience (SITraN) focused on ALS and a small number of other neurodegenerative diseases. Dr. Shaw and her team discovered the biology behind M102 and then discovered M102. We were very much intrigued with the program because M102 is taking a wholly new biological approach in ALS, which couples the underlying biology with a precision medicine approach. Such an approach has the ability to potentially identify the specific ALS patients who could have the greatest response to the drug. Aclipse formed a collaboration with Dr. Shaw and her team that resulted in Aclipse in-licensing the program from her University.

CEOCFO: Would you explain how M102 works?
Mr. Houck: ALS is a complex disease that has ten different disease pathomechanisms, or in other words, ten different pieces of the puzzle. M102 takes a broad approach to the disease, in that it activates both the NRF2 and the HSF1 biological pathways, which then affects nine of these ten disease pathomechanisms. M102 is taking a broader approach to ALS than any other therapeutic to date. In addition, we are coupling this biology with the precision medicine approach that allows us to target the specific patients who will benefit the most from M102.

CEOCFO: Has it not been possible to take this broad approach in the past? Have people not recognized it?
Mr. Houck: The unfolding biology of ALS is gaining a greater understanding, and Dr. Shaw and her team at Sheffield have been on the cutting edge of that research. The M102 molecule and this precision medicine approach all stemmed from their research on the biology of ALS. There are other research teams starting to pursue somewhat broader approaches to ALS, but we believe M102 is the first drug candidate to couple both a very broad approach with precision medicine. In partnership with Dr. Shaw and the SITraN team, we are supporting the development of patient stratification biomarkers that will be applied in the M102 clinical studies, to enable a personalized medicine approach in ALS. The goal of the patient stratification biomarkers is to identify M102 drug responders versus non-responders in order to target M102 to those ALS patients most likely to benefit from the drug.

CEOCFO: Why did it make sense to you?
Mr. Houck: M102 made sense to us because a precision medicine approach allows you to genetically target the specific patient population, in order to identify patients who are expected to have the best drug response and clinical

benefit from the therapy. Industry data show that clinical trials with precision medicine approaches have a three-fold higher probability of clinical success. That is huge – particularly in a degenerative disease such as ALS, where there are no effective treatment options.

CEOCFO: How do you know who might be the best targets? Is that well accepted or becoming accepted, that you can pick out the people that are most likely to respond?
Mr. Houck: Our approach is based upon the genetics of the patient and the matching of the drug to those individual patient genetics. That is precision medicine. Precision medicine has been used for the last ten to fifteen years in cancer with great success. In 2018, forty-two percent of all therapies approved by the FDA had a precision medicine companion diagnostic to better target patients. Now, we are applying a precision medicine approach to central nervous system drugs via patient stratification biomarkers.

CEOCFO: What do you understand about getting a drug through the FDA and the EU process? What have you learned over time?
Mr. Houck: Our Aclipse team has worked on twelve orphan drug programs previously. We have been in front of the FDA and EMA many times with many different types of drugs in a variety of orphan diseases. Most recently, we led the management team of Thar Pharmaceuticals, where we developed a molecule for the treatment of an orphan disease called Complex Regional Pain Syndrome. We took that molecule from inception into Phase 3 development when Grünenthal, a German pharmaceutical company, acquired us. Now we are applying our experience to new orphan disease projects at Aclipse.

CEOCFO: Has COVID stopped interest in what you are doing? Has it increased interest?
Mr. Houck: Covid slowed some aspects of development earlier in 2020. Now those delays have pushed their way through the system, and almost all activities are full steam ahead.

CEOCFO: Will the $2 million plus grant take you through or will you be needing more funds as you continue?
Mr. Houck: Our most recent grant of $2.2 million from the Medical Research Council in the UK, in addition to a $720,000 grant from the Australian ALS non-profit FightMND, and support from investors, will allow us to drive the M102 program into clinical trials. Beyond that, we plan to raise funds to drive M102 through additional clinical trials.

CEOCFO: Once you licensed the M102, what did you learn about it that might have you surprised you?
Mr. Houck: I believe that whenever there is a new biological understanding of a disease, you are pushing the frontiers of science and learning new things. In the case of M102, we are gaining better understandings of the genetics of ALS and the genetic profiles of the patients being targeted. We expect to learn much more as we continue drug development. For me, it is the new science that keeps one super engaged and excited, as you are understanding better the disease and how to help patients.

ALS is a devastating and life-threatening disease that has terrible consequences for patients. ALS patients have a 2-to-5-year life expectancy after diagnosis, so it is incredibly sad and challenging for patients and their families. Therefore, anything we can do to push forward the knowledge of the disease and its biology will help patients and the whole ALS community.

CEOCFO: What else are you looking at for Aclipse?
Mr. Houck: Our goal with Aclipse is to in-license a total of three orphan drug programs. M102 is the first of these three programs. We are currently reviewing potential second programs and are conducting due diligence.

CEOCFO: How many people in the US have ALS today?
Mr. Houck: Approximately 25,000 patients in the United States and 35,000 patients in Europe.

CEOCFO: How much easier is it in the EU to get it through to approval? When you are working on both the FDA and the EU approval processes at the same time, can they feed off one another or are they really two separate processes? Can you take some of the evidence that the FDA already cleared and show it to the EU and they are happy with it?
Mr. Houck: Absolutely! There can be differences between the FDA and Europe's EMA on how they view a disease, but both organizations are driven by science and the desire to help patients, so there is also a large overlap. One needs to understand the differences for the specific disease and conduct the clinical trials that aim to meet both organization's requirements. The data obtained in one geography will be used in another geography, and vice versa. Drug development is really a worldwide effort. A Phase 3 clinical trial is expected to be conducted in the US, EU, and certain other geographies.

CEOCFO: Are there new advances in trials that you are able to take advantage of or that might be particularly applicable for M102?
Mr. Houck: One of the recent advances in ALS is in the area of biomarkers, particularly for protein markers which indicate clinical effectiveness. The field of ALS biomarkers has grown substantially over the last five or more years. Such an advance allows us to better evaluate our drug's target engagement, dose and efficacy. Biomarkers are also employed to enable the precision medicine approach and identify potential patient responders to the drug.

CEOCFO: Why pay attention to Aclipse Therapeutics?
Mr. Houck: Aclipse Therapeutics is developing M102, a therapeutic which combines a broad disease approach to ALS with an innovative precision medicine approach to identify those ALS patients who could benefit most by the drug. Aclipse also plans to develop M102 to treat other CNS disorders such as Friedreich's Ataxia, Huntington's disease and Parkinson's disease.

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