

THE WALL STREET TRANSCRIPT

Questioning Market Leaders For Long Term Investors

Duska Therapeutics, Inc. (DSKA)



DR. JAMES S. KUO is Chairman of the Board and Chief Executive Officer of Duska Therapeutics, Inc. Previously, he was Chairman and Chief Executive Officer of BioMicro Systems, Inc., a private, venture-backed and profitable research tools company. While at BioMicro, he led distribution, marketing and sales of the company's MAUI™ product line. Prior to that time, Dr. Kuo was President, and Chief Executive Officer of Discovery Laboratories, Inc., where he raised over \$22 million in initial private funding and took the company public. Dr. Kuo is the former Managing Director of Venture Analysis for HealthCare Ventures, LLC, which managed \$378 million in venture funds. He has also been a senior pharmaceutical licensing and development executive at Pfizer, Inc., and Vice President of Business Development at Myriad Genetics, Inc. Dr. Kuo is a Board

Director of Monarch Labs, LLC, Chairman of the Board of DOR BioPharma, Inc., and a Board Director of Adeona Pharmaceuticals, Inc. After studying molecular biology and receiving his BA at Haverford College, Dr. Kuo simultaneously received his MD from The University of Pennsylvania School of Medicine and his MBA from The Wharton School of Business at the University of Pennsylvania.



DR. JONATHAN S. STAMLER is the George Barth Geller Professor for Research in Cardiovascular Diseases and a Professor of Medicine and of Biochemistry at Duke University Medical Center in Durham, North Carolina. Dr. Stamler completed his undergraduate studies at Brandeis University, earned his MD from Mount Sinai School of Medicine in New York City and completed his medical residency and fellowship training in both cardiology and pulmonary medicine at Harvard Medical School and the Brigham and Women's Hospital. Dr. Stamler joined the faculty of Harvard Medical School as Assistant Professor of Medicine in October 1993. In December 1993, he

joined the faculty of Duke University as an Associate Professor of Medicine. He was promoted to Professor in 1996. Dr. Stamler's work has centered on elucidating the fundamental roles of nitric oxide in controlling complex physiological responses through S-nitrosylation, a protein modification that he discovered. The ramifications of his work extend to all major classes of proteins: ion channels, receptors, G proteins, transcription factors, membrane trafficking proteins and numerous enzymes that are now known to be regulated by S-nitrosylation. Accumulating evidence suggests that protein S-nitrosylation is aberrant in many diseases. Additional discoveries by Dr. Stamler's group include the enzyme responsible for bioactivation of nitroglycerin, the ability of red blood cells to dilate blood vessels and a role for nitric oxide in the human respiratory cycle.

TWST: Please provide an overview on your company.

Dr. Kuo: Duska Therapeutics is a publicly traded biotechnology company that focuses on the clinical development of new cardiovascular medicines. Our proprietary technology is related to two very critical molecules in the human body. The first molecule is adenosine triphosphate or ATP, which is the energy molecule for all body functions. The second molecule is nitric oxide, otherwise known as NO, which is a key cellular signal transduction molecule. We are in the later stages of clinical trials with our drug candidates, which constitute new disease therapies.

early next year here in the US. However, of course, there is no guarantee of FDA approval.

TWST: So are you just getting a new indication of an approved or previously approved drug?

Dr. Kuo: In the case of ATPace, we're taking a drug very similar to those approved in Europe and bringing it to the US, so it's a different geographic market. ATP has never been approved as a drug in the United States. We already have compiled safety and efficacy data from Europe obtained from over more than 50 years of commercial use in Europe. There is very little likelihood, although

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TWST: What is your corporate strategy and would you comment on the product candidates you have?

Dr. Kuo: Our corporate strategy is to develop drugs for which there already exists a significant amount of human safety and efficacy data. Accordingly, we believe that our pragmatic approach decreases the risk of drug development, in contrast to other companies that are developing new chemical entities. As an example, our most advanced drug, called ATPace, is an intravenous formulation of ATP. We are developing ATPace for the termination of one of the most common heart arrhythmias seen by clinicians. A heart arrhythmia is an irregular heartbeat. Our disease target is known as paroxysmal supraventricular tachycardia, otherwise known as PSVT. The interesting aspect of our heart arrhythmia drug is that various formulations of ATP have been approved in Europe for over the past 50 years for the treatment of PSVT. It is the standard of care in Europe. We presented all this data to the FDA. Based on our communication with them, we believe that the results of a single Phase III clinical trial would suffice for the submission of an application for a marketing approval; i.e., an NDA. We expect to begin this Phase III trial

not guaranteed, that we're going to see anything different when we do our clinical testing in the US.

TWST: Will the Phase III trial be any different from a regular Phase III trial, noting that there is a related approved drug in Europe?

Dr. Kuo: That's an interesting question that we have received from others before. We have met with the FDA and presented them with all the clinical safety and efficacy data we have collected already to ascertain what they would require for approval. We had a face-to-face meeting with the FDA on April 16 of this year and we believe that the FDA will allow us to file for marketing approval following a single pivotal Phase III clinical trial of roughly 100 patients. Once again, when dealing with a regulatory agency there is no guarantee. All we have to do is show non-inferiority to the existing drug, otherwise known as adenosine, that's approved for this indication. So our single Phase III ATPace clinical trial will be a multi-center, prospective, placebo-controlled, double blind, randomized trial. It's a fairly small and simple trial and we should be able to start it soon.

TWST: How long do you expect the trial to last?

Dr. Kuo: The trial should only be about eight months or so to run. It's a fairly quick trial to enroll patients into and simple in that the drug is given in the emergency room of a hospital and within roughly two minutes you know whether the drug worked or not. There is no long period of drug dosing or follow-up. After discharge from the emergency room, we plan to follow-up with these patients the next day to make sure that they are doing fine. PSVT is an acute condition so no long-term drug dosing or follow-up is necessary. The objective of the treatment is to stop this heart arrhythmia and restore the patient to a normal heart rate. The physician would administer our drug and then observe whether the heart arrhythmia stops or not.

TWST: What about the NDA process? Will that be any shorter?

Dr. Kuo: Regarding the NDA process, we've actually made significant progress there as well. Based on discussions we have held with the FDA, we believe they will allow us to submit an NDA under section 505b(2). According to the provisions of this

believe they will. Then the NDA should move through approval, assuming positive results in the Phase III clinical trial. In general, we believe that the FDA is expediting the process for us to get this important drug on the market.

TWST: What are the shortcomings, if any, of the existing drugs in this area and what is so new about your approach?

Dr. Kuo: That's a great question. The existing approved drug for treating PSVT is called adenosine. Our drug is a proprietary formulation of injectable ATP called ATPace, which is adenosine triphosphate. One of the breakdown products of ATP is adenosine. For a long time, it was thought that ATP and adenosine were identical drugs for the treatment of PSVT. After further clinical studies were performed, adenosine was shown to be significantly less efficacious than ATP in terminating PSVT. Furthermore, we believe that ATP exhibits the same safety profile as adenosine so there are no additional side effects when using ATP over adenosine. That's why we are interested in bringing ATPace here to the US. We want to develop a more effective drug than what is currently approved in the US for the termination of PSVT.

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section, we'd be able to support our application not only with data generated by us in our Phase III clinical trial, but also data generated by others with a similar formulation, as well as relevant published data. We've already started drafting certain portions of the clinical safety and efficacy modules of the NDA. Obviously, we need to work toward the completion of the NDA, including adding the safety and efficacy data from our planned Phase III clinical trial. After finishing the CMC modules of the NDA, we can submit the completed NDA to the FDA for their review. We're planning to get a SPA agreement — that's called a Special Protocol Assessment — from the FDA, assuming they agree to our protocol, which we

TWST: What is the patient population that you are targeting and what is the estimated market size?

Dr. Kuo: The patient population is comprised of those patients who have a sudden onset of this rapid heartbeat known as PSVT. PSVT is an arrhythmia that people recognize they have because they may experience chest pains, a rapid heart rate of up to 200 beats per minute, and shortness of breath. These symptoms prompt a trip to the emergency room. If for whatever reason PSVT doesn't stop on its own, then our drug would be administered to the patient in the emergency room setting. We estimate the size of the potential market to be about \$65 million for our drug in the US annually.

TWST: What are some of your other candidates?

Dr. Kuo: As I mentioned before, we are also focused on nitric oxide. This is perhaps a good time for me to turn the discussion over to Dr. Jonathan Stamler to talk about the role of nitric oxide in heart failure. By way of a brief introduction, Dr. Stamler is a thought leader in the pathophysiology of heart disease, particularly as it relates to nitric oxide cell signaling. Dr. Stamler is the George Barth Geller Professor of Research in Cardiovascular Diseases and Professor of Medicine and Biochemistry at Duke University. He has conducted scientific studies that establish a ubiquitous role for nitric oxide in the regulation of protein function.

Dr. Stamler: There is a fair body of preclinical evidence and some clinical evidence to indicate that there is an inadequate amount of nitric oxide in heart failure. As a result, there is what we call a nitric oxide/redox disequilibrium. That's a fancy way of saying there is excessive "rust" or oxidation that occurs in the failing heart as a consequence of there not being enough nitric oxide to control heart function. Overall, the beneficial effect of nitric oxide is diminished in heart failure. One example of the benefit of nitric oxide was shown in a previous clinical trial with a drug called BiDil from a company called NitroMed. This trial of this nitric oxide-like generic compound resulted in a 43% decrease in all-cause mortality in heart failure patients in their trial. Duska's trial is designed to correct that nitric oxide-oxidant imbalance in the failing heart, that is, it is again a combination of drugs that are well tolerated and have known efficacies. This drug combination is designed to ameliorate or reduce the "rust" in the cardiovascular system, so that nitric oxide can be efficiently delivered in these patients.

TWST: What is the market for your heart failure product candidate?

Dr. Kuo: Heart failure is a major unmet clinical need in the US with over half a million new cases and 30,000 deaths each year. It is the single-largest Medicare expense. Our novel therapeutic strategy is to correct NO/redox disequilibrium in the failing heart by using two approved drugs. We are still working on the exact formulation and dosage for these drugs. One drug is a drug commonly used to treat a form of joint pain. Accumulating evidence suggests that this drug shows beneficial effects in heart disease. The other drug is a nitric oxide donor drug. We will use these existing drugs in our Phase II proof-of-concept studies, which we expect to begin early next year. The Phase III clinical trial is likely to be conducted with an optimized formulation of those two drugs

in a single pill given once a day. We are using two safe and efficacious drugs that have already been approved for different indications. We are just using them as a unique combination for the treatment of heart failure, one of the largest unmet clinical needs. It's a real shortcut in terms of the drug development process, yet the market potential is still tremendous. We can utilize all the safety and efficacy data that's already been generated with regard to the two approved drugs used in the combination.

TWST: How long will the Phase II trials last?

Dr. Kuo: Most likely, we will conduct a series of Phase II studies that address several clinical questions that we would like answers for. We are going to be looking at things like specific populations of heart failure patients who might optimally benefit from our drug combination. We will also look at different dosages as well to determine the optimal daily dose. These studies are going to be small and rapidly conducted. With this strategy, we expect a series of positive results that give us confidence that a larger Phase III study would be successful.

TWST: Is this going to be your future emphasis looking ahead for the company?

Dr. Kuo: We want to be a cardiovascular biotech company that has drugs on the market. When we look at other companies that fit this profile, their market capitalizations are fairly substantial. Companies like Medicines Company, CV Therapeutics and Cardione generally tend to have valuations of about \$500 million and I think that it is a very nice spot to occupy.

TWST: How will your drug be superior to the current new heart failure drugs?

Mr. Kuo: Because of the large and growing patient population with this disorder, heart failure has been the focus of a lot of attention by biotech companies. I think our therapeutic approach is vastly different from that of the other companies. Specifically, their me-too drugs treat heart failure by acting as diuretics or lowering blood pressure. They decrease the work the failing heart needs to do. These me-too drugs don't necessarily affect the heart directly — some do, but only to a partial extent. Our approach is different from most of the me-too drugs out there and in development in that we believe our drug directly works on the heart and fixes what is one of most the critical defects that causes heart failure. As Jonathan mentioned, the problem with heart failure is that the heart fails to contract properly because it "rusts." We are developing our combination drug therapy to prevent the "rust" and correct the contractility problem.

TWST: What are your business development plans, taking into consideration that you are about to embark on therapy that is so widely already recognized, on such a widely recognized disease, as well as your attitude toward partnership?

Dr. Kuo: I think that at some future point we would be very open to establishing partnerships with other companies. The profile of our drug candidates, the fact that they are at late stages of development and address larger markets will generate interest in corporate partnering. That being said, we're not actively trying to partner our drugs right now, for the reason that we think that there are some very pivotal events that we expect to occur with our two lead drugs over the next year. Accordingly, we think we will create a lot of value for our shareholders, assuming those clinical trials are started and completed as planned and yield positive results. So after those clinical trials are run, I think we would be much more open to partnership with another company.

TWST: What is a realistic picture of your company 12 to 24 months down the road?

Dr. Kuo: I expect in that time period that we will have finished our pivotal Phase III clinical trial and submitted an NDA under section 505b(2) for our ATPace program, which will generate a lot of value for shareholders. Regarding our heart failure program, we also expect that we will complete several Phase II clinical studies that we have planned, and will establish positive proof-of-concept for our drug combination. We have been working on an optimized formulation for our Phase III clinical trial in heart failure. I think with both those events occurring, there is the potential that you will see corporate partnerships on one or possibly both of these lead programs.

TWST: Have you received any overtures from companies as of now?

Dr. Kuo: Yes, we did receive one proposal from a biotech company, which our Board met to discuss and turned down. Despite not having a corporate partnering effort underway, we have been approached for partnerships and are in discussions with other companies. We'll see how those discussions go. We have no urgency to partner at this time on terms less than we think the value of our programs are at.

TWST: Will Dr. Stamler work exclusively on your heart failure drugs or will you be involved on a broad basis with the company as a consultant?

Dr. Stamler: My immediate focus is certainly the heart failure program. The company has some important expertise of its own in the area of ATP. Dr. Amir Pelleg, who is the Chief Scientific

Officer, is internationally recognized and extremely knowledgeable. However, I will help advise the company in all areas of cardiovascular biology and physiology.

TWST: Would you comment on your own expertise and give us a quick overview of your company's management expertise?

Dr. Stamler: My expertise is in cardiovascular medicine and in pulmonary medicine. I'm both a cardiologist and a pulmonologist and I practice in both areas. My scientific interest is in the area of nitric oxide biology and the oxidant or redox system. This collaboration is a perfect opportunity for these areas of interest of mine to play out with Duska's drug development expertise, so I'm very pleased to have this opportunity.

Dr. Kuo: The management team is composed of people who I would describe as veterans of the biotech industry. Each of us has a very successful track record. For myself, I am a physician from the University of Pennsylvania. I also have an MBA from the Wharton School of Business. I've been a Managing Director of Health-Care Ventures, a \$378 million biotech venture capital fund located in New Jersey. I've also been head of cardiovascular licensing and development at Pfizer, during which our group completed the licensing of Lipitor from Parke-Davis. Furthermore, I've been head of business development for Myriad Genetics in Salt Lake City. I did about five deals for them including sequencing of the rice genome. In addition, I have been a founder and CEO of other biotech companies. One in particular was Discovery Laboratories, which I started, became CEO, took the company public and raised \$22 million for. They are in the process of getting final approval for their life-saving drug for premature babies.

Amir Pelleg is our President and Chief Scientific Officer. He is an international expert in the area of ATP, as Jonathan mentioned, and so we can't be working with anyone better than him in my mind. He has also been on the team at Medco Research, a very successful biotech company that was sold for about \$350 million to King Pharmaceuticals. They successfully developed two cardiovascular products including adenosine, which is our competition. So he is highly familiar with adenosine. He has been a Professor at Drexel University College of Medicine. Wayne Lorgus is our Chief Financial Officer. He has a Wharton MBA and is a Certified Public Accountant. Previously, he has been an Arthur Andersen accountant and CFO of other companies.

TWST: Do you feel your company is as well understood in the financial markets as you'd like it to be?

Dr. Kuo: We're a micro-cap company and people are just starting to get to know about us. We need to make every effort to educate people about what we're doing. Right now, we are setting the stage with investors by laying out our drug development plans. As people find out about our progress, they'll realize its potential and get more involved with the company as long-term shareholders. So we're actively trying to get in front of the investment community at every opportunity to tell our story. We have a great story to tell.

TWST: What is the company's current burn rate?

Dr. Kuo: The company has a fairly minimal administrative burn rate. We basically operate as a virtual company. We have only three full-time employees. We outsource much of our regulatory activities. We work with Cato Research and Allen Cato, the head of Cato Research, has been personally involved in all of our communications

Dr. Kuo: Our Board is always monitoring the financial markets and considering how much to raise and when to raise it. I can't give you the precise amount and timing for it. I would generally expect it to be some time next year. I think some good milestones to key off a financing would be having both our drugs in clinical trials so that potential investors can see that we are making concrete progress toward getting our drugs approved.

TWST: When should investors expect the next piece of major news from your company?

Dr. Kuo: We have a whole series of press releases that we would expect to put out that are consistent with our drugs entering clinical trials. That is true of any company preparing to enter a pivotal Phase III clinical trial or proof-of-concept Phase II studies. You can look forward to those press releases as they are put out by us.

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with the FDA. So we really have a very minimal burn rate in terms of our administrative infrastructure. I feel that it's very important for the success of a biotech company to preserve cash by not having a lot of people and infrastructure. We have flexibility because we can shift our financial resources to other programs versus having a staff of people who may have only expertise in one area. And, we've also many times contracted out with universities to conduct research that we need done. We have worked with Yale University, University of Pennsylvania and several of the leading universities in Europe. We think that we get a lot more value working with universities than if we have had our own laboratories and researchers. In most cases, we are working with academic scientists who we feel are the world's experts in their particular field. So our administrative burn is fairly minimal yet we work with the top scientists and have lots of flexibility.

TWST: When do you expect to raise more capital and what will that amount be?

TWST: What else would you like to touch upon?

Dr. Kuo: In summary, the distinguishing features of our company are that first of all, we're working with international experts in cardiovascular medicine, particularly as it applies to ATP and nitric oxide pharmacology. I don't believe you can be a successful biotech company unless you're working with the leaders and experts in the field. The second point I'd like to make is that we're in later stages of clinical development. We're not preclinical or Phase I. We're ready to commence Phase III and Phase II trials for our lead drug candidates. The third point is that the markets we are targeting are very, very large in certain cases, such as with heart failure. That's important because those indications are the ones that the pipeline-starved major pharma companies are looking for. We want our drugs to target these large indications, so that we can explore doing partnerships in the future that are of high value to ensure significant return for our shareholders.

It has certainly been a pleasure to be able to tell your readers about the exciting new cardiovascular medicines in our pipeline. Tell them to stay tuned.

TWST: Thank you.

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