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Afraxis Delivers High-Content Central Nervous System (CNS) Pharmaceutical Screening Technologies to Evaluate Pre-Clinical Efficacy in Neurological Disorders with ESP Technology

Healthcare/Biotech CNS/Neurology

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Carmine Stengone President & CEO

BIO:

Mr. Stengone has more than 14 years of experience in the pharmaceutical and biotechnology industries, including positions in finance, strategic planning, corporate development, licensing, alliance management and venture funding. In his previous role as vice president of corporate development for Afraxis Holdings, Mr. Stengone led and executed a \$187.5 million license agreement with Roche's subsidiary, Genentech. After the transaction, Mr.

Stengone helped establish Afraxis, Inc. as a spin-out from Afraxis Holdings. Mr. Stengone also serves as chief business officer for Avelas Biosciences, an Avalon Ventures Portfolio VIII company. Prior to joining Afraxis. he was with Phenomix Corporation from 2006 to 2010, where he was responsible for strategic collaborations and licensing. He was also a member of the Phenomix executive management team as the senior director of business development. Mr. Stengone served as senior manager of business development and strategic marketing for Anadys Pharmaceuticals, Inc. from 2004 to 2006. Prior to that, Mr. Stengone held a variety of positions at Johnson & Johnson Pharmaceutical Research and Development.

Mr. Stengone received his MBA from Johnson Graduate School of Management at Cornell University. He also holds a M.S. degree in organic chemistry from Duke University and a B.S. in chemistry from Wake Forest University.

About Afraxis:

Afraxis, Inc. is a San Diego-based drug discovery platform company recently spun-out of Afraxis Holdings. The company is part of a growing wave of innovative neuroscience that applies cutting-edge technical and computational approaches to fundamental issues in brain science that promise to generate new insights into CNS diseases. Afraxis develops and uses high-content central nervous system (CNS) pharmaceutical screening technologies to evaluate pre-clinical efficacy for potential treatments for neurological and psychiatric disorders.

Afraxis developed the Enhanced Spine Platform (ESP) Technology platform, which quantifies the morphology and maturity of synaptic dendritic spines which are fundamental to information processing by neural synapses in the brain. Abnormal dendritic spine quantity and morphology have been associated with numerous CNS disorders, including schizophrenia, Alzheimer's disease. Fragile X syndrome and autism. Afraxis has a strategic alliance with PsychoGenics to offer its ESP Technology as part of PsychoGenics' comprehensive testing capabilities and drug discovery sci-

Interview conducted by: Lynn Fosse, Senior Editor CEOCFO Magazine

CEOCFO: Mr. Stengone, would you tell us the vision at Afraxis?

Mr. Stengone: Afraxis delivers a platform technology, ESP (Enhanced Spine Analysis Platform), which reads and interprets the fundamental building block of biological neural networks the synapse. Until the technology was developed by Afraxis, this information was unavailable to companies and organizations interested in accessing specific synaptic data to be used in a central nervous system drug discovery setting. We are able to provide input on how certain central nervous system disorders impact the brain and, more specifically, dendritic spines. Dendritic spines, which are the receptive ends of synapses, are related to specific high-level processes like learning and memory. In addition to evaluating dendritic spine abnormalities in animal model disease states, Afraxis can

investigate therapeutic/chemical manipulation in these CNS disease models, with a goal of testing a potential treatment's ability to reverse the disorder. Dendritic spine analysis has been looked at in academia for some time, but the work has been limited by time and capacity restraints. The speed and robustness of our analysis is something that the industry has not seen before.

CEOCFO: How are you able to do this? What is it that you have figured out that others have not so that you can provide this in depth level?

Mr. Stengone: Our scientific team has been working in this area, essentially for their entire career. They have built this platform from the ground-up and understand the nuances

in performing these analyses while increasing the throughput to incredible levels. For instance, when a typical analysis like this has been done in the past, the entire experiment would take anywhere from six to nine months and one would be limited to analyzing a few thousand dendritic spines. Using Afraxis' ESP Technology, we can provide analysis on over a million spines per month. And the system is completely scalable so we can seamlessly increase the capacity. We are also able to do much more

involved morphology characterizations than other methodologies, providing a more robust dataset than other groups had been able to provide in the past. Our partners have been ecstatic with the level of analysis and the speed with which it is performed. Using ESP. for the first time one can use dendritic spine measures in a drug discovery setting. **ESP** lends itself to assessments of drug efficacy and permits us to assess dosing windows and time courses of impact that otherwise would have been overlooked in preclinical testing. The pharmaceutical industry was forced to rely on animal behavior models for drug evaluation, despite a general acceptance that the behavioral models are not predictive for the human condition. Afraxis is able to look at the specific impact therapeutic compounds have on brain morphology

rather than looking at what are often times artifacts that occur in behavioral models. The real goal for Afraxis is to make drug discovery and drug development for potential therapeutics and central nervous system disorders more efficient.

CEOCFO: Does the portion of the medical community or the research community that should know about you; do they?

Mr. Stengone: We are still a relatively new company. Here is a little bit on the company background. Afraxis Holdings spun out Afraxis, Inc. in early April 2013. Afraxis Holdings was the parent company that was researching therapeutics; leading to a collaboration with Genentech-Roche in January 2013. The Genentech-Roche deal did

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not include the platform technology and we saw real value in continuing to advance the platform. There was strong pharmaceutical interest from companies as well as research organizations working in CNS diseases to access this technology. This led to the formation of Afraxis, Inc. as a spin-out from Afraxis Holdings. We announced our first collaboration as a new company within a week of forming the new organization. We signed a collaboration with Servier, a leading French pharmaceutical company, to incorporate our platform into their CNS drug discovery efforts. Prior to that, when we were still part of Afraxis Holdings, we actually did a number of smaller agreements which were not publicly announced. At this time, we are on the verge of a couple of larger scale collaborations. I think that people are still learning the However, Afraxis story. most

organizations working in the field and dedicated to finding cures for neurological disorders recognize the benefit and value that Afraxis can provide.

CEOCFO: What is the business strategy going forward? What will you be doing in the next six months to year or so to really get on the map?

Mr. Stengone: There are two different parts to the company. One is a "feefor-service" organization. Interested parties can access our expertise in dendritic spine analysis using ESP for specific disease or compound evaluations and we can turn around data very quickly in a typical fee-forservice setting. The other component is focused on collaborative research and development. We are willing to

bear risk on some discovery programs from other organizations and participate in future upside as the drug progresses through development. At this point we are trying to build our client base: executing on high potential collaborations and fee-forservice work in order to focus on top line growth.

CEOCFO: If you can do this so much faster and so much more effectively should it not just be a matter of time till your

organization is the standard? It seems to me from what you say, how could anyone not come to you?

Mr. Stengone: There will always be skeptics until the platform is firmly established as an industry standard. We try to alleviate the initial skepticism by offering collaborations with interested groups as pilot studies. We ask to be provided with a blinded compound or a blinded disease model; we do not need to know the specifics. Allow us to perform our analysis, completed at below market cost, and we will be able to give you a solid, meaningful data package. Taking this pilot study approach, we have found that repeat business is very high. Partners receive valuable data from that initial pilot study and are able to recognize how much value the ESP technology can add to their drug discovery efforts.

CEOCFO: Is Afraxis funded to do all that you would like?

Mr. Stengone: At this point, yes. We are adequately funded and, if we continue on our current path, we do not foresee a need for additional financing in the near future.

CEOCFO: Are there competing technologies that you are aware of that might duplicate what you are doing or bring a different way of looking at it with a similar result?

Mr. Stengone: Not that we have identified and I think that that is part of the Afraxis' value proposition. Other

groups have looked into dendritic spine analysis for CNS applications, but never with the throughput and the analysis capabilities that we are able to provide, as well as the speed to make it relevant in a drug discovery setting. With that in mind, there are a οf contract number research organizations that look to assist in drug development in the central nervous system arena, with complementary technologies to the Afraxis ESP technology. For instance, we have signed a collaboration with a group based out of New York called PsychoGenics. They offer a suite of

CNS drug discovery services; whether they are behavioral models or specific proprietary models that they have built in-house.

CEOCFO: Why should investors and people in the business community pay attention to Afraxis today?

Mr. Stengone:

We provide something that no one else can. We can make CNS drug discovery, in an otherwise very risky field – less risky. And we can do it faster and better than anybody else.



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