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(August 29th – originally sent as a fax on August 24th, 2008)

8/24/2008

Good Morning Jeff,

As per your instructions, I am summarizing the Kre-alkalyn stability data from the 8/20/08 fax and from our discussion for your legal people.

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Re: Kre-alkalyn stability data

Samples of Kre-alkalyn were tested at two independent laboratories: the Laboratory of Bio-inorganic and Bio-analytical Chemistry (Department of Analytical Chemistry) at Sofia University – St. Kliment Ohridsky, in Bulgaria; and Atlas Bioscience, Inc. in Tucson, Arizona. Both facilities used the Jaffe reaction for creatine-creatinine detection.

The Bulgarian laboratory used the Jaffe reaction quantitative, for the purpose of determining the amount of creatinine generated from any Kre-alkalyn degradation detectable at fixed time points (10 - 20 - 30 -, and 60 minute, respectively), under acetic pH conditions (1.2, 4.5, and 6.8, respectively). Multiple duplicated runs of Kre-alkalyn under these conditions generated data which indicated an average of approximately 12.5 micrograms (\pm 1.5 micrograms) of creatinine per every one-milligram* of creatine in the sample, irrespective of when the sample was assayed. This consistent finding suggests that any creatinine found was either, (a) co-existing in the Kre-alkalyn samples at the time of dissolution, or (b) was the result of self-limiting degradation which occurred rapidly, and before the first sampling (at 10 minutes), across the entire range of pHs tested. Given the static nature of the creatinine-data generated, the first explanation ('co-existing') would be the most logical assumption.

*(One milligram is equal to 1000 micrograms).

The Tucson laboratory used the Jaffe reaction to observe the reaction kinetics (the rate of any creatine-to-creatinine reaction). Creatine (buffered at pH 12) was subjected to degradation at physiological temperature, over the course of 120 minutes. Data indicated that the transformation proceeded very, very slowly with the first verifiable indication of creatinine's existence found at 3 minutes into the reaction. It is important to note that a kinetic study does not attempt to quantify the actual amount of creatine being converted.

Based upon the test results generated, Kre-alkalyn appears generally stable under physiological temperature, in a wide range of pHs.

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