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From: O'Brien Shawn SP
Sent: Thursday, November 11, 1999 3:28 PM
To: Richards Adam AB; Czupryna Michael MJ; Fitton Lesley LR; Mullen Jamie JA; Grant Tom T
 - WWRA; Bache Ricky RA
Cc: Birkett Geoff G; Hickey Michael MP; Beamish Don; Tugend Georgia GL; Brandreth, Tim; De
 Vriese, Geert; Duffy, Paul; Johnston, Alwyn; Lindstrom, Diane; Mackay, James; Nathan, Ivor;
 Sepelyak, Robert; Wong, James
Subject: Seroquel Bipolar/Mania TAMT presentation

Dear Team

I would like to thank the Mania team for their strong efforts in putting together the revised Mania plan in such a short period of time. We have been successful in convincing the TAMT the need to progress a more robust Global Mania plan.

Mike Czupryna has given you some feedback on the response from the TAMT, the key messages are;

- 1) The TAMT accepts that the current Mania PES is at high risk to deliver a mania label for USA.
- 2) That an integrated Global mania clinical/regulatory plan is required to ensure success for a sNDS in Bipolar/Mania as outlined in our proposal.
- 3) That increased funding in the neighbourhood of \$ 20 to \$ 25 million may be required to deliver a global successful plan.
- 4) That our plan needs to be finalised by using all internal & external resources available to us to ensure we have a plan that will deliver a competitive label in Bipolar/Mania.
- 5) That there is an urgency to get the Mania program going with a confident plan.
- 6) That the SET has expectations that Seroquel will need extra funding above current plans to deliver competitive data in order to secure sales of \$ 1 billion.
- 7) Please come with solid LCM plans that will enhance Seroquel value in psychosis and other areas of commercial attractiveness to the January TAMT.

The actions for the Mania team as I see them are;

- 1) Develop the Mania/Bipolar plan to a fully robust state for success.
 - use all customer market research (prescribers & regulators) we need to ensure that our TPP will deliver market share gains
 - ensure that our regulatory strategy fits the USA & EU (Japan ?) needs in the most efficient way
 - use all required expertise to ensure that the clinical program will deliver a positive outcome, and that all possible steps are taken to reduce the clinical risk for Seroquel, and that the studies are powered for success

The opportunity is there for us to deliver \$ 1 billion in Seroquel sales, and your Mania plan is a critical element of that success.

Shawn

