Data Supplement for Suppes et al., Maintenance Treatment for Patients With Bipolar I Disorder: Results From a North American Study of Quetiapine in Combination With Lithium or Divalproex (Trial 127), American Journal of Psychiatry (doi: 10.1176/appi.ajp.2008.08020189)

TABLE S1. Hazard Ratios for Time to Recurrence of a Mood Event Stratified According to Lithium or Divalproex and Rapid-Cycling Disease Course (Intent-to-Treat Population)[a]

Parameter	Any Mood Event
Lithium	
Quetiapine (N=131)	35
Placebo (N=134)	70
Hazard ratio (95% CI)	0.40 (0.27–0.61)
Divalproex	
Quetiapine (N=179)	28
Placebo (N=179)	93
Hazard ratio (95% CI)	0.25 (0.16–0.38)
Rapid-cycling disease course	
Quetiapine (N=153)	26
Placebo (N=165)	80
Hazard ratio (95% CI)	0.30 (0.19–0.46)
No rapid-cycling disease course	
Quetiapine (N=156)	37
Placebo (N=147)	83
Hazard ratio (95% CI)	0.32 (0.22–0.48)

[a] Recurrence was defined as initiation of an antipsychotic, antidepressant, mood-stabilizing agent other than lithium or divalproex, anxiolytic other than lorazepam, or any other medication to treat a manic, depressed, or mixed event; hospitalization for a manic, depressed, or mixed event; total score ≥20 on the Young Mania Rating Scale or Montgomery-Åsberg Depression Rating Scale at two consecutive assessments or at the final assessment if the patient discontinues; or discontinuation from the study by the patient if, according to the investigator, the discontinuation was due to a mood event (manic, depressed, or mixed).

TABLE S2: Summary of Secondary Efficacy Variables as Measured Prior to a Mood Event (ITT Population)

	Quetiapine + Lithium or Divalproex (N=310) Versus Placebo + Lithium or Divalproex (N=313)		
Outcome Measure	Estimated Difference	SE	p
Young Mania Rating Scale	–0.78	0.185	<0.0001
Montgomery-Åsberg Depression Rating Scale	–0.86	0.254	0.0008
Clinical Global Impression–Bipolar scale, severity of illness subscale	–0.14	0.039	0.0003
Clinical Global Impression–Bipolar scale, global improvement subscale	–0.05	0.094	0.5650
Positive and Negative Syndrome Scale, positive subscale	–0.18	0.093	0.0521
Sheehan Disability Scale[a] (observed case data)	–0.50	0.482	0.3017
Psychological General Well-Being Scale	1.12	1.004	0.2664

[a] The mean change in score from randomization up to but excluding the first assessment was analyzed using analysis of covariance. All other secondary efficacy outcomes were analyzed using repeated-measures mixed models.