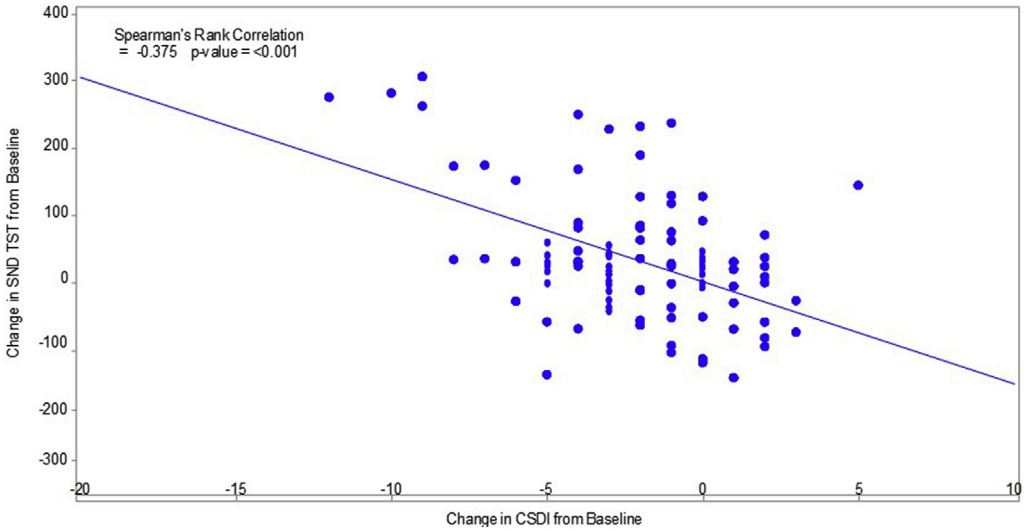
FIGURE S1 Relationship Between Change in Composite Sleep Disturbance Index (CSDI) Score and Change in Total Sleep Time (TST) Recorded in the Sleep and Nap Diary (SND)



Note: *Change was measured between baseline and 13 weeks of treatment, and a significant correlation was found.*

TABLE S1 Most Commonly Reported Serious Adverse Events (Safety Set)

	Double-blind phase (13 weeks)		Open-label phase (91 weeks)
	PedPRM group (n = 60)	**Placebo group (n = 65)**	**All participants (n = 95)**
Participants with at least 1 serious AE	15 (25.0%)	13 (20.0%)	24 (25.3%)
Serious AEs			
Agitation	6 (10.0%)	3 (4.6%)	0
Fatigue	4 (6.7%)	2 (3.1%)	4 (4.2%)
Mood swings	4 (6.7%)	5 (7.7%)	5 (5.3%)

Note: This table includes serious adverse events (AEs) reported by ≥5% patients in any group. PedPRM = pediatric prolonged-release melatonin.

TABLE S2 Most Commonly Reported Treatment-Emergent Adverse Events (AEs) (Safety Set)

	Double-blind phase (13 weeks)				Open-label phase (91 weeks)	
	PedPRM		Placebo		All PedPRM	
	Participants (n = 60)	Events	Participants (n = 65)	Events	Participants (n = 95)	Events
Participants with at least 1 TEAE	51 (85.0%)		50 (76.9%)		80 (84.2%)	
Total number of AEs		208		156		524
AEs reported by ≥10% participants						
Somnolence	17 (28.3%)	18	8 (12.3%)	8	24 (25.3%)	31
Rate of somnolence events per participant per 1 year of treatment[a]		1.2		0.49		0.19
Fatigue	15 (25.0%)	19	12 (18.5%)	13	25 (26.3%)	33
Rate of fatigue events per participant per 1 year of treatment[a]		1.27		0.8		0.20
Mood swings	10 (16.7%)	10	11 (16.9%)	12	17 (17.9%)	24
Rate of mood swings events per participant per 1 year of treatment[a]		0.67		0.74		0.14
Upper respiratory tract infection	9 (15.0%)	9	7 (10.8%)	8	14 (14.7%)	24
Vomiting	8 (13.3%)	11	10 (15.4%)	10	20 (21.1%)	33
Agitation	11 (18.3%)	12	7 (10.8%)	8	8 (8.4%)	10
Headache	8 (13.3%)	8	4 (6.2%)	4	12 (12.6%)	12
Cough	7 (11.7%)	7	5 (7.7%)	5	16 (16.8%)	27
Dyspnea	6 (10.0%)	6	4 (6.2%)	4	10 (10.5%)	10
Rash	3 (5.0%)	3	3 (4.6%)	3	10 (10.5%)	10

Note: PedPRM = pediatric prolonged-release melatonin; TEAE = treatment-emergent adverse event.

[a]*Rate = number of observed events for the entire group divided by 13 (double-blind) or 91 (open-label), which equals the number of events for the entire group by week. This value is divided by the number of participants in the group to provide the number of events per week per participant. The value is multiplied by 52 (weeks/year) to determine the number of events per year of treatment per participant.*

TABLE S3 Most Commonly Reported Treatment-Related Adverse Events (AEs) (Safety Set)

	Double-blind phase (13 weeks)				Open-label phase (91 weeks)	
	PedPRM		Placebo		All PedPRM	
	Participants (n = 60)	Events	Participants (n = 65)	Events	Participants (n = 95)	Events
Participants with at least 1 treatment-related AE	12 (20.0%)		11 (16.9%)		8 (8.4%)	
Total number of AEs		28		17		13
Rate of AEs per participant per 1 year of treatment[a]		1.87		1.05		0.078
AEs						
Somnolence	7 (11.7%)	7	2 (3.1%)	2	6 (6.3%)	6
Rate of somnolence events per participant per 1 year of treatment[a]		0.47		0.12		0.036
Fatigue	2 (3.3%)	4	3 (4.6%)	3	6 (6.3%)	8
Rate of fatigue events per participant per 1 year of treatment[a]		0.27		0.18		0.048
Mood swings	1 (1.7%)	1	4 (6.2%)	4	4 (4.2%)	4
Rate of mood swings events per participant per 1 year of treatment[a]		0.067		0.25		0.024

Note: This table includes AEs reported as treatment-related by ≥5% patients in any group. PedPRM = pediatric prolonged-release melatonin.
[a]Rate = number of observed events for the entire group divided by 13 (double-blind) or 91 (open-label), which equals the number of events for the entire group by week. This value is divided by the number of participants in the group to provide the number of events per week per participant. The value is multiplied by 52 (weeks/year) to determine the number of events per year of treatment per participant.