

	Scenario A: America First-FDA Total N=200	<i>Aiming for 2 successful Phase 3 Trials 1 & 2 for FDA (N=100 each, effect size medium or large)</i>				
	Chart 7. MDMA/PTSD Phase III Cost Projections					
	Phase III MDMA/PTSD Research Projects	Projected 2017-18	Projected 2018-19	Projected 2019-20	Projected 2020-21	
	End-of-Phase-2 Meeting w/ FDA					
	GMP MDMA Supply	\$ 309,275	\$ 12,000	\$ 12,000		
	GMP MDMA Packaging & Distribution	\$ 382,000				
	MDMA Therapist Training-Protocol (MT-1)	\$ 128,512	\$ 75,000			
	Human Abuse Liability study		\$ 500,000 [1]	\$ 500,000		
	Pharmacokinetics and QT studies		\$ 458,717	\$ 458,717		
	MDMA Literature Review	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	
	MDMA Therapist Adherence Criteria	\$ 20,000	\$ 20,000			
	Phase 3 Therapist Training	\$ 212,240	\$ 78,660			
	Phase 3 Program General	\$ 321,452	\$ 334,310	\$ 347,683	\$ 361,590	
	Clinical Research General	\$ 182,256	\$ 189,546	\$ 197,128	\$ 205,013	
	Preclinical Toxicity Studies			\$ 1,000,000 [2]		
	Clinical Trial Management System	\$ 38,022	\$ 71,229	\$ 41,229	\$ 41,229	
	Electronic Trial Master File	\$ 17,880	\$ 17,880	\$ 17,880	\$ 17,880	
	Phase III Trial 1 (N~30 supervision)	\$ 1,215,476			\$ 11,964,08	
	Phase III Trial 1 (N=100 treated, US)	\$ 2,156,397	\$ 3,011,761	\$ 400,434		
	Phase III Trial 2 (N=100 treated, US)		\$ 3,116,096	\$ 1,992,402		
	NDA Process			\$ 354,060.00		
	Overhead (10% Allocation for Projected)	\$ 448,980.25	\$ 737,134.30	\$ 478,672.20	\$ 6,910.90	
	Total Phase III MDMA/PTSD Research	\$ 5,442,490.56	\$ 8,632,333.37	\$ 5,810,205.12	\$ 642,622.93	
	Total Phase III Projected Costs	\$ 20,527,651.98				
	Scenario B - America First Plus -FDA OR FDA/EMA Total N=300	<i>Aiming for 2 successful Phase 3 Trials 1 & 2 For FDA (N=150 each, effect size medium or less) OR 2 successful Phase 3 Trials 1 & 2 for FDA (N=100 each, effect size medium or large) and 1 successful Phase 3 Trial 1 for EMA (N=100 each, effect size medium or large)</i>				
	Chart 7. MDMA/PTSD Phase III Cost Projections					
	Phase III MDMA/PTSD Research Projects	Projected 2017-18	Projected 2018-19	Projected 2019-20	Projected 2020-21	
	End-of-Phase-2 Meeting w/ FDA					
	GMP MDMA Supply	\$ 309,275	\$ 12,000	\$ 12,000		
	GMP MDMA Packaging & Distribution	\$ 382,000				
	MDMA Therapist Training-Protocol (MT-1)	\$ 128,512	\$ 75,000			
	Human Abuse Liability study		\$ 500,000 [3]	\$ 500,000		
	Pharmacokinetics and QT studies		\$ 458,717	\$ 458,717		
	MDMA Literature Review	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	
	MDMA Therapist Adherence Criteria	\$ 20,000	\$ 20,000			
	Phase 3 Therapist Training	\$ 212,240	\$ 78,660			
	Phase 3 Program General	\$ 321,452	\$ 334,310	\$ 347,683	\$ 361,590	
	Clinical Research General	\$ 182,256	\$ 189,546	\$ 197,128	\$ 205,013	
	Preclinical Toxicity Studies			\$ 1,000,000 [4]		
	Clinical Trial Management System	\$ 38,022	\$ 71,229	\$ 41,229	\$ 41,229	
	Electronic Trial Master File	\$ 17,880	\$ 17,880	\$ 17,880	\$ 17,880	

Phase III Trial 1 (N~30 supervision)	\$	1,215,476						
Phase III Trial 1 (N=150 treated, US)	\$	2,132,470	\$	3,970,130	\$	1,174,323		
Phase III Trial 2 (N=150 treated, US)			\$	2,951,530	\$	4,426,775	\$	90,150
NDA Process							\$	354,060
Overhead (10% Allocation for Projected)	\$	443,589	\$	827,603	\$	783,805	\$	71,833
Total Phase III MDMA/PTSD Research	\$	5,413,172.44	\$	9,516,605.28	\$	8,969,540.11	\$	1,151,755.24
Total Phase III Projected Costs	\$	25,051,073.07						
Scenario C: America First Plus FDA & Europe/EMA Total N=450	<i>Aiming for 2 successful Phase 3 Trials 1 & 2 for FDA (N=150 each, effect size medium or less and one Phase 3 Trial for EMA (N=150, effect size medium or less)</i>							
Chart 7. MDMA/PTSD Phase III Cost Projections								
Phase III MDMA/PTSD Research Projects		Projected 2017-18		Projected 2018-19		Projected 2019-20		Projected 2020-21
End-of-Phase-2 Meeting w/ FDA								
GMP MDMA Supply	\$	309,275	\$	12,000	\$	12,000		
GMP MDMA Packaging & Distribution	\$	382,000						
MDMA Therapist Training-Protocol (MT-1)	\$	128,512	\$	75,000				
Human Abuse Liability study			\$	500,000 [5]	\$	500,000		
Pharmacokinetics and QT studies			\$	458,717	\$	458,717		
MDMA Literature Review	\$	10,000	\$	10,000	\$	10,000	\$	10,000
MDMA Therapist Adherence Criteria	\$	20,000	\$	20,000				
Phase 3 Therapist Training	\$	212,240	\$	78,660				
Phase 3 Program General	\$	321,452	\$	334,310	\$	347,683	\$	361,590
Clinical Research General	\$	182,256	\$	189,546	\$	197,128	\$	205,013
Preclinical Toxicity Studies					\$	1,000,000 [6]		
Clinical Trial Management System	\$	38,022	\$	71,229	\$	41,229	\$	41,229
Electronic Trial Master File	\$	17,880	\$	17,880	\$	17,880	\$	17,880
Phase III Trial 1 (N=33 supervision)	\$	1,215,476						
Phase III Trial 1 (N=150, US)	\$	2,132,470	\$	3,970,130	\$	1,174,323		
Phase III Trial 2 (N=150, US)			\$	2,951,530	\$	4,426,775	\$	90,150
Phase III Trial 3 (N=150, EMA)			\$	209,800	\$	5,147,033	\$	4,076,878
NDA Process							\$	354,060
Overhead (10% Allocation for Projected)	\$	446,588	\$	837,495	\$	1,278,796	\$	459,020
Total Phase III MDMA/PTSD Research	\$	5,416,171	\$	9,736,297	\$	14,611,564	\$	5,615,820
Total Phase III Projected Costs	\$	35,379,851						

[1] Research Scientist:
moved forward based on planned pre-NDA meeting in 2020 per SPA response

[2] Research Scientist:
moved up one year due to planned pre-NDA meeting in 2020 per SPA response

[3] Research Scientist:
moved forward based on planned pre-NDA meeting in 2020 per SPA response

[4] Research Scientist:
moved up one year due to planned pre-NDA meeting in 2020 per SPA response

[5] Research Scientist:
moved forward based on planned pre-NDA meeting in 2020 per SPA response

[6] Research Scientist:
moved up one year due to planned pre-NDA meeting in 2020 per SPA response