Rick Doblin, Ph.D.

Building a Sustainable Non-Profit through MDMA Research

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MAPS' Sustainability Plan (MSP) is intended to communicate to MAPS' donors that their support helps to develop MDMA-assisted psychotherapy into a legal prescription treatment for PTSD, while also empowering MAPS to fulfill our rare opportunity to become a sustainable non-profit.

Unlike most non-profit organizations, MAPS' mission to develop psychedelics and marijuana into FDA-approved prescription medicines is explicitly intended to result in the sale of products, initially MDMA for PTSD and for other "off-label" uses. Through such sales, MAPS could generate funds for further research, relying to a substantial extent on earned mission-related income to sponsor research into the risks and benefits of other potential medicines such as LSD and the marijuana plant. We've used conservative assumptions in the MSP since it is intended not as a precise estimate but rather as an initial reality check on the concept.

We're seeking venture philanthropists, not venture capitalists. From a social perspective, it seems healthier for MDMA to be distributed by a not-for-profit that can take into account factors other than just maximizing income: factors like the quality of therapists, the effectiveness and efficiency of the treatments, the careful integration of MDMA and psychedelic psychotherapy into our society in a manner than avoids backlash, and the maximization of the social utility of MDMA that comes from reasonable pricing.

Making our sustainability plan public is part of our overall prioritization of transparency. If any other company, non-profit or for-profit, decides on the basis of our income projections that they want to start developing MDMA-assisted psychotherapy into a legal prescription treatment to be first to market before MAPS, we welcome them to the field. An essential part of MAPS' mission is to open the door for the full cornucopia of prescription psychedelic medicines. The more research underway, the sooner that part of our mission will be realized and the closer we will be to the full mainstreaming of psychedelic experiences in our culture and laws.

INTRODUCTION

The MAPS Sustainability Plan (MSP) illustrates how MAPS intends to build a sustainable long-term income stream from prescription sales of MDMA to support MAPS' mission. These income projections are not intended to be used to seek investors in MDMA/PTSD research. Rather, they are intended to further motivate donors to support the development of MDMA-assisted psychotherapy for PTSD into a legal prescription treatment, thereby generating income to further fund MAPS research into MDMA, other psychedelics, and medical marijuana.

Major milestones to reach the start of the MSP include:

1. Completion by 2016 of Phase II studies of MDMA-assisted psychotherapy in subjects with chronic, treatment-resistant PTSD.

2. $18.6 million raised for Phase II and III studies for MDMA-assisted psychotherapy in subjects with chronic, treatment-resistant PTSD—of which over $5.3 million has already been raised.

3. Completion by early 2021 of Phase III studies of MDMA-assisted psychotherapy in subjects with chronic, treatment-resistant PTSD.

4. FDA approval in late 2021 for the prescription use of MDMA-assisted psychotherapy in treating PTSD and start of 5 year period of marketing and data exclusivity during which time our data cannot be used by any other entity as the basis for selling MDMA on a generic basis.

5. Government and/or private sector insurance provides reimbursement for the expense of the treatment.

OVERALL RESULTS

Key variables include annual number of prescribers, annual number of patients treated, sales price of MDMA, and production costs of MDMA. The MSP is based on conservative estimates and is projected to generate net income of $9.2M per annum at the end of the five year data exclusivity period. Due to the one year or more processing time required by FDA to approve a generic medication, it is likely that the MSP will generate additional net income of $11.2M at the end of the sixth year of operation. In total, the cumulative net income from the project is projected to be $23.4M over five years and $34.7M over six years. At the end of that time, new competitive factors are likely to emerge in the form of generic competition. Starting in year 7, competitive pressures are projected to reduce pricing by 50% going forward. The following table summarizes the projected proceeds from the MSP over a 10-year period.

REVENUE DRIVERS

MARKET SIZE

PTSD Patients: The National Comorbidity Survey Replication (NCS-R), conducted between 2001–2003, estimated that current past year PTSD prevalence from all causes was 3.5% among adults over 18, who comprise 76.5% of the population in 2012 according to the US Census. Assuming a population of 300 million, there are 7.91 million people every year with PTSD to some degree. If MAPS were to solely focus on PTSD caused by Combat and Cancer treatment, by way of illustration but which we are not going to do, after 5 years we would serve 27,000 or 3.5% of the total Combat and Cancer-related PTSD market. The table below shows the current PTSD market data for these segments and the anticipated growth of MDMA-assisted psychotherapy treatment expected over a 10 year period. This part of the MSP is using conservative estimates for therapists trained and patients treated. There will also be prescription sales to treat patients with PTSD from other causes and off-label prescription to other patient groups which we are not estimating.

Therapists: The primary constraint on serving a larger proportion of the market is MAPS' ability to train qualified psychiatrists and psychotherapists in administration of the protocol. There are an estimated 50,000 psychiatrists and 93,000 psychotherapists, (total 143,000) currently practicing in the United States alone. The VA has already trained over 6,000 of its therapists in evidence-based psychotherapies for PTSD. MAPS is projecting that it will train 300 net new therapy providers each year accounting for a 5% attrition rate. This will result in a total of 1,500 therapy providers at the end of 5 years or 3,000 trained MDMA therapists at the end of 10 years. The following table shows the estimated number of practicing therapists and the percentage of primary trained therapists in MDMA-assisted

Net Profit ($1,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Income	4,283	6,428	9,723	13,019	16,314	19,676	12,306	13,982	15,657	17,332
Expenses	3,148	4,129	5,097	6,510	7,021	8,383	9,227	10,227	10,493	11,394
Net Profit	1,134	2,299	4,627	6,508	9,293	11,293	3,079	3,755	5,164	5,938
Cumulative Net Profit	1,134	3,433	8,060	14,568	23,861	35,154	38,234	41,988	47,152	53,090

PTSD Market Data (in ,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Est. PTSD Market Size (non Combat/Cancer)	7,096	7,160	7,169	7,176	7,183	7,190	7,196	7,202	7,207	7,211
PTSD (Combat)	260	247	235	223	212	201	191	182	172	164
PTSD (Cancer)	554	558	562	566	570	574	578	582	586	590
Total Market Size	7,910	7,965	7,965	7,965	7,965	7,965	7,965	7,965	7,965	7,965
Total Patients Treated	5.40	10.80	16.20	21.60	27.00	32.40	37.80	43.20	48.60	54.00
% of Market	0.1%	0.1%	0.2%	0.3%	0.3%	0.4%	0.5%	0.5%	0.6%	0.7%

psychotherapy over a 10 year horizon. In addition to the primary therapists, we also estimate that we'll train 75 co-therapists per year in MDMA-assisted psychotherapy. These co-therapists assist the primary therapists in treatment but do not themselves offer MDMA-assisted psychotherapy on a stand-alone basis. Other co-therapists will be selected and trained by the primary therapists and could include nurses, social workers, students and interns. Some of these other co-therapists themselves will eventually become trained by MAPS in order to become primary therapists with approval to prescribe.

These estimates of numbers of therapists able to prescribe MDMA post-approval do not include any therapists trained to prescribe as a result of possible FDA approval of Expanded Access. FDA's program of Expanded Access is for drugs that treat serious and life-threatening illnesses in patients who are treatment-resistant to currently available therapies, criteria that MDMA-assisted psychotherapy for subjects with chronic, treatment-resistant PTSD can reasonably meet. Should it be granted, patients can pay the costs of receiving treatment outside of our Phase 3 studies but MAPS cannot make a profit and cannot slow down our Phase 3 studies. We will be applying for Expanded Access at our End-of-Phase 2 meeting sometime in 2016. If Expanded Access is granted, we'd be able to start training therapists to provide therapy at cost for 5 years while simultaneously conducting our Phase 3 studies. Once FDA approval is granted for prescription use, we'd be starting with a group of therapists with the training to prescribe MDMA that is well over 300 people, the estimate we're using in this MSP of the number of therapists that can treat patients in the first year that MDMA is an approved prescription medicine.

Revenue Sources: The MSP assumes two revenue sources—the sale of MDMA to licensed practitioners and training in the administration of MDMA therapy. Both revenue streams are highly dependent on the number of trained practitioners providing MDMA-assisted psychotherapy. The primary source of revenue is the recurring sale of MDMA to licensed practitioners. Training is assumed to be a one-time source of revenue from therapists at this time—yet as time passes and new techniques are developed additional types of trainings may be added. Estimated revenues for both sources are displayed in the table below. A third revenue source will come from MAPS owning and operating a network of treatment clinics to set the standard of care in the field. We've not yet modeled this revenue source due to the complexity of the analysis but will do so before the end of 2014.

MDMA Sales: As noted, the primary source of income is the sale of MDMA by MAPS to therapy providers. The incremental quantity of MDMA sold is related to the average dose per session, average number of MDMA-assisted therapy sessions per patient treated, and of course the actual price of the drug itself.

Practicing Therapists	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
US Based Psychiatrists & Psychotherapists	143,000	143,000	143,000	143,000	143,000	143,000	143,000	143,000	143,000	143,000
MDMA Trained Psychiatrists & Psychotherapists	300	600	900	1,200	1,500	1,800	2,100	2,400	2,700	3,000
% of Practicing Psychiatrists & Psychotherapists	0.2%	0.4%	0.6%	0.8%	1.0%	1.3%	1.5%	1.7%	1.9%	2.1%
MDMA Trained Co-Therapists	75	150	225	300	375	450	525	600	675	750

Revenues	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Drug Sales	2,970	4,995	8,235	11,475	14,715	18,023	10,598	12,218	13,838	15,458
Training	1,313	1,433	1,488	1,544	1,599	1,654	1,709	1,764	1,819	1,874
Total Sales	4,283	6,428	9,723	13,019	16,314	19,676	12,306	13,982	15,657	17,332

For an individual patient, the MDMA-assisted therapeutic protocol assumes that each session will have an initial dose of 125 mg as well as a supplemental dose of 62.5 mg administered 1 ½ to 2 ½ hours after the initial dose. The protocol further assumes that patients will, on average, have 3 MDMA-assisted therapeutic sessions in total. Finally, the price of the MDMA per session is currently estimated to be $150 per session (initial dose plus supplemental dose). A review of historical drug pricing indicates that MAPS is likely to have significant upward flexibility in its pricing strategy should it choose to exercise that option since the cost of MDMA is only a small fraction of the cost of the therapists.

The total amount of MDMA sold will be dependent on the total number of therapy providers offering treatment as well as the number of patients they can see over the course of any given year. As previously mentioned, it is assumed that the number of therapy providers will grow to a total of 1,500 over 5 years. It is also assumed that we'll train 75 co-therapists per year who will pair with other trained therapists. The remaining 225 therapy providers trained per year without a co-therapist who has also been trained by MAPS will each select an intern/student as a co-therapist who has not yet gone through the training. Some of these intern/students will eventually become trained by MAPS to be lead therapists, such that there would be 1500 co-therapist teams at 5 years and 3000 teams at 10 years. This is another conservative assumption since many therapists may choose to work alone rather than in pairs, though our model is a male/female co-therapist team.

Each co-therapist team will treat an average of 18 patients per year or 6 patients at any given time. With each patient receiving three MDMA-assisted therapeutic sessions per treatment plan, MAPS total revenue per therapist team per year will average $8,100 at an average price of $150/session. At the end of five years, it is estimated that MDMA sales will total $14.7M/annum. At the end of 6 years, that will amount to $18 million. We estimate that the data exclusivity will in practice last 6 years since generic manufacturers cannot file for approval for generic sales until the five year data exclusivity period is over and FDA review and processing time is about 12–18 months.

Therapist Training & Credentialing: As part of the treatment process, therapists are required to undergo a 10 day intensive training program which will culminate with a MAPS MDMA-assisted psychotherapy credential required for prescribing authority. The price of this training is anticipated to be $3,500 and MAPS estimates that it will train approximately 300 new primary therapists per year and 75 co-therapists as well as replace exiting therapists (estimated at 5% churn/annum). The total revenue derived from therapist trainings is estimated to be roughly $1.3M in the first year rising to $1.52M in the fifth year. The increase in revenue is driven by the rate of churn—i.e. therapist attrition rate. As a proportion of total revenue, trainings represent just under 8% of total revenue by the 5th year of operations. The table below shows training-derived revenue over the forecast period.

Therapist Income (Non-MAPS Revenue): Based on a treatment protocol of no more than 6 patients at any given time, the 15 week protocol requires therapists to put in an average work week of just less than 15 hours per week. The amount of time required varies depending on the stage that the patient group is at and can run as high as 21 hours/week. For reference purposes, an actual MDMA-assisted therapeutic protocol has a duration of 39 hours and includes 3 eight hour MDMA

Therapist Training Revenue ($,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Therapist Training Revenue	1,313	1,365	1,418	1,470	1,523	1,575	1,628	1,680	1,733	1,785

Expenses	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Drug Costs	1,075	1,541	2,165	3,015	3,295	4,032	4,737	5,457	5,267	5,879
Training Costs	518	645	669	694	718	743	767	791	816	840
Marketing	150	300	450	600	750	900	1,050	1,200	1,350	1,500
Admin	1,405	1,643	1,812	2,202	2,258	2,709	2,673	2,779	3,060	3,176
Total Expenses	3,148	4,129	5,097	6,510	7,021	8,383	9,227	10,227	10,493	11,394

-assisted psychotherapy sessions three to five weeks apart along with about 12 non-drug psychotherapy sessions for preparation and integration, each lasting between 60-90 minutes. With an assumed average reimbursement rate of $200/hour/therapy team, total therapist revenue is estimated at $7,800/patient. This creates an average income stream of $140,000/therapist team per year. MAPS believes this will be highly competitive from a remuneration perspective.

It is also anticipated that government and private insurance providers will react favorably to this treatment protocol as it represents a significant cost reduction compared with PTSD disability payments. For example, the average annual cost to the VA for a veteran receiving disability payments for PTSD is $20,000 per year. In 2012, there were an estimated 275,000 vets receiving disability payments for a total of $5.5 billion per year in PTSD disability payments, with this number increasing every year.

EXPENSE DRIVERS

The MSP plan expenses are loosely divided into four groups: Drug Costs, Training Costs, Marketing Costs, and Administrative Costs. Total annual expenses are projected to grow to $6.5M at the end of 5 years. The cost of manufacturing, encapsulating, and distributing the MDMA to licensed therapists is the largest cost center ($3.3M). Administrative costs ($2.3M) are the second largest cost center. The need for highly trained personnel to oversee and grow the operation from day one comprises the bulk of these costs. After that, Training ($.7M) and Marketing ($.2M) make up the balance of the expenditures.

Drug Costs: Drug costs consist of GMP certified manufacture of MDMA, encapsulation, and distribution costs. The total cost per kilogram in the first year of operations is estimated at $289,601 or $54.30 per dose. These costs are subject to economies of scale even in the first year as the estimated end to end cost for a single kilogram is actually $340,000 or $63.75/dose.

MDMA Costs	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Kilograms Sold	3.71	4.07	8.12	12.17	16.22	20.27	24.32	28.37	32.42	36.47
Production Cost (per kg)	178,500	151,725	128,966	128,966	109,621	109,621	109,621	109,621	93,178	93,178
Encapsulation Cost (per kg)	106,250	90,313	76,766	76,766	65,251	65,251	65,251	65,251	55,463	55,463
Shipping	4,851	4,803	4,614	4,432	4,257	4,090	3,928	3,774	3,625	3,482
Total Cost (per kg)	289,601	246,840	210,346	210,164	179,129	178,962	178,800	178,646	152,266	152,123
Cost/Dose	54.30	46.28	39.44	39.41	33.59	33.56	33.53	33.50	28.55	28.52

Admin Costs ($,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Total Payroll & Benefits	1,108	1,313	1,380	1,645	1,706	1,971	2,105	2,167	2,391	2,459
Communications (Phones, Internet)	32	48	73	98	122	148	92	105	117	130
Occupancy	53	63	70	84	88	102	109	112	123	130
Office Equipment & Supplies	81	38	53	83	77	83	79	77	81	79
Travel & Entertainment	54	80	122	163	204	246	154	175	196	217
Other Admin	16	24	36	49	61	74	46	52	59	65
Total Admin Costs	1,344	1,566	1,733	2,121	2,258	2,622	2,585	2,688	2,966	3,079

Training Costs ($,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Trainers	362	466	484	501	519	536	554	571	589	606
Training Space	63	81	84	88	91	94	97	100	103	106
Materials	94	98	101	105	109	113	116	120	124	128
Total Training Costs	518	645	669	694	718	743	767	791	816	840

Marketing Costs ($,000's)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Marketing	150	300	450	600	750	900	1,050	1,200	1,350	1,500

This cost is based on an actual bid obtained by MAPS from a Canadian manufacturer. We're currently negotiating with a German company for roughly half the price, but we have not yet signed a contract. By the 5th year the cost per kilogram is expected to be reduced to $179,129 per kilogram or $33.59 per dose. The table on page 23 illustrates MAPS' estimated manufacturing and distribution costs on a per kilogram basis as well as the resultant cost per dose. Costs are assumed to decline as volume increases during the initial years with a flattening of costs starting in 2026 as volume growth percentage slows.

Administrative Costs: Administrative costs primarily consist of salaries and benefits (75% of total administrative costs by 2025). The balance of the costs is distributed across general overhead—office expenses, travel, communications, supplies and equipment, etc…The table on page 23 illustrates the projected administrative cost structure over the 10 year projected horizon. Certain costs, such as Communications and Travel and Entertainment, are capped after reaching a certain level as the growth of these costs is not assumed to be proportional to revenue growth after a certain period.

Training Costs: Training expenses include the cost of trainers ($12,000/training), the training venue ($2,500/venue) which is held at a clinical site, and materials ($250/therapist). The trainings are 80 hours in length over a period of 10 days. Trainings are held quarterly and on a regional basis. Each cohort has a maximum size of 12 therapists and is led by a MAPS-certified MDMA therapist trainer. Each therapist is provided with course materials covering the training and current clinical research literature on MDMA/PTSD therapy. Each therapist who successfully completes the training will also receive $500 in initial marketing support—see the marketing budget above.

Marketing Costs: Marketing costs are driven by the number of new therapists added each year. The intent of marketing expenses is to provide basic support to enable new therapists to advertise their availability to provide services to the community. Marketing expenses are estimated at $500/new therapist trained and include the provision of marketing materials detailing the therapy and its prospective benefits.

CLOSING THOUGHTS

The completion of Phase II studies and the implementation of Phase III studies over the next few years will help refine the assumptions presented above and provide additional data which may lead to further improvements in the therapeutic model currently being used in MAPS' clinical trials. The model attempts to make allowances for potential improvements by using highly conservative pricing (sale of MDMA), production (cost of MDMA production and distribution), and therapist adoption rate assumptions. In addition, the model assumes that the eventual loss of exclusivity will have an immediate and dramatic effect on the MSP's revenue stream from the seventh year forward. Overall, the MAPS staff believes that the assumptions are a conservative estimate of the potential that lies ahead for MDMA-assisted psychotherapy.

Nonetheless, we would be remiss in not seeking out the input and comment of others who are also well versed in the details of various aspects of the proposed plan. To that end, MAPS would like to solicit comments and suggestions at **sustainability@maps.org**. It is our hope that the thoughtful contributions of others will help hasten the day when MDMA-assisted psychotherapy becomes a reality and that the damage done by PTSD can be treated more successfully and at a lower long-term cost than is currently the case.