Market Assessment and Commercialization Strategy for MBapp+

By

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B.S. Biology, B.A Biochemistry, University of Washington, 2024

Thesis

Submitted in partial fulfillment of the requirements for the Degree of Master of Science in the Graduate Program of Biotechnology at Brown University

PROVIDENCE, RHODE ISLAND

February 2026

This thesis by Saloni Taneja is accepted in its present form by the Graduate Program in Biotechnology as satisfying the thesis requirements for the degree of Master of Science

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Acknowledgements

I would like to express my deepest gratitude to the Brown University Biotechnology Master's Program for providing an environment that has encouraged both intellectual growth and professional development. This program has allowed me to merge my interests in science, healthcare, and business, and has equipped me with the knowledge and confidence to pursue innovation at the intersection of these fields. The community I have found here has been invaluable to both my academic and personal journey.

I want to thank Dr. Adam Lewkowitz for his guidance, mentorship, and unwavering support. I am honored to have had the opportunity to contribute to this project under his leadership. His expertise and vision in advancing maternal health have shaped this work from its earliest stages, without which this thesis would not be possible. To the whole team at Women and Infants Hospital, you have been amazing to work with.

I would also like to extend my sincere appreciation to all the faculty in the Biotechnology Program for their dedication to fostering curiosity, critical thinking, and innovation. The coursework and conversations throughout this program have significantly shaped my development in the field. I am especially grateful to our program director, Dr. Jacquelyn Schell, for being so accessible and providing guidance and support every step of the way. I would like to give a special thank you to Dr. Yong Jong and Dr. Adam Crego for generously serving on my thesis committee and for their help and encouragement.

Finally, I would like to thank my family, especially my parents, for their endless love, patience, and encouragement. Their belief in me has been the foundation of every step in my journey and I could not have accomplished this without their constant support and inspiration.

Table of Contents

Table of Figures

Table of Tables

Abstract of Market Assessment and Commercialization Strategy for MBapp+, by Saloni Taneja, ScM, Brown University, February, 2026.

MBapp+ is a digital therapeutic smartphone app developed at the Women and Infants Hospital of Rhode Island under Dr. Adam Lewkowitz in collaboration with Brown University. The app was designed to prevent and treat postpartum depression (PPD), using an evidence-based cognitive behavioral therapy (CBT) program uniquely adapted from the Mothers and Babies in-person curriculum. MBapp+ incorporates interactive modules, ecological momentary assessments, dynamic educational materials, and personalized progress tracking to improve engagement and support better treatment outcomes. Currently, the app is in development and available for research use.

This thesis proposes a path to commercialization for MBapp+, providing an integrated analysis of key business development considerations and a potential go-to-market strategy. It outlines the prevalence and burden of PPD, the challenges of existing pharmacological and psychotherapeutic treatments, and the urgent need for accessible, evidence-based, non-pharmacological options. The PPD treatment market is assessed while emphasizing the overall potential of digital therapeutics. The app's development process is explored, including a qualitative study that resulted in end-user feedback to iteratively refine the app and inform the addition of new features. Competitive analysis reveals an opportunity for MBapp+ to differentiate itself through its unique ability to deliver psychotherapy specifically for PPD patients. The financial model proposes a hybrid commercialization strategy beginning with direct-to-consumer distribution to establish traction, followed by payer partnerships to ensure scalability and equitable access. Following this, market adoption and revenue projections are estimated for the first three years after commercialization to demonstrate commercial viability and inform strategic planning. Regulatory considerations acknowledge the app's classification

within a lower-risk digital therapeutic category but highlight the importance of rigorous clinical validation to support payor and provider acceptance. The intellectual property strategy protects MBapp+'s innovations by safeguarding its creative content, proprietary methods, and brand identity through copyrights and trademarks.

This comprehensive commercialization roadmap aims to translate MBapp+ from a research prototype into a widely accessible, effective, and sustainable digital therapeutic for maternal mental health care.

Chapter 1. Introduction

1.1 Background on Postpartum Depression

Postpartum depression (PPD) is a severe and complex mood disorder that can develop after giving birth. Each year approximately 3.6 million births occur in the United States and PPD affects one in eight mothers, or roughly 460,000 women annually. Some of the most prevalent symptoms include persistent hopelessness, severe mood swings, anxiety, intense fatigue, changes in sleep and appetite, withdrawal from others, difficulty concentrating and thoughts of self harm. PPD can appear anytime within the first year after giving birth but typically within the first few weeks, and despite its prevalence, up to 50% of cases remain undiagnosed [1].

In the United States, maternal mental health conditions, particularly PPD, account for nearly 23% of pregnancy-related deaths, and an estimated 80% of these deaths are considered preventable. Alarmingly, treatment access remains profoundly inadequate: fewer than 15% of mothers with maternal depression receive any treatment, and fewer than 9% receive adequate care [2]. These statistics reveal systemic deficiencies in detection, diagnosis, and treatment pathways driven by ineffective screening protocols, poor integration of mental health into perinatal care, and the lack of continuous, personalized follow-up for postpartum women.

PPD arises from a complex interplay of biological, psychological, social, and environmental factors. Contributing elements include hormonal shifts, prior mental health history, childbirth complications, socioeconomic stressors, and limited social support [1]. Consequently, accurate assessment and consistent diagnosis of PPD remain challenging. The subjective nature of mental health disorders like PPD complicates objective evaluation, often relying heavily on self-report screening tools, which can be influenced by patient stigma, underreporting, or variations in patient-provider communication.

Current treatment approaches for PPD include both pharmacological and non-pharmacological methods, yet access and adherence remain limited. Many mothers are hesitant to initiate pharmacological treatments such as antidepressants, often due to concerns about side effects, dependency or infant exposure through breastfeeding, and instead choose non-pharmacological therapies as their first-line option [3].

Cognitive behavioral therapy (CBT) and interpersonal therapy (IPT) are well-established, evidence-based psychotherapies for preventing and treating PPD. However, barriers such as the limited availability of trained clinicians, cost, scheduling challenges, and social stigma make these interventions difficult to access for many women [4]. To overcome these limitations, there is an urgent need to modernize and digitize CBT-based interventions—transforming them into scalable, user-centered formats that maintain their evidence-based integrity while broadening accessibility and adherence among postpartum populations.

1.2 Digital Innovation and Commercialization Potential with MBapp+

The persistent gaps in PPD management highlight the need for scalable, accessible solutions beyond traditional in-person therapy. Digital mental health interventions, particularly those delivering CBT, have demonstrated effectiveness in reducing depressive symptoms in perinatal populations [5].

This is the focus of the research program led by Dr. Adam Lewkowitz at the Women & Infants Hospital of Rhode Island, affiliated with Brown University. His team is developing MBapp+, a novel smartphone application designed to deliver prevention-focused, CBT-based support to perinatal individuals at risk of PPD through leveraging digital innovation to mitigate symptoms.

MBapp+ uniquely adapts the Mothers and Babies (MB) in-person CBT curriculum—one of only two psychotherapy interventions endorsed by the U.S. Preventive Services Task Force (USPSTF) for the prevention of perinatal depression [6] —into an interactive, engaging digital platform to increase accessibility and scalability. The first version of MBapp integrated evidence-based modules, reward-based incentives, and bilingual content for both English- and Spanish-speaking users [7]. Building on iterative user feedback and findings from pilot studies created a second iteration, MBapp+**.** These enhancements, shaped by direct input from perinatal individuals during usability testing, are discussed in greater detail in later sections of this report.

This digital health solution aligns strategically with the broader biopharmaceutical industry's increasing emphasis on patient engagement, measurable health outcomes, and preventive healthcare strategies. MBapp has already demonstrated initial success, supported by NIH-funded pilot studies, acceptance into innovation programs such as Brown Biomedical Innovations to Impact (BBII), and active exploration of strategic partnerships with leading healthcare payers and industry stakeholders.

Given the shortage of accessible, non-pharmacological options for addressing postpartum depression, a central question emerges: What commercialization strategies can ensure MBapp+ effectively reaches and serves its target population? This report provides an integrated analysis of key business development considerations and a potential go-to-market strategy. The work includes in-depth market research and competitive benchmarking, evaluation of user-informed feature enhancements, and an assessment of intellectual property and regulatory factors. It also incorporates findings from a qualitative study of perinatal women that directly shaped MBapp+'s design and feature set. In addition, a financial model explores both direct-to-consumer and insurance-based reimbursement approaches, offering insight into the scalability of MBapp+.

Together, these elements outline potential strategies for bringing MBapp+ from research to real-world dissemination in a way that maximizes accessibility, impact, and long-term growth.

Chapter 2: Postpartum Depression Market Analysis

2.1 Epidemiology of Postpartum Depression

Postpartum depression (PPD) is one of the most prevalent complications of childbirth, affecting hundreds of thousands of families each year. Overall, PPD affects one in eight mothers, or roughly 460,000 women annually in the United States, though rates of PPD are much higher in some populations. For example, women with a prior history of mental health issues have a more than 20-fold higher risk of developing PPD compared to those without such a history [8].

Within the U.S., epidemiologic patterns reveal marked disparities across age, race, and socioeconomic groups. Young mothers under the age of 20 experience nearly double the risk of developing PPD compared with older women. Racial and ethnic differences are also pronounced. American Indian/Alaska Native, Black, and Hispanic women consistently report higher rates of postpartum depressive symptoms, 20 to 40%, more than double those of White women, typically 8 to 12% [9]. Additionally, Latina and Black women are 57% and 41%, respectively, less likely to start treatment for maternal depression than White women. Additionally, there was a 280% increase in PPD diagnoses for Asian American and Pacific Islanders from 2010-2021 [10].

Socioeconomic disadvantage further amplifies risk. Women with four socioeconomic risk factors—low income, limited education, unemployment, and unmarried status—were 11 times more likely to develop clinically significant depressive symptoms at three months postpartum compared to women without any such risks, even after adjusting for prenatal depression levels [11]. More recent population-level analyses confirm that socioeconomic context operates independently of individual risk: women living in socially disadvantaged neighborhoods have a

13.7% higher odds of PPD compared to those in more advantaged areas, regardless of insurance status [12].

Globally, the prevalence of postpartum depression varies sharply between high- and low-resource settings. A systematic review estimated prevalence at 25% in low- and middle-income countries (LMICs) compared with just 11% in high-income countries (HICs), nearly a twofold difference [13]. This disparity is attributed to structural and social determinants, including limited access to maternal mental health care, lower availability of trained providers, weaker postpartum support systems, and heightened socioeconomic stressors that disproportionately affect women in LMICs.

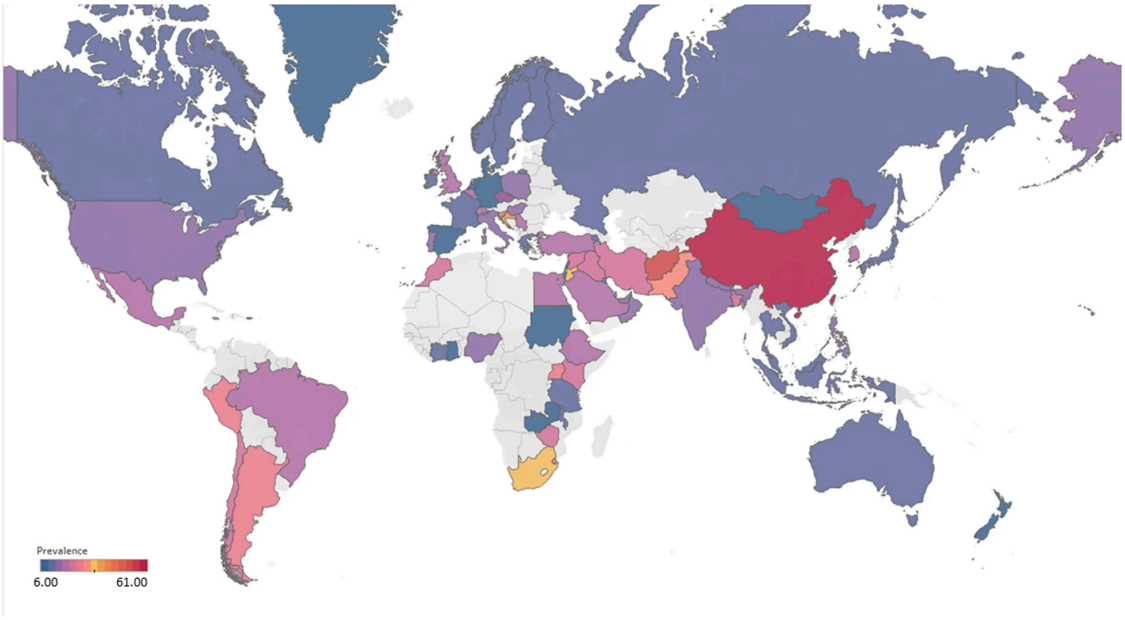

Figure 1. Global prevalence of postpartum depression [14]

The consequences of untreated PPD extend far beyond the postpartum period. Women with perinatal depression are at markedly increased risk for subsequent psychiatric disorders, including recurrent major depressive disorder, anxiety, and post-traumatic stress disorder.

Emerging evidence also highlights serious physical health consequences. A large UK Biobank cohort study found that women with perinatal depression had a 29% higher risk of developing cardiovascular disease, particularly ischemic heart disease and hypertension, compared to those without depression [15].

Epidemiologic research also links maternal PPD to poorer infant outcomes, including lower breastfeeding rates, impaired mother-infant bonding, reduced adherence to immunization schedules, and heightened risk of developmental and behavioral challenges. Long-term studies show maternal PPD leads to cognitive delays in language development and executive functioning in children [16].

2.2 Financial Implications of Postpartum Depression Management & Market Size Analysis

PPD exerts a profound economic toll, encompassing both direct healthcare costs and broader socioeconomic impacts. In the United States, a comprehensive societal model found that untreated perinatal mood and anxiety disorders including PPD result in an estimated $14.2 billion in costs for births in 2017, amounting to nearly $31,800 per mother–child pair when followed through six years postpartum [17]. At the household level, data from commercially insured populations reveal that PPD incurs elevated medical expenses. Affected households spend approximately 22% more on medical and pharmaceutical costs in the first year postpartum compared to matched controls, roughly $36,000 vs. $29,400, and have, on average, 16 additional outpatient visits [18].

Globally, the PPD treatment market is valued at USD 8.68 billion in 2023, with projections soaring to USD 55.24 billion by 2031, representing a CAGR of 30.25% [19]. In

terms of PPD-specific pharmacotherapy, the drugs market alone was valued at USD 838.4 million in 2023 and is forecasted to reach USD 1.59 billion by 2030, at a CAGR of 9.63% [20].

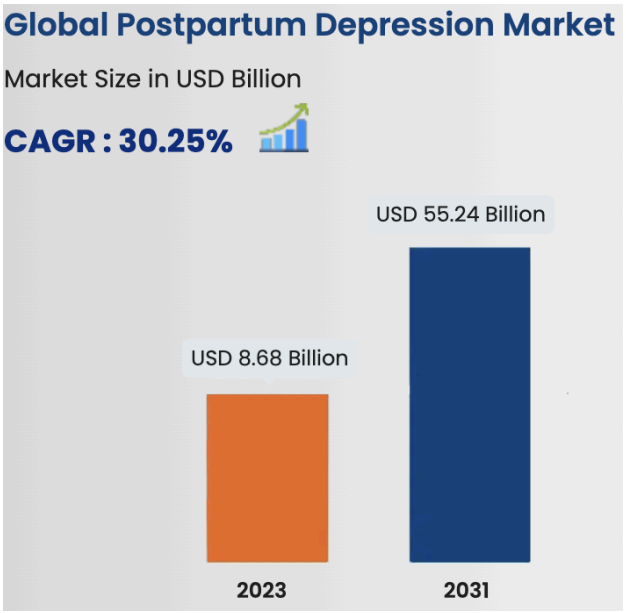

Figure 2. Global Postpartum Treatment Depression Market [19]

Pharmacological treatments, primarily antidepressants, are among the most frequently utilized interventions for postpartum depression. Despite widespread use, antidepressants often pose significant side effects, including dizziness, insomnia, gastrointestinal disturbances, and emotional numbing, leading to low adherence and compromised effectiveness over extended treatment periods.

Beyond direct medical expenses, untreated PPD imposes substantial economic burdens through reduced workforce participation and productivity. Estimates show that annual costs per affected woman amount to around $2,871 in lost productivity (presenteeism) and $888 in absenteeism, with potential additional $40,000 in employment-related productivity losses per individual [21].

Non-pharmacological treatments for PPD, such as cognitive behavioral therapy (CBT) and interpersonal therapy (IPT), are highly effective but remain underutilized. Limited insurance coverage, low reimbursement rates, and a shortage of trained providers push many women to pay out of pocket, where therapy typically costs $100–200 per session [22]. These financial and logistical barriers contribute to substantial unmet demand for accessible, affordable interventions tailored to postpartum populations.

2.3 Digital Therapeutics Market and Future Market Trends

Digital therapeutics (DTx) are software-based interventions designed to clinically prevent or manage conditions like PPD and are experiencing rapid global expansion. The global DTx market grew to approximately USD 7.67 billion in 2024 and is projected to reach USD 32.5 billion by 2030, exhibiting a compound annual growth rate (CAGR) of 27.8% [23]. North America commands around 40% of this market, with the U.S. leading the regional share. Within the United States specifically, the DTx market was valued at around USD 1.8 billion in 2022, and is forecast to grow to USD 10.5 billion by 2030, at a CAGR of 25.9% [24].

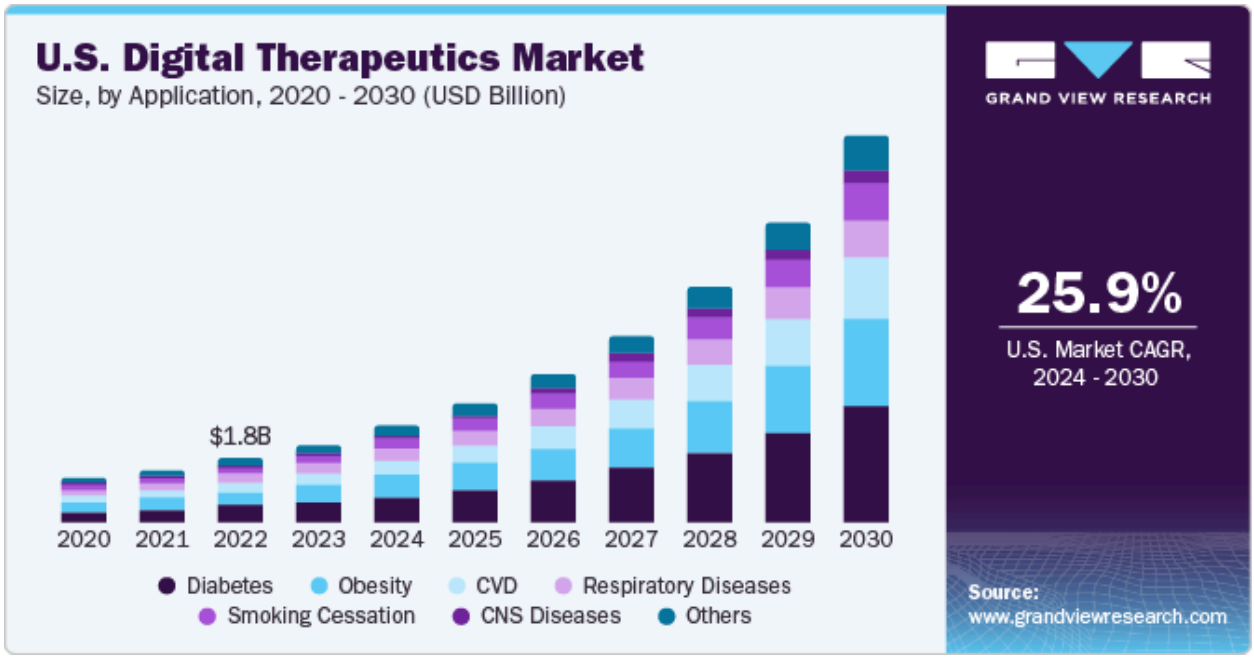

Figure 3. Digital therapeutics market in the US reaching a revenue forecast of $10.5 billion by 2030 [23]

The broader digital mental health sector is also expanding rapidly. Valuated at approximately USD 24.4 billion in 2025, it is expected to reach USD 57.2 billion by 2030, reflecting a CAGR of 18.4% [25]. Within this domain, a growing subset includes PPD-focused digital platforms, which deliver scalable access to interventions such as CBT, mindfulness exercises, and peer support communities.

Technological advancements significantly shape the future of digital therapeutics for PPD. Artificial intelligence (AI) is increasingly utilized to personalize treatment plans by analyzing user-generated data, predicting symptom escalation, and recommending timely interventions. Integration with wearable devices allows continuous monitoring of physiological indicators like sleep patterns and stress levels, which can further inform treatment customization. Such technologies enable proactive management of PPD symptoms, potentially enhancing therapeutic effectiveness and patient engagement. Additionally, digital therapeutics combined with telemedicine platforms expand healthcare accessibility, especially critical during global health crises or for patients with limited mobility or residing in remote locations. Virtual consultations and remote monitoring capabilities facilitate continuous patient-provider communication, adherence to treatment plans, and greater patient empowerment.

Looking ahead, the future of digital therapeutics for postpartum depression is centered on delivering personalized, data-driven, and evidence-based interventions. Emerging platforms are expanding beyond static content to incorporate real-time feedback, AI-supported adaptation, and culturally tailored resources that improve accessibility and treatment adherence. MBapp+ reflects

this next phase of innovation by integrating cognitive behavioral therapy within an engaging, scalable, and user-informed digital framework.

Chapter 3. MBapp+ Product Description and Competitive Landscape

3.1 Determining MBapp+'s Place in the Postpartum Depression Market

To understand MBapp+'s potential impact in addressing postpartum depression, this section outlines the user-informed development process, the app's core features, and its positioning relative to existing digital mental health solutions. Clarifying these points provides the foundation for evaluating commercialization strategies, with a focus on how MBapp+ can be sustainably scaled to reach perinatal women at risk for PPD.

3.2 Research Evidence Supporting Development of MBapp+

As discussed earlier, the Mothers and Babies (MB) program, recognized by the USPSTF for effectively preventing postpartum depression, was originally created as an in-person Cognitive Behavioral Therapy (CBT) program for low-income English- and Spanish-speaking women. Although effective, the need for trained facilitators has limited MB's scalability and dissemination. To address this limitation, MB was adapted into a digital format known as MBapp through NIH-funded research. First, a qualitative research study was conducted to evaluate the feasibility, usability, and acceptability of this digital adaptation, ensuring that the app's design and features were directly informed by feedback from perinatal women [7]. Once optimized as an intervention, the NIH is supporting a pilot randomized controlled trial to explore the feasibility, acceptability, and effects of MBapp+ [26]. This trial is currently underway and will be discussed in the final section of this report.

Creating the Draft Wireframe

The draft wireframe for MBapp was created by restructuring the in-person MB curriculum into a smartphone-compatible format in Canva, an online graphic design platform used for creating visual content and mockups. Long text passages were transformed into short, direct phrases; worksheets were re-designed as interactive modules; and visual elements including graphics from the MB curriculum and stock images of pregnant and postpartum people were embedded. This version also incorporated ecological momentary assessments (EMAs), gamification elements, and reward-based incentives. There are eight modules which are as follows: Parenting Education, Stressors and Realities, Pleasant Activities and My Health, My Thoughts and Mood, Creating Helpful Thoughts, Connecting With Others, Communicating With Others and Conclusion/Review.

Study Population and Recruitment

The research study recruited 25 perinatal women (pregnant or within 12 months postpartum) between the ages of 18 and 40. Participants were recruited primarily from Women & Infants Hospital of Rhode Island through obstetric clinic referrals, community outreach, and word-of-mouth. Eligibility criteria included elevated risk for PPD, either due to psychosocial stressors, prior mental health history, or screening scores. All participants were either English- or Spanish-speaking and insured through Medicaid, making the sample representative of an underserved, high-risk population.

Demographically, the participants reflected the diverse populations most affected by PPD: a mix of racial/ethnic backgrounds, varying education levels, and different stages of the perinatal period. Many participants reported prior experience with mental health challenges, emphasizing their suitability for evaluating a preventive intervention like MBapp.

Characteristic	Value
Age (years)	
Median (IQR)	29 (24-35)
Minimum, Maximum	20, 43
Advanced maternal age (35 years or older at time of delivery), n (%)	6 (24)
Race, n (%)	
American Indian or Alaska Native	3 (12)
Asian	2 (8)
Black	5 (20)
White	6 (24)
Other[a]	9 (36)
Ethnicity, n (%)	
Hispanic	13 (52)
Language of interview[b], n (%)	
English	13 (52)
Spanish	12 (48)
Primiparous (pregnant with first child or recently delivered first child), n (%)	13 (52)
Pregnancy status, n (%)	
Pregnant	13 (52)
Postpartum	12 (48)

Table 1. Sociodemographic and obstetric characteristics of study participants [7]

Data Collection

Individual in-depth interviews were conducted via video teleconferencing in each participant's preferred language (English or Spanish) by the same investigator using a semi-structured interview guide. Interviews began with questions about participants' personal experiences, preferences, and challenges with apps particularly those focused on perinatal or

mental health before shifting to a detailed review of MBapp's draft wireframe through navigation of the app on a study-provided smartphone. This process elicited feedback on clarity of content, ease of navigation, relevance of images, and overall acceptability. Participants were encouraged to verbalize their thought processes ("think-aloud" method) to capture real-time usability challenges and impressions. All interviews were audio-recorded, professionally transcribed, reviewed for accuracy, and stripped of identifiers.

Utilizing an Evidence-Based Framework to Determine Sample Size

Similar to other web-based adaptations of MB [27,28], a human-centered design approach was used to optimize MBapp based on end-user feedback about the intervention itself and other perinatal or mental health apps. The evolution of MBapp was recorded using the Framework for Modification and Adaptation (FRAME), an established method of systematically reporting adaptations and modifications to evidence-based interventions via end-user feedback. FRAME provided insight into when modifications were made to MBapp's wireframe and the reasons for those changes.

Feedback on themes, content, and function was extracted after each set of five to seven interviews. The draft wireframe was then revised accordingly, and subsequent participants were shown the updated version so that earlier modifications could be confirmed, refined, or further adapted. The research team anticipated recruiting up to 36 participants but planned to cease recruitment once content saturation was achieved, defined as three successive participants providing only positive feedback without further suggestions for improvement. In practice, thematic saturation was reached after 25 participants, confirming adequacy of the sample size.

Data Analysis

All data was managed using NVivo software and analyzed thematically. The coding process followed an inductive approach, allowing themes to emerge directly from participant feedback rather than imposing pre-set categories. Coding was conducted independently by multiple members of the research team to ensure reliability, with discrepancies resolved through discussion. Thematic categories were developed to capture participant perspectives on usability, navigation, aesthetics, content clarity, and engagement features. To strengthen validity, findings were triangulated across English- and Spanish-language interviews, and representative quotes were selected to illustrate core themes.

Principal Findings/Results

Several key findings emerged from the analysis:

- Simplification of content was strongly preferred, with participants requesting shorter, more digestible modules supported by visuals and interactive activities.
- Language and cultural tailoring were critical, particularly for Spanish-speaking participants, who emphasized that translations needed to be idiomatic and culturally sensitive.
- Visual and structural revisions were frequently suggested, including larger fonts, brighter colors, more diverse imagery, moving the parenting module earlier in the sequence, and creating a central “home” button.
- Feature requests included audio narration for accessibility, an “ask a clinician” function for non-urgent questions, and brief module summaries accessible after completion.
- Flexibility in assessments was requested, with participants asking for the ability to defer EMAs in order to continue progressing through modules uninterrupted.

- Engagement incentives were seen as valuable, with participants recommending modest financial rewards tied to completion of mood scales.

Adapting the Wireframe

Based on participant feedback, the draft MBapp wireframe on Canva was iteratively revised to better align with user needs. The developer then implemented these adaptations into the beta version of the app. Major adaptations included moving the parenting module earlier in the sequence to increase relevance, adding a home button to simplify navigation, and creating a digital bookshelf of module summaries for quick review after completion. Additionally, the following features were added to MBapp secondary to end-user feedback:

1. Audio narration
2. An “ask a clinician” function for non-urgent questions
3. On-demand module summaries accessible upon module completion
4. The choice to defer assessments and proceed directly to the next module

The feedback also informed minor aesthetic changes (font size, color schemes). Finally, modest incentive structures tied to mood scale completion were refined to encourage engagement without overburdening participants.

Table 2 summarizes major adaptations categorized using the FRAME methodology, systematically documenting each adjustment's rationale and timing based on qualitative end-user feedback. These adaptations did not alter MBapp’s core CBT content, thereby maintaining fidelity to the evidence-based MB curriculum.

MB Feature	MBapp Adaptation	Reasons	Timing of change implementation	Participant recommendation addressed
Not in MB	"Ask a clinician" non-urgent questions	Recipient: Access to resources	After interview #16	Resource for women's perinatal or mental health advice, support, or education
Not in MB	Audio narration, turn on or off on each page	Recipient: First/ spoken languages	After interview #11	Increase engagement with MBapp via additional method to deliver content
Mood assessments given between the in-person classes	Choice to defer week of mood assessments and pass immediately to next module	Recipient: Cognitive capacity	After interview #11	Flexible schedule
Parenting education module in middle of curriculum	MBapp module order restructuring, with parenting module in beginning	Recipient: Cognitive capacity	After interview #6	Optimize MBapp flow by removing the parenting education from middle of curriculum
Not in MB	The module summaries to access high-yield content after module is completed	Recipient: Cognitive capacity	After interview #6	Practical, high-yield content for fast review
Not in MB	Small financial reimbursement based on number of responses to EMA prompts	Recipient: Motivation and readiness	After interview #21	Increase meaningful engagement with MBapp via gamification

Table 2. Major End-user-requested Adaptations to MBapp's wireframe, categorized according to the Framework for Reporting Adaptations and Modifications [7]

3.3 Iterative Refinement of MBapp & Next Steps

Qualitative research identified additional advanced features important for ongoing user engagement that could not be initially included due to funding constraints.The enhancements were added to the wireframe and have now been implemented in MBapp+, the next iteration of the app. They include:

1. A personalized mood data dashboard for tracking mental health trends over time
2. A user forum for asynchronous community support
3. Swiping instead of tapping to change pages
4. Ability of the app to allow users to access their most recent page instead of returning to the table of contents

These features have since been beta tested by the team to identify and fix usability issues prior to implementation in the study setting.

Looking forward, the next milestone involves embedding Marigold Health's AI-based texting and peer-support capabilities within MBapp+. This enhancement responds directly to end-user requests for real-time support. Marigold Health, a venture-capital–funded digital health company, specializes in synchronous peer-support scheduling and the use of natural language processing to virtually proctor chat between users at any time of day. This expertise enables a live chat feature capable of identifying participants reporting depressive symptoms or suicidal ideation without requiring continuous human monitoring.

Additional features could further strengthen MBapp+'s clinical impact and market positioning. Integration with wearable devices would allow continuous monitoring of sleep, activity, and stress biomarkers, enabling predictive analytics for early symptom detection. Modules designed for partners and families would extend the app's influence beyond the individual mother, supporting social networks that have been shown to improve postpartum outcomes.

With these strategic enhancements, MBapp+ positions itself as a scalable, comprehensive, and evidence-based digital therapeutic tailored specifically for perinatal mental

health, with significant potential for widespread adoption and sustained engagement among English- and Spanish-speaking populations.

3.4 Mobile Apps for Postpartum Depression: Competitive Analysis for MBapp+

The mobile health marketplace is saturated with wellness and mental health applications, yet the vast majority emphasize lifestyle tracking or general mood support rather than evidence-based psychotherapy. Systematic reviews of perinatal mental health apps show that most contain psychoeducation or symptom monitoring but lack structured psychotherapeutic interventions, highlighting a critical gap for postpartum populations. MBapp+ is designed to directly address this gap by delivering preventive CBT tailored specifically to perinatal women.

A. CBT & Self-Report Tracking Apps

Apps such as Happify [29] and Sanvello provide module-based CBT content and asynchronous self-help curricula, allowing users to access tools on demand. Sanvello additionally offers the option to connect with licensed therapists for a fee. While these platforms have demonstrated usability and general effectiveness for mood management, they were not designed for perinatal populations and have not been validated for postpartum depression prevention [30]. Other apps like MoodTools [31] and Daylio [32] focus mainly on mood tracking, enabling users to visualize their symptoms over time, but they lack structured CBT modules designed for PPD prevention.

B. Peer & Community Support Platforms

Platforms such as Peanut and Connect by PSI enable mothers to connect with peers based on geographic proximity or shared experiences. While these apps can help reduce feelings of isolation and normalize the postpartum experience, they do not provide structured psychological

interventions or integrate evidence-based psychotherapy leaving a major gap in evidence-based treatment [33].

C. AI / Live-Interaction Tools

Woebot represented one of the most studied AI-based mental health apps. It provided conversational support grounded in CBT principles and has demonstrated efficacy in reducing depressive symptoms in general adult populations through clinical trials. However, Woebot does not include a perinatal-specific curriculum or peer community functionality, limiting its utility for postpartum depression prevention. Notably, despite raising over $120 million in venture capital, Woebot Health announced in June 2025 that it was shutting down operations due to challenges in achieving sustainable reimbursement and regulatory hurdles in the digital mental health market [34]. This highlights both the promise and the risks inherent in scaling AI-driven mental health tools.

D. Research-Focused Apps

PPD ACT was created by academic researchers to collect phenotypic and genetic data from women with postpartum depression. Although it shares a focus on perinatal populations, its primary goal is to collect phenotypic and genetic data to improve risk prediction models for PPD, not dissemination of preventive CBT or provision of scalable therapeutic interventions [35].

E. Prescription Digital Therapeutics

MamaLift Plus, cleared by the FDA in 2024, represents the first prescription-only digital therapeutic for postpartum depression. This can be seen as one of the biggest competitors for MBapp+ as it is specifically for postpartum depression. It delivers evidence-based therapies including CBT, IPT, DBT, and behavioral activation over an eight-week program. It includes interactive tools, personalized daily care kits, mood and progress tracking and live access to a

therapist. While this marks an important step forward for digital therapeutics in maternal mental health, MamaLift Plus is accessible only by prescription and therefore is not widely available across diverse populations. Additionally, it also does not contain community forum or chat features and is only offered in English, further limiting users [36]. MamaLift plus is

Table 3 provides an overview of commercially available postpartum depression apps highlighting their core features, target populations, and pricing.

App Name	CBT Content	Mood Tracking	Community Features	Live Chat/AI	Target Population	Cost
Happify	Yes	Yes	No	No	General Mental Health	$14.99/month; $139.99/year
Sanvello	Yes	Yes	Limited (premium peer/therapy)	No	General Mental Health	$8.99/month; $53.99/year
MoodTools	No	Yes	No	No	General Depression	Free with in-app options
Daylio	No	Yes	No	No	General Mood Tracking	Free / Premium tiers
Peanut	No	No	Yes	No	Perinatal Women	Free (community-based)
Woebot	No (AI chat only)	No	No	Yes (AI chatbot)	General Mental Health	Historically ~$39/month; retired June 2025
PPD ACT	Limited (psycho-education/ surveys)	Limited	No	No	Research Participants	Free (research use)
MamaLift Plus	Yes (CBT, IPT, DBT, BA)	Yes	No	No	Perinatal / PPD	Prescription-only
MBapp+	Yes	Yes	Yes	Yes	Perinatal / PPD	Free in research; TBD commercial

Table 3. Competitive Analysis of Postpartum Depression Apps

As mentioned previously, MamaLift Plus is a prescription-only digital therapeutic designed for the treatment of clinically diagnosed postpartum depression, whereas MBapp+ is intended for commercial availability, emphasizing prevention and early intervention among at-risk perinatal women. This distinction positions MBapp+ as a more accessible, scalable solution targeting symptom reduction. Despite the abundance of mental health applications on the market, only three publicly available apps worldwide deliver psychotherapy specifically tailored to perinatal populations—and all are international, non-English platforms (Japanese, South Korean, and Farsi). Currently, no such app is commercially available in the United States. This lack of U.S.-based competition for app-delivered PPD prevention or treatment highlights a major opportunity. Furthermore, MBapp+ is built upon the Mothers and Babies program, an evidence-based intervention explicitly recommended by the U.S. Preventive Services Task Force for all pregnant individuals at risk of PPD which helps it stand apart from existing apps in the marketplace.

3.5 Viability of the Market Represented by Multiple Players

Many companies are generating substantial revenue and delivering measurable improvements in patient outcomes within the digital therapeutics market for postpartum depression. For example, MamaLift Plus, an FDA-cleared prescription digital therapeutic, demonstrated that 86.3% of participants (82 out of 95) experienced clinically meaningful improvement in depressive symptoms over eight weeks, compared to only 23.9% in the sham control group [37]. This dynamic environment, characterized by numerous competitors and continuous new entrants, indicates a thriving market that is far from monopolistic, offering substantial growth potential and viability for MBapp+.

Success within the digital therapeutics space depends on multiple factors beyond merely having the most advanced product. Tailoring solutions to specific user segments, such as perinatal populations, mental health providers, and research communities, plays a crucial role. Although product quality is essential, other aspects significantly influence market success. Effective market reach and strong brand recognition often result from targeted marketing efforts and strategic partnerships, enabling apps to achieve widespread user adoption even when technical features may not be superior.

User experience (UX) also impacts user attraction and retention. In a feasibility study, perinatal participants described MamaLift Plus as usable, satisfactory, and worth their time [38]. Apps that offer intuitive navigation, visual appeal, and seamless integration with health-tracking tools often experience greater sustained usage. Moreover, adherence to regulatory compliance and robust data security measures is critical, particularly in handling sensitive health information, as these elements build user trust and long-term engagement [39].

Customer support, community engagement, and empathy toward user experiences further enhance user loyalty and organic growth through positive word-of-mouth. Thus, a strategic combination of user-centric design, rigorous regulatory adherence, intelligent marketing, and strong customer relationships can effectively position apps like MBapp+ within this vibrant and evolving marketplace.

Chapter 4: Commercialization Plan

4.1 Pricing and Route to Revenue

It is recommended for MBapp+ to follow a hybrid commercialization strategy, leveraging both direct-to-consumer (DTC) and payer-based distribution models. The long-term goal is to license the app to insurance companies so that it can remain free to consumers. The target

population is postpartum women at risk of or experiencing postpartum depression, giving a clear focus for pricing, marketing, and reimbursement discussions

Direct-to-Consumer (DTC): MBapp+ will be available on the Apple App Store and Google Play Store at a subscription rate of $10–15 per month. This rate is based on benchmarking from competitors to maintain a comparable market rate. For example, Sanvello offers premium access for $8.99/month or $53.99/year and Happify's premium subscription is $14.99/month or ~$139.99/year with a lifetime option for those seeking full access to all features [40].

Payer-Based Distribution: The majority of long-term revenue is expected from contracts with private insurers and Medicaid programs, which would license MBapp+ on a per-patient or per-episode basis. Surveys of U.S. payers show growing interest in covering digital mental health interventions, provided they demonstrate cost-effectiveness and measurable health outcomes [41]. This aligns with ongoing shifts toward bundled maternity care payment structures, in which maternal mental health is increasingly recognized as a driver of outcomes and costs [42]. By positioning MBapp+ as a preventive, evidence-based intervention, the app can be incorporated into these coverage models to expand access while reducing financial barriers for high-risk populations.

This dual-path strategy will maximize accessibility by providing individuals an affordable option while ensuring large-scale dissemination through insurers. Insurance partnerships will also mitigate out-of-pocket costs, increasing adoption among populations at highest risk for postpartum depression. MBapp+'s ability to offer pay-per-patient licensing directly aligns with how insurers currently reimburse maternal care, positioning it for rapid integration into existing healthcare systems.

4.2 Total Addressable Market

The total addressable market (TAM) for MBapp+ can be estimated by combining U.S. epidemiological data on PPD prevalence with pricing benchmarks from comparable digital mental health tools. As mentioned previously, each year approximately 3.6 million births occur in the United States and PPD affects 1 in 8 mothers, or roughly 460,000 women annually.

Direct-to-Consumer (DTC) Market

Pricing will be benchmarked against competing mental health apps such as Sanvello ($8.99/month or $53.99/year) and Happify ($14.99/month or ~$139.99/year). Using this range:

$10/month ($120 annually): $55.2 million TAM (460,000 × $120)

Payer-Based Market

Due to MBapp+ being a self-guided digital therapeutic (not FDA-cleared), a per-member-per-month (PMPM) model is the most relevant benchmark. Recent analyses suggest self-guided digital mental health solutions are often priced around $2 PMPM [43], which translates to $24 per covered user annually .

$2/month ($24 annually): $11 million TAM (460,000 × $24)

This payer-based TAM represents a conservative, evidence-aligned scenario for MBapp+, with upside potential if coverage is extended to all perinatal women regardless of diagnosis.

4.3 Market Adoption Projections

As discussed, while MBapp+'s long-term financial sustainability will depend on payer partnerships, the near-term commercialization strategy should prioritize the DTC channel. This approach allows revenue generation from the outset, while simultaneously generating adoption metrics, engagement data, and clinical outcomes that will strengthen payer negotiations. By demonstrating that postpartum women are willing to engage with and pay for MBapp+, the

company can de-risk insurer concerns and position itself as a validated, in-demand intervention worth covering.

Under conservative but realistic adoption assumptions, this report will only discuss estimates of the first three years after commercialization. MBapp+ is projected to gradually capture market share over this period, culminating in 5% penetration of the incident PPD population by Year 3. This translates to roughly 23,000 paying users by the end of Year 3.

The growth trajectory is staged to mirror typical adoption curves of digital health applications. In Year 1, MBapp+ is expected to capture less than 1% of the market, focusing on brand awareness and early adopters. Year 2 marks accelerated growth, with penetration reaching 2–3% as user testimonials, clinician endorsements, and broader marketing efforts drive adoption. By Year 3, MBapp+ will achieve 5% market share, which remains modest relative to the total incident population but represents strong traction for a specialized digital therapeutic in the postpartum space.

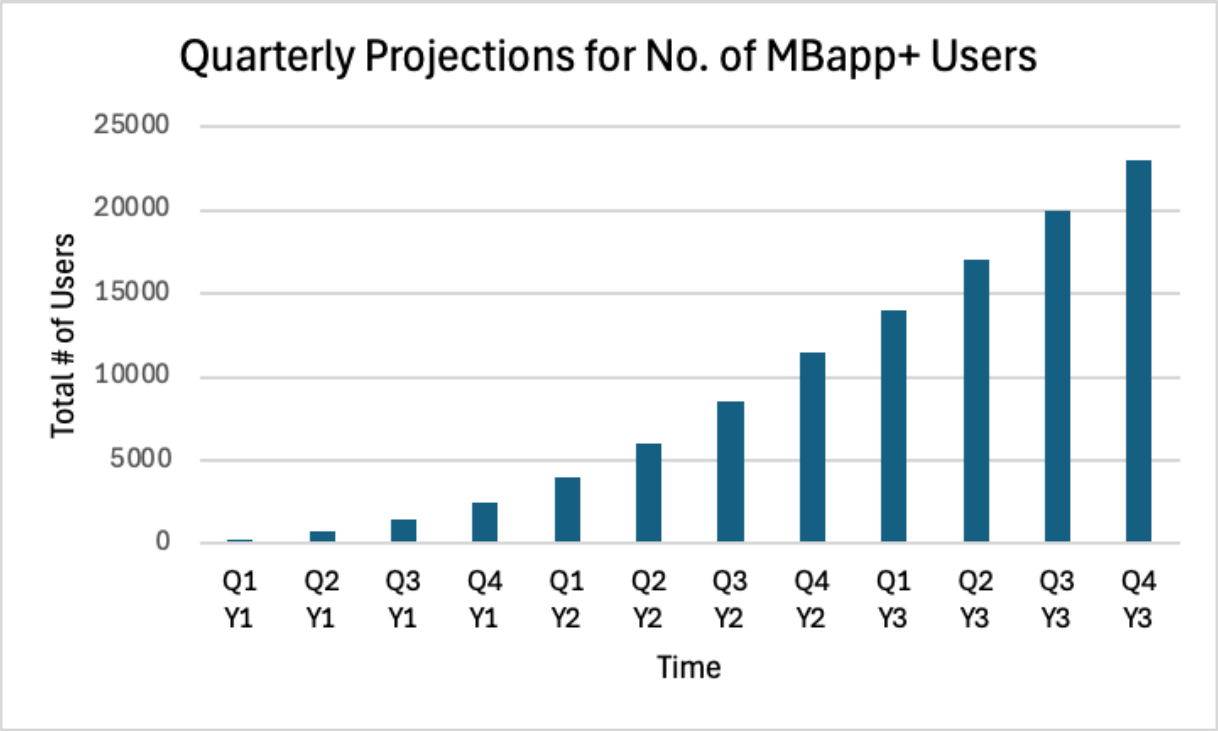

Figure 4: Total MBapp+ Users Over the First 3 Years after Commercialization

4.4 Revenue Forecast (Years 1 - 3)

MBapp+'s revenue forecast reflects the phased approach: Year 1 driven entirely by DTC subscriptions, followed by the introduction of payer-based reimbursement in Year 2. This dual-revenue structure allows MBapp+ to generate early income while building a data-driven case for insurer adoption. By Year 3, payer contracts become the dominant revenue stream, illustrating the scalability of the hybrid commercialization model.

Our long-term goal is to make MBapp+ freely available to consumers and as accessible as possible. To achieve this, ramping up insurance coverage is prioritized over maximizing profit margins, ensuring that financial barriers do not prevent postpartum women from accessing care. Channel mix assumptions:

Year 1: 100% DTC (no insurance yet).

Year 2: DTC ~65%, Payer ~35%.

Year 3: DTC ~40%, Payer ~60% (reflecting our accessibility goal to shift cost burden from consumers to payers).

Year	Total Users (DTC + Payer)	DTC Users (at $10/mo)	DTC Revenue	Insured Users (at $24/yr)	Payer Revenue	Total Revenue
1	2,500	2,500	$300,000	0	$0	$300,000
2	11,500	7,500	$900,000	4,000	$96,000	$996,000
3	23,000	9,200	$1,104,000	13,800	$331,200	$1,435,200

Table 4. Total Revenue Forecast for Years 1-3 after Commercialization

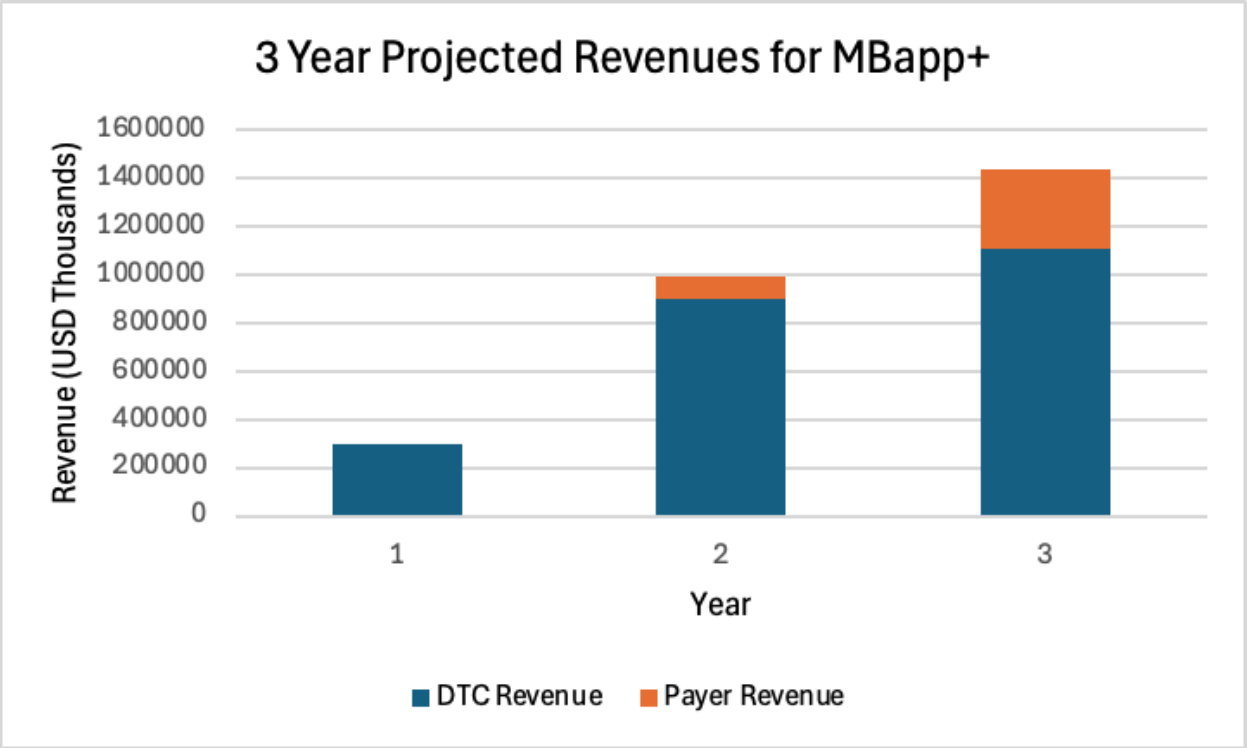

Figure 5. Total Projected Revenue from both Direct to Consumer and Payers for Years 1-3 after Commercialization

4.5 Cost Breakdown and Milestones

The development of MBapp+ has been supported through multiple funding sources, reflecting both early-stage academic investment and targeted commercialization support. The initial milestone transforming the Mothers and Babies (MB) curriculum into the first MBapp prototype was made possible by an NIH grant that allocated approximately $15,000 directly to app development. The NIH grant, in total, supported over $750,000 of funds to indirectly support MBapp's creation and the two research studies described previously, but only $15,000 was allocated directly for app development. In addition, approximately $15,000–20,000 in start-up funds from the study PI were invested to cover related expenses, including personnel support and

supplementary development needs. Together, these resources enabled the launch of the first MBapp wireframe and prototype.

The second milestone was achieved through a $75,000 award from Brown Biomedical Innovations to Impact (BBII), designed to transition MBapp into MBapp+ and prepare it for commercialization. To date, $42,000 has been spent, with the remaining balance allocated to specific feature enhancements and commercialization activities.

Breakdown of BBII Allocation

- Developer Enhancements ($26,800): Updating English and Spanish wireframes, coding new features such as swiping navigation, a personalized mood dashboard, an anonymous peer forum, and module resumption from the last page.
- Marigold Health Integration ($35,000): Embedding AI-based peer support and live text functionality, including natural language processing to flag depressive or suicidal ideation.
- Consulting Support ($5,000): Expert guidance on market entry strategy.
- Maintenance and Hosting ($5,000): Ongoing server costs, updates, and web support.
- Remaining BBII Funds**:** The remainder (~$3,200) is reserved for marketing, costs associated with payers, final beta testing activities and any unforeseen costs.

When combined, the $15,000 NIH grant, $15,000–20,000 in start-up support, and the $75,000 BBII award bring MBapp+'s total development investment to approximately $105,000. As seen in the revenue calculations, more than double this amount is expected to be earned in the first year, and additional funding can be raised if needed to support scaling and long-term sustainability.

4.6 Valuation

MBapp+ has received ~$105,000 in non-dilutive funding to date through an NIH grant, start-up funds, and a Brown Biomedical Innovations to Impact (BBII) award. These resources supported prototype creation, iterative user testing, and advanced feature development, positioning the app for early adoption in the postpartum depression digital therapeutics market.

Since MBapp+ is still pre-revenue, valuation is best estimated using forward revenue multiples applied to a steady-state year. While Year 1 and Year 2 provide early signals of traction, they are not reliable bases for valuation because user adoption, payer reimbursement, and feature rollouts will still be ramping. By Year 3, however, MBapp+ is expected to have stabilized adoption, payer contracts in place, and a more predictable revenue stream, making it the most appropriate reference point for valuation. Year 3 revenue is projected at $1.435 million. Applying a 3x forward revenue multiple yields an implied enterprise value of $4.3 million. This method is commonly used for early-stage technology and digital health ventures, where profitability has not yet been realized, and forward revenue offers the most practical benchmark for enterprise value [44].

As calibration, a second method uses the 3x profit heuristic, a simplified valuation framework that multiplies a chosen profit metric—such as net profit, EBITDA, or operating profit—by three to estimate enterprise value [45]. The multiplier can be adjusted upward or downward depending on growth potential, competitive dynamics, and risk profile. While this approach will become more relevant as MBapp+ achieves payer contracts and recurring profitability, it provides a useful secondary benchmark for long-term valuation.

A discount rate of 20% is applied to account for execution risks, competitive pressures, and payer adoption timelines typical of early-stage digital therapeutics. Incorporating this risk

adjustment decreases the Year 3 valuation from $4.3 million to approximately $3.5 million, providing a more conservative and defensible figure for early investors.

4.7 Entity Formation

As MBapp+ transitions from prototype to commercialization, the choice of legal structure becomes central to its growth trajectory. Three primary options are under consideration. A Benefit Corporation (B-Corp) would legally enshrine MBapp+'s mission to prioritize accessibility and social impact alongside financial sustainability, appealing to mission-driven investors and reinforcing the app's focus on maternal mental health equity. A Delaware C-Corporation represents the traditional pathway for venture-backed digital health startups, offering favorable governance, equity allocation, and investor familiarity. Finally, an LLC or nonprofit-for-profit hybrid could provide flexibility in the early stages, particularly if MBapp+ continues to rely on grant funding, with a nonprofit arm stewarding research and IP while a commercial arm drives dissemination.

The recommended structure for MBapp+ is to incorporate as a Delaware C-Corporation. This structure provides the clearest path to raising capital from institutional investors while maintaining flexibility to establish an option pool, form an advisory board, and structure licensing agreements with partners such as Marigold Health. Although a B-Corp could reinforce the social mission, the C-Corporation model offers the necessary scalability and investor familiarity to support MBapp+'s long-term commercialization and payer integration strategy.

Upon incorporation, the equity structure will include common stock issued to the study PI and founding team, alongside a stock option pool (10–15%) reserved for future hires. Shares will vest over a standard four-year schedule with a one-year cliff, incentivizing long-term commitment.

4.8 Regulatory Considerations

Though the FDA categorizes mobile applications intended for diagnosis, treatment, or prevention of adverse outcomes as medical devices, the agency applies regulatory oversight selectively. Specifically, the FDA states that it only regulates software functions "whose functionality could pose a risk to a patient's safety if the device were to not function as intended" [46].

By definition, MBapp+ falls within the FDA's broad category of medical devices, as they aim to prevent postpartum depression. However, because the app delivers a CBT-based curriculum that does not introduce direct physiological risks, it is highly unlikely that FDA approval will be required prior to commercialization and dissemination. In this respect, MBapp+ benefits from a relatively low regulatory burden, allowing for faster market entry compared to other digital therapeutics that involve diagnostic or physiological monitoring functions.

While FDA clearance is not expected to impact deployment, MBapp+ will remain under regulatory oversight through clinical research pathways. All pilot and efficacy trials will be reviewed and approved by the Institutional Review Board (IRB) at Women & Infants Hospital of Rhode Island. A pilot trial examining the feasibility and acceptability of MBapp in high-risk perinatal populations has been approved by the IRB. The study PI is currently conducting a fully powered efficacy trial designed to evaluate whether MBapp+ reduces rates of postpartum depression in at-risk women as well as feasibility and acceptability of features.

Importantly, these clinical trials are not only academic endeavors but also commercially critical. In early discussions, the Chief Medical Officer of Blue Cross Blue Shield Rhode Island emphasized that payer adoption would depend on the availability of robust efficacy data demonstrating improvements in maternal outcomes. Thus, while regulatory risks are minimal,

generating IRB-approved, high-quality clinical evidence remains essential for payer partnerships and large-scale dissemination.

Chapter 5. Intellectual Property Strategy

5.1 Patent Potential

To secure intellectual property (IP) protection, an invention must meet three statutory criteria under U.S. patent law: subject matter eligibility (35 USC § 101), novelty (35 USC § 102), and non-obviousness (35 USC § 103) [47]. Eligible subject matter includes processes, machines, manufactures, and compositions of matter, while abstract ideas, laws of nature, and natural phenomena are excluded. However, if an abstract idea is integrated into a practical application, it may still qualify. Novelty requires that the invention not be disclosed publicly more than a year prior to filing, and non-obviousness requires that the invention represent more than a minor improvement recognizable to someone skilled in the field.

The most significant hurdle for software-based inventions such as digital health apps is subject matter eligibility, evaluated under the Alice/Mayo test. This two-step framework, established by the U.S. Supreme Court in *Alice Corp. v. CLS Bank* (2014) and *Mayo v. Prometheus* (2012), first asks whether the claim is directed to an abstract idea, natural law, or phenomenon. If it is, the second step examines whether the claim includes an "inventive concept" that transforms the abstract idea into a practical application producing a concrete, useful result [48]. In practice, this means that most apps that simply digitize existing content, deliver information, or provide routine user interactions are considered ineligible for patent protection. To qualify, the app must generate unique insights or functional outcomes for example, by producing real-time predictions, tailoring interventions, or enabling processes that materially improve clinical decision-making.

For MBapp+, while the underlying MB curriculum is in the public domain, the adaptation into a mobile application can introduce novel contributions. These include ecological momentary assessments delivered via push notifications, gamified engagement mechanisms designed to increase adherence, module summaries stored in a digital bookshelf for on-demand access, and an AI-driven peer support system capable of flagging risk behaviors through natural language processing. Such features are not present in the in-person MB program and represent original, functional innovations that enhance usability and engagement. Features such as predictive symptom tracking or AI-enabled clinical decision support, if integrated into future versions, could further strengthen MBapp+'s patentability by demonstrating that the app produces concrete health outcomes rather than serving as a static digital tool.

Accordingly, MBapp+'s current form may only support limited patent protection, such as design patents for user interface features or narrow utility claims tied to ecological momentary assessment workflows. However, as the platform evolves to incorporate AI-based prediction and personalization, its ability to satisfy the Alice/Mayo inventive concept requirement increases. In this way, MBapp+ aligns with broader trends in digital health patentability, where applications that generate new insights or enable measurable improvements in care are more likely to secure robust intellectual property protection than those that simply deliver existing clinical content in digital form.

5.2 Copyright and Trade Secret Protections

While patents may provide only limited protection for MBapp+, other forms of intellectual property, namely copyright, trade secrets, and trademarks, offer meaningful safeguards for the app's content, brand, and competitive position.

Copyright protection applies automatically under U.S. law once original works of authorship are fixed in a tangible medium (17 U.S.C. § 102). For MBapp+, this covers the original user interface designs, iconography, audiovisual materials, gamified features, and written content created specifically for the app. Although the underlying Mothers & Babies curriculum is in the public domain and not itself copyrightable, MBapp+'s adaptation into digital form including graphics, layout, interactive modules, and multimedia elements constitutes new creative expression eligible for copyright protection [49]. This protection is particularly important for safeguarding against direct copying of the app's look, feel, and educational content by competitors.

Trade secret protection may also be valuable for MBapp+, particularly for non-public elements that provide competitive advantage but are not easily patentable. Examples include the app's back-end algorithms for tailoring ecological momentary assessments, engagement metrics that guide reward-based incentives, or proprietary data insights generated through user testing. Unlike patents, trade secrets do not require registration but depend on maintaining confidentiality through measures such as nondisclosure agreements (NDAs), restricted access, and contractual obligations with developers and collaborators [50]. Properly managed, trade secrets can provide indefinite protection so long as the information remains confidential.

Trademarks represent another critical IP layer by protecting the branding and market identity of MBapp+. The app's name ("MBapp" or "MBapp+"), logo, and distinctive design elements may be registered as trademarks with the U.S. Patent and Trademark Office under the Lanham Act (15 U.S.C. § 1051 et seq) [51]. Trademark protection would prevent competitors from using confusingly similar names or branding in the maternal mental health digital health space, thereby strengthening MBapp+'s market presence and supporting user trust. Beyond

protecting against imitation, trademarks also enhance the company's value in fundraising and partnership negotiations by establishing brand recognition and goodwill. Trademarks also support scalability: if MBapp+ expands into related maternal health interventions (e.g., anxiety or perinatal stress management), consistent branding will provide continuity across products. The ability to enforce trademarks internationally could also support dissemination into non-U.S. markets.

Taken together, copyright, trade secret, and trademark protections form a comprehensive intellectual property strategy for MBapp+. While patents may be more limited in scope until advanced predictive features are integrated, these additional IP layers secure the app's creative content, proprietary methods, and brand identity, thereby reinforcing its competitive advantage in the growing digital therapeutics marketplace.

5.3 Collaboration with MB Creators and Marigold Health

The original MB creators have provided written authorization for the study PI to adapt the curriculum into a digital application. They have not granted permission to any other entity to digitize MB, making MBapp+ the sole authorized digital version. This collaboration not only establishes legitimacy but also ensures that fidelity to MB's evidence-based curriculum is preserved while innovations expand access.

Collaboration with Marigold Health further strengthens MBapp+'s IP framework. Marigold brings proprietary AI-driven peer support technology, which will be embedded into MBapp+ while preserving distinct IP ownership between the two organizations. A dual-enrollment model ensures that users experience seamless integration, while MBapp+ retains independence of its curriculum and platform. This model protects both parties' IP while ensuring patients receive safe, supervised, and scalable mental health support.

5.4 Value of Holding IP in the Digital Health Market

In digital health, IP isn't just defensive—it's a signal of differentiation that can strengthen investor confidence, payer discussions, and partnership leverage. For MBapp+, selective patenting becomes more compelling as the product evolves beyond digitized content to novel, outcome-oriented functionality (e.g., predictive symptom modeling, AI-assisted peer moderation, or adaptive CBT workflows). This aligns with broader trends: GlobalData reports that AI has been the fastest-growing major technology area in global patent filings, with a 28% average annual growth rate through Q1 2022, highlighting how companies use patents to anchor algorithmic advantages [52].

That said, patenting algorithms is not always the dominant strategy. Software claims must clear Alice/Mayo eligibility, prosecution is costly, and detecting infringement of back-end models is inherently difficult so enforcement value can be limited. In these cases, keeping core ranking, risk-scoring, or personalization logic as trade secrets (backed by tight access controls and NDAs) often provides stronger, longer-lived protection without disclosure. The pragmatic path for MBapp+ is a hybrid: seek targeted patents around truly novel AI/ML features tied to measurable clinical outcomes (which bolster fundraising and dealmaking), while retaining key algorithmic methods and data heuristics as trade secrets to preserve practical exclusivity.

Chapter 6. Final Recommendations for MBapp+

6.1 Summary of Go To Market Strategy

This thesis has evaluated the commercialization strategy for MBapp+, a digital health intervention adapted from the Mothers & Babies program to address postpartum depression (PPD). Unlike most general-purpose health apps, MBapp+ is tailored specifically to perinatal

women and integrates evidence-based CBT modules, ecological momentary assessments, gamification, and forthcoming AI-driven peer support.

The initial go-to-market strategy emphasizes a direct-to-consumer (DTC) launch to quickly demonstrate adoption and generate revenue. Priced competitively with other digital mental health apps at approximately $10 per month, MBapp+ can establish traction while refining features based on user behavior and feedback. This approach provides a scalable pathway to validate demand, support payer negotiations, and create proof-of-concept data. Ultimately, insurance reimbursement will be essential to reach vulnerable populations unable to afford subscription fees, but DTC offers a pragmatic starting point that minimizes delays and establishes MBapp+'s presence in the digital health marketplace.

6.2 Assumptions, Limitations, and Risks

The financial modeling presented in this thesis is based on assumptions and should be viewed as illustrative rather than predictive. Similarly, market share projections assume a 5% capture of the U.S. population experiencing PPD by Year 3, with adoption and retention rates benchmarked against comparable digital health apps. However, real-world uptake may diverge substantially depending on marketing effectiveness, payer adoption timelines, competitive dynamics, and user trust in digital maternal health solutions.

The qualitative study that informed early design decisions engaged 25 English- and Spanish-speaking perinatal patients with Medicaid insurance. While this provided valuable user-centered feedback, the small sample size and single recruitment site limit generalizability, particularly to higher-income or privately insured groups. Moreover, the study focused on usability and content preferences rather than willingness to pay, which constrains the accuracy of demand projections.

Operational risks also warrant consideration. Sustaining user engagement in digital health apps is notoriously challenging, and churn could undermine revenue projections. Additionally, the broader app marketplace is saturated, with hundreds of mental health tools competing for attention. Integration into payer reimbursement structures may face administrative and regulatory hurdles, and the cost of ongoing app maintenance, security updates, and technical support may exceed current estimates. These risks highlight that MBapp+'s commercialization pathway requires cautious execution and flexibility to adapt to emerging challenges.

6.3 Future Directions, Long-Term Growth, and Market Opportunities

Looking ahead, the continued success of M.Bapp+ depends on generating robust clinical and economic evidence to support its adoption by healthcare systems and payers. A key step in this process is the randomized controlled trial currently being conducted with support from the NIH. This study evaluates the feasibility, acceptability, and preliminary efficacy of MBapp+ in PPD. 90 participants are randomized to receive either MBapp+, which delivers nine interactive CBT modules and daily voluntary assignments, or an attention-matched parenting education app offering general maternal wellness content without CBT components.

The trial employs a quadruple-masked design, ensuring that participants, care providers, investigators, and outcomes assessors remain blinded to group assignment to reduce bias. Primary outcomes include feasibility, measured by recruitment and engagement rates, and acceptability, assessed using the System Usability Scale (SUS) and Client Satisfaction Questionnaire (CSQ) at six months postpartum. Secondary outcomes examine reductions in depressive, anxiety, and stress symptoms, along with relationship satisfaction, loneliness, and skill utilization across multiple follow-up points. Depressive symptom reduction will be assessed using validated psychometric measures such as the Edinburgh Postnatal Depression Scale

(EPDS), providing standardized, quantitative evidence of MBapp+'s impact on mental health outcomes [26].

Comparing M.Bapp to an active digital control will generate pivotal data on the app's clinical effectiveness, usability, and scalability as a digital therapeutic for maternal mental health. The findings will guide future iterations of M.Bapp+, inform long-term dissemination strategies, and support payer reimbursement discussions.

While DTC provides a near-term entry point, MBapp+'s long-term growth lies in institutional adoption. Insurance companies are a natural next step, particularly since USPSTF recommendations obligate coverage of preventive services. Embedding MBapp+ into bundled maternity care packages could reduce downstream costs of untreated PPD, aligning with payer incentives to improve maternal outcomes while lowering healthcare expenditures. Large employers also represent a promising market, as untreated PPD contributes to absenteeism and decreased productivity. Offering MBapp+ through employee wellness programs could improve workforce retention and performance.

Beyond clinical deployment, partnerships in this space could create new revenue streams while reinforcing MBapp+'s role as both a therapeutic and research-enabling tool. The study PI is also exploring a partnership with Sage Therapeutics, a biopharmaceutical company focused on developing and commercializing therapies for brain health disorders. The company is known for creating Zurzuvae (zuranolone), the first and only FDA-approved oral medication for PPD [53]. The partnership would consist of providing de-identified participant data from longitudinally collected psychometric surveys in exchange for funding to cover app maintenance, further highlighting the commercial and research utility of MBapp+.

Future development will further strengthen MBapp+'s position. The planned integration of AI-driven peer moderation through collaboration with Marigold Health will enhance engagement, provide timely support, and increase user trust. These features will allow MBapp+ not only to support users directly but also to generate unique insights into maternal mental health trends, creating more opportunities for payer partnerships, employer adoption, and collaborations with biopharmaceutical and research organizations.

Collectively, these strategies position MBapp+ for sustainable growth, bridging the gap between clinical evidence and scalable digital implementation to improve maternal mental health outcomes.

6.4 Conclusion

In summary, this thesis has demonstrated the urgent unmet need for scalable, non-pharmacological interventions to address postpartum depression, a condition affecting hundreds of thousands of women in the U.S. annually. MBapp+ adapts the evidence-based Mothers & Babies program into an accessible digital format, incorporating user-driven features such as ecological momentary assessments, gamification, and AI-supported peer moderation. The commercialization analysis outlined a phased strategy: beginning with a direct-to-consumer launch to establish demand, transitioning to payer reimbursement models to maximize accessibility, and exploring institutional partnerships with employers, insurers, and research organizations. Financial modeling and valuation exercises demonstrated a viable revenue pathway, while intellectual property and regulatory reviews clarified the opportunities and risks in securing defensibility. Although limitations remain, MBapp+ is positioned as a promising digital therapeutic that can improve maternal mental health outcomes, reduce healthcare costs, and generate long-term market value.

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