IDS. 334 Systems Design and Management in a Changing World. Projects

FLEXIBLE OPTIONS IN A MEDTECH STARTUP PRODUCT - SYSTEMS DESIGN AND MANAGEMENT UNDER UNCERTAINTY

Ignacio Rodriguez de Castro
MSc in Mechanical Engineering Candidate
Supervisor: Richard de Neufville
Spring (H3) 2025

Table of Contents

Executive Summary

The Context
The MedTech industry is a rapidly evolving sector that encompasses a wide range of healthcare technologies, including diagnostic, therapeutic, monitoring, and surgical devices. BREATHEBAND, a wearable device designed to anticipate asthma attacks in children, represents a promising innovation within this industry. However, its development and commercialization are fraught with uncertainties, including regulatory hurdles, market demand variability, and cost fluctuations.

The Issue (Management Under Uncertainty)
Managing uncertainty is a critical challenge in the MedTech industry. Traditional deterministic planning approaches often fail to account for the inherent variability in factors such as regulatory costs, market demand, and manufacturing expenses. This can lead to inaccurate financial projections and an increased risk of project failure. BREATHEBAND's success hinges on effectively navigating these uncertainties.

The Analysis
This report employs systems design and management (SDM) principles to analyze BREATHEBAND's development under uncertainty. It contrasts a deterministic financial model with a more realistic, uncertainty-considering approach using Monte Carlo simulations. The analysis identifies key uncertainties affecting BREATHEBAND, including variability in R&D costs, regulatory expenses, demand fluctuations, and manufacturing costs. A sensitivity analysis using a tornado diagram highlights the significant impact of demand variability on the project's net present value (NPV). Embedded Flexible Options triggered by Decision Rules were designed to profit from this uncertain development landscape.

The Results
The Monte Carlo simulations reveal that the deterministic NPV of $49.31 million is unlikely, with most scenarios yielding lower or negative NPVs. Flexible options (FOs) are introduced to mitigate these risks. FO #1 involves adjusting the product price in response to increased development costs, FO #2 involves investing in manufacturing when costs are favorable, and FO #3 involves canceling the project if early-stage costs exceed expectations. The combined use of these options (FO #4) offers the most favorable NPV distribution, reducing potential losses and increasing upside potential.

The Recommendations
Based on the analysis, the following recommendations are made for BREATHEBAND's development:

- Account for Uncertainty: Incorporate flexible planning to manage uncertainties.
- Implement Flexible Option #1.
- Implement Flexible Option #3.
- Conduct Thorough Market Research.
- Partner with Experienced MedTech Investors.

Glossary

MedTech: abbreviation for Medical Technology.

BioTech: abbreviation for Biological Technology.

Pharma: abbreviation for Pharmaceuticals.

MRI; Magnetic Resonance Imaging.

CT: Computerized Tomography.

ECG: ElectroCardioGram.

FDA: Food and Drug Administration.

EMA: European Agency of Medicines.

PMA: Pre-Market Approval.

COGS: Cost of Goods Sold.

SGA: Selling, General, and Administrative (costs).

TAM: Total Addressable Market.

SAM: Serviceable Addressable Market.

SOM: Serviceable Obtainable Market.

BREATHEBAND: the product.

SIGH: the premium software package.

DCF: Discounted Cash Flow.

MC Simulation: Monte Carlo Simulation.

FO: Flexible Option.

P#: the probability of a value X being smaller than #.

NPV: Net Present Value.

R&D: Research and Development.

DTC: Direct to Consumer

B2C: Business to Consumer

F&F: Friends and Family

MVP: Minimum Viable Product

V&V: Verification & Validation (of an idea/product/technology)

GLP: Good Lab Practices

IDE: Investigational Device Exemption

FIH: First in Human

PH#: Phase #

CT: Clinical Trial

List of Tables

List of Figures

Disclaimer

This report is the final deliverable of the MIT class named *IDS 333. Projects (Spring 2025)*, instructed by Prof. Richard de Neufville. Hence, its purpose is fundamentally educational, and its aim is not to provide an exhaustive description of the technology, or the situation exposed. Similarly, I do not claim that the data is accurate, as it is mainly representative, for the obvious reason of being a (yet non-existent) start-up project. The project aims to analyze the design of an entrepreneurial product/system (MedTech start-up) under uncertainty.

1. Introduction

The medical technology (MedTech) industry is rapidly evolving, with innovations transforming healthcare delivery and patient outcomes. One area of significant focus is pediatric asthma, a chronic condition affecting millions of children worldwide. Current management strategies often react to asthma attacks rather than prevent them, highlighting the need for proactive solutions. BREATHEBAND, a wearable device designed to anticipate asthma attacks in children, represents a promising approach to this challenge. However, its development and commercialization are fraught with uncertainties, including regulatory hurdles, market demand variability, and cost fluctuations. This report examines the design and management of BREATHEBAND under these uncertainties, employing systems design and management (SDM) principles and embedded flexible options to optimize its development and market success.

2. Background

2A. Starting Up in MedTech

i. The Industry

The MedTech industry, also known as the medical device industry, encompasses a wide range of products and technologies used in healthcare to diagnose, prevent, monitor, and treat diseases and medical conditions (1). These products can be classified into the following categories:

1. *Diagnostic Devices*
    - Examples: Thermometers, blood glucose meters, MRI scanners, CT scanners, X-ray machines, ECG machines, and ultrasound devices.
    - Function: These devices help in diagnosing diseases by analyzing body functions or structures.
2. *Therapeutic Devices*
    - Examples: Bandages, inhalers, insulin pumps, pacemakers, dialysis machines, ventilators.
    - Function: These devices are used to treat or manage medical conditions.
3. *Monitoring Devices:*
    - Examples: Blood pressure monitors, pulse oximeters, fitness trackers, continuous glucose monitors (CGMs), and Holter monitors.
    - Function: These devices track vital signs or health metrics over time.
4. *Surgical Instruments:*
    - Examples: Scalpels, forceps, and robotic surgical systems.
    - Function: Used in surgical procedures to assist in operations.
5. *Implants:*
    - Examples: Cochlear implants, orthopedic screws and plates, coronary stents, artificial heart valves, and dental implants.
    - Function: These are inserted into the body to replace or support damaged tissues or organs.
6. *Emerging Trends*

- Examples: Internet of Medical Things (IoMT or Digital Health), which integrates IoT technologies into medical devices, Artificial Intelligence (AI), and Machine Learning (ML) for Health.

To avoid confusion, it's important to draw a line between MedTech and two similar industries: Pharma and Biotech. While Pharma companies focus on developing small-molecule drugs, which are chemically synthesized compounds, biotech companies focus on developing biologics (large-molecule drugs derived from living organisms) through biological techniques such as genetic engineering, cell culture, and molecular biology. However, MedTech companies develop electromechanical (hardware) and digital (software) products. All these industries are categorized as Life Sciences fields.

ii. FDA and Regulatory Frameworks

Medical devices are regulated by various bodies globally, including the FDA in the U.S. and the European Medicines Agency (EMA) in the EU. Devices are classified based on their risk and complexity, with different regulatory requirements for each class (2).

As happens in every health-related industry, medical devices must undergo an exhaustive regulatory approval process before they can be used on a patient, which is their final goal. This regulatory process ensures efficacy and safety before the product reaches the open market. Medical devices are regulated by various bodies globally, including the FDA (Food and Drug Administration) in the U.S. and the European Medicines Agency (EMA) in the EU. As the product would be initially marketed in the U.S., we will focus solely on the FDA's regulatory process, mentioning that other agencies' procedures and requirements are very similar.

The FDA classifies medical devices into three categories based on their risk profile and the level of regulatory control required to ensure safety and effectiveness. Devices belonging to each class have their regulatory process, with the pre-market requirements becoming increasingly more complex, lengthy, and costly as the class increases. For simplicity, here is a short description of the different FDA classes and their regulatory specificities (3).

1. Class I Medical Devices

- Risk Level: Low to moderate risk.
- Examples: Enema kits, elastic bandages, manual stethoscopes, bedpans, hospital beds, oxygen masks, tongue depressors, and arm slings.
- Regulatory Requirements: Most Class I devices are exempt from premarket notification and clearance. However, they must undergo general controls and manufacturers must register their establishment and list their products with the FDA (2). They sometimes require a 510(k) premarket notification.

2. Class II Medical Devices

- Risk Level*:* Moderate to high risk.
- Examples*:* Powered wheelchairs, some pregnancy test kits, CT scanners, catheters, infusion pumps, X-ray systems, contact lenses, syringes, and blood transfusion kits.

- Regulatory Requirements: Class II devices are generally subject to general and special controls, which leads to a premarket notification in the form of a (510(k)) to demonstrate safety and effectiveness before marketing.

3. Class III Medical Devices

- Risk Level*:* High risk.
- Examples: Implantable pacemakers, breast implants, orthopedic implants, and artificial heart valves.
- Regulatory Requirements*:* Class III devices require a premarket approval (PMA) application, which involves a rigorous review process to ensure safety and effectiveness. However, these devices can apply for a 510K based on substantial equivalence (SE) to an existing device. This is always the preferred path for these types of devices as PMA application requirements are much more expensive than 510(k) requirements. If they deny their 510(k), they can apply for a "De Novo" pathway (cheaper than a PMA but more expensive than a 510(k)).

	Class I	Class II	Class III
Regulatory Requirements	General Controls	General Controls and Special Controls	General Controls and Premarket Approval
Categorical Risk	Low	Mild-to-high	High
Device Tendencies	Simple design and low risk profile. Often exempt from regulatory processes	Comprise the majority of medical devices. These devices benefit from the assurances of special controls (i.e,. Labeling requirements, postmarket surveillance, etc.)	Devices that are life sustaining, life supporting, implanted, or otherwise inherently associated with risk
Example Devices	Elastic bandages (Product code: FQM)	Over the Counter pregnancy tests (Product code: LCX)	Implantable cardioverter defibrillator (Product code: LWS)

Table 1: Medtech Intelligence´s FDA Classes Summary Table (3).

2B. The Start-up – BREATHEBAND

i. Clinical Unmet Need

Asthma remains a critical public health issue, affecting millions globally and posing a particular challenge for children. In the United States alone, approximately 5 million children are diagnosed with asthma, making it the most common chronic disease among youth. For parents, the risk of an unexpected asthma attack—especially when they're not nearby—can be a constant source of anxiety. Despite the prevalence of pediatric asthma, no current solutions on the market offer comprehensive monitoring capabilities that integrate patient-specific health indicators and real-time environmental data.

ii. The Product

BREATHEBAND is a wearable band (wristband) that anticipates asthma attacks in kids (ages 5-14 years). It measures and analyzes two types of data (1. internal, patient data and 2. external, atmospheric data) to accurately calculate the probabilities of an asthma attack. When these chances surpass the patient's safety threshold (individual to the patient thanks to learning and predictive AI models), it triggers an alarm that indicates to the parents that medical assistance must be provided to the kid. All this happens BEFORE the kid shows severe symptoms of an asthma attack, as opposed to the current modus operandi in asthma handling, which is based on therapeutic action when the patient shows problematic asthma attack symptoms (medical help is provided DURING the attack, at its beginning in the best-case scenarios). This difference majorly impacts patient populations' health and healthcare systems' costs and resources.

iii. Product Development Roadmap

The roadmap for BREATHEBAND's development is for a Class II wearable device comprising hardware and software components. The following figure showcases the BREATHEBAND'S Development Road, with timelines, stages, and key financing moments.

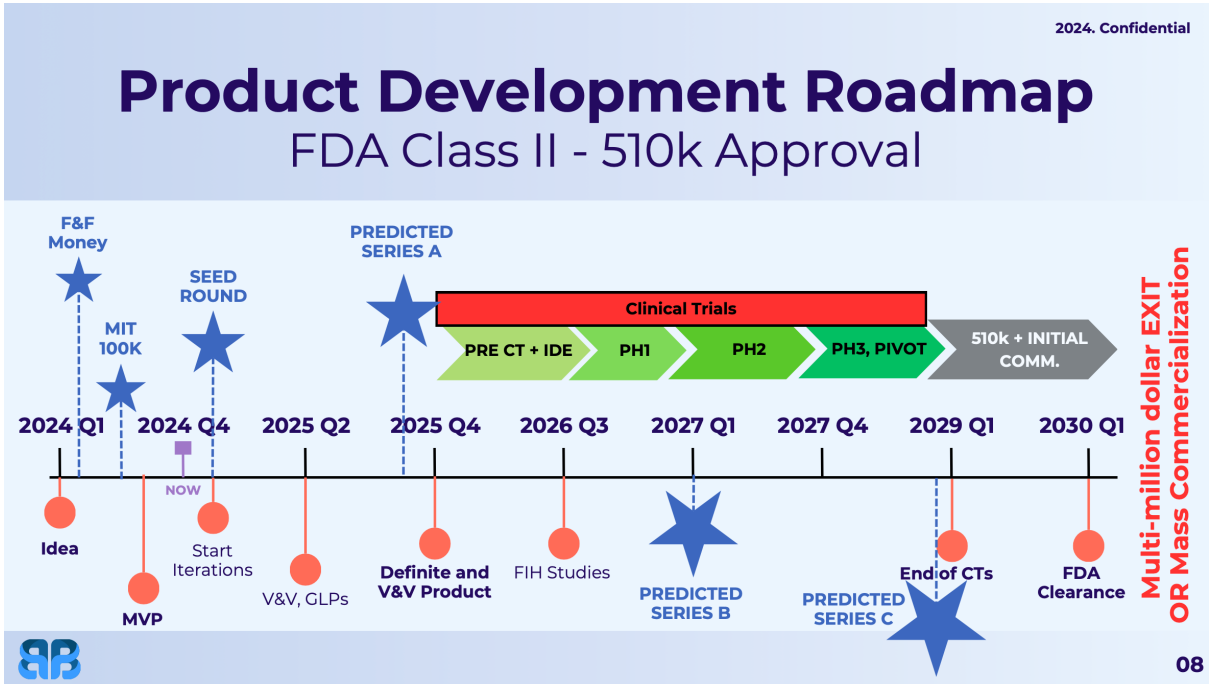

Figure 1: Product Development Roadmap Prediction for BREATHEBAND. The graph covers the initial R&D iterative phase (2024 Q1 – 2025 Q4), which includes Verification and Validation (V&V) and Good Lab Practices (GLP) periods and the regulatory compliance phase (2025 Q4 – 2030 Q1). The latter starts with pre-clinical trial (Pre-CT) studies (in vitro and animal models). Once this phase is completed, the subsequent phases 1, 2, and 3 (PH1, PH2, and PH3, respectively) human studies take place with sufficient time in advance for the 510k request and approval by the FDA.

iv. Revenue/Pricing Model

Our post-commercialization revenue model is based on the basic + premium structure, which yields two pricing options for the consumer. It is important to clarify that both options ensure the patient's safety.

- **Option 1 (Gold).** Includes BREATHEBAND with all its basic asthma attack anticipation capabilities (the ones described). One-time purchase of $799.99.

- **Option 2 (Platinum).** Includes BREATHEBAND and SIGH, an additional software bundle that includes a more extensive asthma attack prediction system (several levels of severity until reaching the threshold, key recommendations within each level based on the retrieved data, additional information regarding the data retrieving methods, and additional historical visualization and graphics. It is an improved version of BREATHEBAND. One-time purchase of $799.99 for BREATHEBAND and a monthly payment of $9.99 for the SIGH software package.

v. Sales Channels

For BREATHEBAND, we have chosen a B2C model. We will sell through two main channels:

1. **DTC (Direct-To-Consumer)** through our website.
2. **B2C**, using major health retailers as intermediaries that work on a fee (e.g., CVS, Amazon)

The idea is to increase product awareness through marketing as the years pass and maximize revenue coming from channel 1 (most profitable), minimizing revenue coming from channel 2 (less profitable). Selling to hospitals and using medical supply distributors is initially discarded but can be introduced in the future.

2C. Systems Design and Management Under Uncertainty

i. Systems, Design, and Management in a Changing World

In a rapidly evolving world, systems, design, and planning must be adaptive and resilient. With technological advancements, shifting economic landscapes, and environmental challenges, traditional rigid approaches to planning are no longer effective. This report explores the key aspects of planning methodologies, including deterministic planning, uncertainties, simulation techniques, and flexible decision-making strategies.

Systems design refers to the structured organization of components and processes to achieve desired outcomes. Effective planning and management are crucial for ensuring sustainability and efficiency in various domains, such as business, infrastructure, and technology. However, planning in a changing world requires the ability to anticipate disruptions, integrate technological innovations, and develop strategies that enhance adaptability.

ii. Deterministic Evaluation

Deterministic evaluation is a methodology that assumes a predictable and controlled environment where all inputs, constraints, and future states are known with certainty. This

approach is useful in structured environments where variability is minimal. Deterministic models are commonly used in:

- Project scheduling and management
- Logistics and supply chain optimization
- Infrastructure development

While deterministic planning seems to provide clear and precise outcomes, it does not recognize the reality of uncertainty and therefore lacks the flexibility to accommodate unexpected disruptions. As a result, industries operating in dynamic environments often require more robust approaches that integrate uncertainty management.

iii. Uncertainties and Randomized (Realistic) Planning

While deterministic planning provides clear and predictable outcomes, it lacks the flexibility to accommodate unexpected disruptions and, consequently, accuracy in many scenarios. As a result, industries operating in dynamic environments often require more robust approaches that integrate uncertainty management.

Unlike deterministic planning, realistic planning acknowledges uncertainties inherent in real-world scenarios. Uncertainty arises due to various factors, such as market fluctuations, environmental changes, human decision-making behavior, and technological disruptions.

To manage uncertainty, randomized or stochastic planning methods use probability distributions to model different possible outcomes. These approaches are based on yielding a distribution of possible results compared to the unique value of the deterministic approach. This helps organizations develop risk mitigation strategies, optimize resource allocation, and improve resilience in unpredictable environments. Stochastic modeling is widely applied in finance, healthcare, and disaster management.

iv. Simulation. Monte Carlo.

A way to calculate the distribution of results is through a Monte Carlo Simulation. This statistical method randomizes a significant set of simulated system performances and classifies them according to their value. Through this “binning” process and considering a sufficient amount of samples, we can obtain a distribution of results with their frequency or probability percentage and a target curve. The target curve, which can be a cumulative distribution function (CDF) or a probability distribution function (PDF), is a performance measure of a system based on the frequency of the distribution of its outcomes. For example, the CDF of BREATHEBAND is the result of performing a Monte Carlo simulation on the uncertainty-considering (randomized) scenario, which yields the incremental sum (the integral) of the distribution of the 2,000 randomized outcomes.

As the target curve depicts the range of outcomes and performance of a system, it highlights the possible risks of the project, such as finding simulated scenarios where the Expected Value is lower than considered in our deterministic approach and that may lead to long-term losses. Equally, it can reflect the parameters we should vary to maximize the upsides of the distribution of outcomes, and hence, it does graphically show ways to optimally benefit from our design.

Leaving aside specific cases (such as a bimodal function), the distribution of results of a correctly designed system that accounts for uncertainty and that can trigger a profitability option when desired should NOT be symmetric. It should have a lower span to the lower side of the graph (minimize the losing scenarios) and a higher span to the right of the graph (maximize the upsides).

By generating multiple scenarios, Monte Carlo methods provide valuable insights that enhance decision-making and reduce uncertainty.

v. Flexible Options and Decision Rules

Given the uncertainties in modern planning, flexibility is a key component of effective decision-making. Flexible options allow organizations to adjust their plans in response to emerging conditions, minimizing losses and capitalizing on opportunities. Decision rules provide structured guidelines that help determine the best course of action based on available information, i.e., they trigger the option based on predictive and accurate planning (6).

The key aspect of an option is its non-mandatory nature: it should be triggered only when the environment is favorable for this triggering. To do this, we establish decision rules. These are based on industry expertise and are an automated way to execute the option when convenient.

By incorporating flexibility into planning processes, organizations can improve resilience, optimize performance, and navigate complex challenges more effectively.

3. SDM Approaches

3A. The Deterministic Approach

Our deterministic model for BREATHEBAND is a simplified version of the company's forecasted financials during its development (Year 0: 2024 – Year 5: 2029) and early commercialization stages (Year 6: 2030 – Year 9: 2033). This financial sheet (similar to an income statement) accounts for major costs (COGS and SGAs) what are these and revenue. While revenue is computed based on the Serviceable Obtainable Market (SOM, obtainable share of our serviceable addressable market or SAM), cost values come from market research. Hence, the used parameters are figurative but realistic and based on reports from similar companies publicly available (5).

With the revenue and costs, we calculated the cash flow, which can be thought of as the company's profitability each year. As one of the aims of this project is to assess the profitability of investing in or pursuing BREATHEBAND's idea at the beginning of the journey (2024), the discounted cash flow (DCF) is computed. The DCF is a financial valuation method used to estimate the value of an investment based on its expected future cash flows. It calculates the present value of these cash flows by applying a discount rate, which reflects the time value of money and the risk associated with the investment. The chosen discount rate was 10.40% (6). This high value reflects the high risks associated with the MedTech industry. We summed the DCF value from each year to obtain BREATHEBAND's expected Static NPV (2024), $49.31 million. A summarized view of BREATHEBAND's deterministic financial projection is depicted as follows:

Discount rate	10.40%		Variable Salaries Percentage	10%						
	Pre-Commercialization Stage (2024 - 2029)						Commercialization Stage (2030 -)			
Year	0	1	2	3	4	5	6	7	8	9
$1,000,000s	Year 0 (2024)	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)	Year 7 (2031)	Year 8 (2032)	Year 9 (2033)
Sales	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 52.23	$ 105.17	$ 131.48	$ 156.47
Cash Inflow	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 52.23	$ 105.17	$ 131.48	$ 156.47
Variable Expenses (Variable COGS)										
Manufacturing & Materials	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 16.32	$ 31.95	$ 38.62	$ 45.57
Variable Salaries	$ 0.00	$ 0.09	$ 0.14	$ 0.21	$ 0.30	$ 0.42	$ 0.77	$ 0.83	$ 1.11	$ 1.33
Total Variable Expenses	$ 0.00	$ 0.09	$ 0.14	$ 0.21	$ 0.30	$ 0.42	$ 17.09	$ 32.78	$ 39.73	$ 46.90
Fixed Expenses (Fixed COGS)										
R&D	$ 0.20	$ 5.50	$ 2.00	$ 1.50	$ 1.00	$ 0.25	$ 0.50	$ 0.80	$ 0.70	$ 1.00
Regulatory	$ 0.00	$ 0.50	$ 5.00	$ 6.00	$ 8.00	$ 6.75	$ 0.50	$ 0.00	$ 0.00	$ 0.00
Marketing	$ 0.00	$ 0.01	$ 0.02	$ 0.05	$ 0.08	$ 1.50	$ 4.25	$ 5.50	$ 6.75	$ 7.00
Product Maintenance	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 6.53	$ 13.15	$ 16.44	$ 19.56
Office Rent	$ 0.00	$ 0.11	$ 0.11	$ 0.11	$ 0.11	$ 0.11	$ 0.11	$ 0.24	$ 0.25	$ 0.25
Insurance	$ 0.00	$ 0.02	$ 0.02	$ 0.02	$ 0.02	$ 0.02	$ 0.03	$ 0.05	$ 0.10	$ 0.21
Fixed Salaries	$ 0.00	$ 0.81	$ 1.27	$ 1.86	$ 2.72	$ 3.82	$ 6.90	$ 7.49	$ 9.95	$ 11.98
Total Fixed Expenses	$ 0.20	$ 6.95	$ 8.42	$ 9.54	$ 11.93	$ 12.45	$ 18.83	$ 27.23	$ 34.19	$ 40.00
TOTAL EXPENSES	$ 0.20	$ 7.04	$ 8.56	$ 9.75	$ 12.23	$ 12.88	$ 35.91	$ 60.01	$ 73.92	$ 86.90
Cashflow	-$ 0.20	-$ 7.04	-$ 8.56	-$ 9.75	-$ 12.23	-$ 12.88	$ 16.31	$ 45.16	$ 57.56	$ 69.57
DCF	-$ 0.20	-$ 6.38	-$ 7.03	-$ 7.24	-$ 8.24	-$ 7.85	$ 9.01	$ 22.59	$ 26.09	$ 28.55
NPV	$ 49.31									
DEMAND GRAPH										
DETERMINISTIC DEMAND	0	0	0	0	0	0.00	0.06	0.18	0.33	0.50
BREAKEVEN GRAPH										
Cumulative Discounted Losses	$ 0.20	$ 6.58	$ 13.60	$ 20.85	$ 29.08	$ 36.93	$ 36.93	$ 36.93	$ 36.93	$ 36.93
Cumualtive Discounted Gains	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 9.01	$ 31.60	$ 57.69	$ 86.24

Figure 2: Excel Spreadsheet Summary for the Deterministic Financial Model.

Additional values were calculated for the product's demand and cumulative cash flow to obtain visuals for the Deterministic Demand, Deterministic Expenses vs Revenue, and Deterministic cash flow break-even projection.

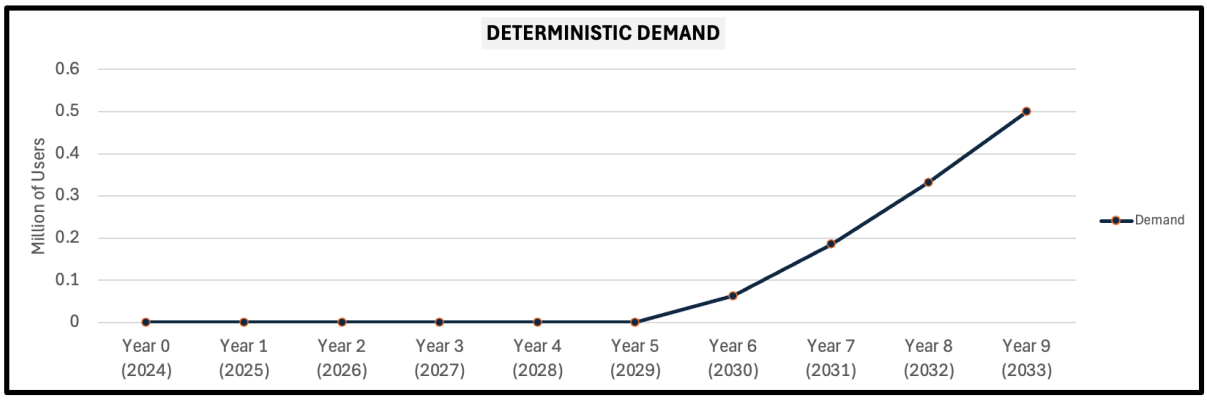

Figure 3: Deterministic Demand Graph.

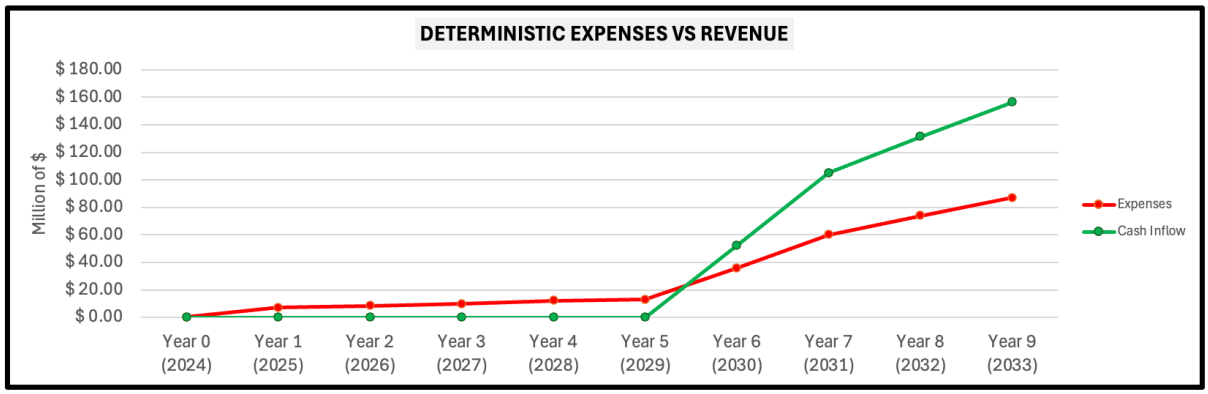

Figure 4: Deterministic Expenses vs Revenue Graph.

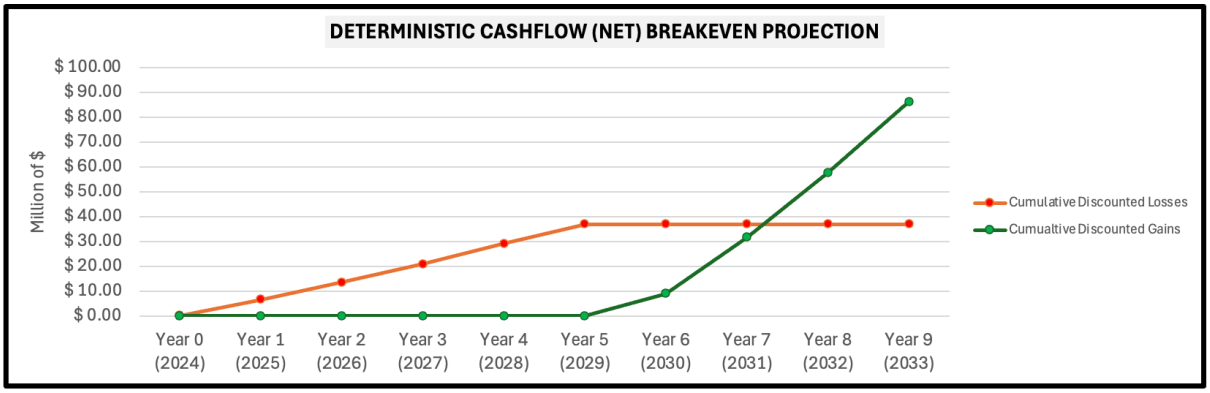

Figure 5: Deterministic Cashflow Breakeven Projection.

3B. The Realistic Approach – Modeling Under Uncertainty

As introduced in the Background section, a deterministic forecast and approach is inaccurate and rarely applies to engineering systems design. Hence, introducing uncertainty through a variable range of input values and using a randomization simulation, such as Monte Carlo, better describes BREATHEBAND's potential.

- *The Uncertainties*

Based on industry knowledge and research, we derived five major uncertainties that may have implications for BREATHEBAND's forecasted (deterministic) development.

i. Variability in Costs (Pre-commercialization Stage): Increase/Decrease in R&D Costs During the Development Phase (Pre-commercialization). This is a common situation in tech and medical device startups (20% variability).

ii. Increase in Costs (Pre-commercialization Stage): Increase in Regulatory Costs coming from clinical trials (FDA approval). Clinical Trial costs are very volatile and variable, as many factors influence them. This has a major impact on costs, as it makes regulatory costs increase by up to 50%.

iii. Decrease in Demand/Revenue (Post-commercialization Stage): Decrease in Demand (Overall, Gold and Platinum). SOM is 50% lower than the projected, caused by the lack of demand for our product.

iv. Variability in Demand/Revenue (Post-commercialization Stage): Decrease/Increase in Platinum (Subscription) Demand. Demand for the subscription-based product is 25% different than projected.

v. Variability in Costs (Post-commercialization Stage): Variability in Manufacturing and Materials Costs. A 30% change derived from medical devices' supply chain volatility and how the uncertain geopolitical situation may affect international trade and low-cost manufacturing (e.g., China).

The following table summarizes the uncertainties and their implications in BREATHEBAND'S model.

Uncertainty #	Stage	Magnitude	Effect	Affected Parameter
i	Pre-comm.	20%	+ or -	R&D Costs
ii	Pre-comm.	50%	-	Regulatory Costs
iii	Post-comm.	50%	-	Demand/Revenue
iv	Post-comm.	25%	+ or -	Demand/Revenue
v	Post-comm.	30%	+ or -	Manufacturing Costs

Table 2: BREATHEBAND'S Main Uncertainties.

- Uncertainties' Tornado Diagram

A fantastic tool to assess the impact of the uncertainties and their magnitude (range) on the outcome (NPV) is the Tornado Diagram. A tornado diagram is a graphical tool used primarily for sensitivity analysis as they are used to visualize and compare the impact of different variables or uncertainties on an outcome or output variable. Each bar represents the range of outcomes for a variable, with longer bars indicating greater sensitivity or influence on the result.

The following table shows the input parameters of the Tornado Diagram. The low and high inputs are the result of applying the maximum and minimum deviation % to the deterministic value, respectively. The low and high results are the NPV values that yield from using the low and high inputs. The spread is the difference between these two and highlights the sensitivity to perturbance of the system concerning a specific uncertainty.

		Uncertainty #	Initial input	Low Input	High Input	Low Result	High Resul	Result Spread
1.1.	Variability in R&D Costs During the Development Phase.	Uncertainty 1	$ 10.20	$ 8.16	$ 12.24	$ 51.06	$ 47.56	$ 3.50
1.2.	Increase in Regulatory Costs coming from clinical trials (FDA).	Uncertainty 2	$ 19.50	$ 19.50	$ 29.25	$ 49.31	$ 40.05	$ 9.26
1.3.	Decrease in Demand (Overall, Gold and Platinum).	Uncertainty 3	1.08	0.54	1.08	-$ 50.42	$ 49.31	$ 99.73
1.4.	Varaibility in Platinum (Subscription) Demand.	Uncertainty 4	30%	23%	38%	$ 45.26	$ 53.94	$ 8.68
1.5.	Variability in Manufacturing & Materials Costs.	Uncertainty 5	$ 132.46	$ 92.72	$ 172.20	$ 67.67	$ 30.95	$ 36.72

Figure 7: Inputs for Tornado Diagram – Effect of Uncertainties on Outcome.

This sensitivity analysis was done for each uncertainty isolated, yielding the following diagram:

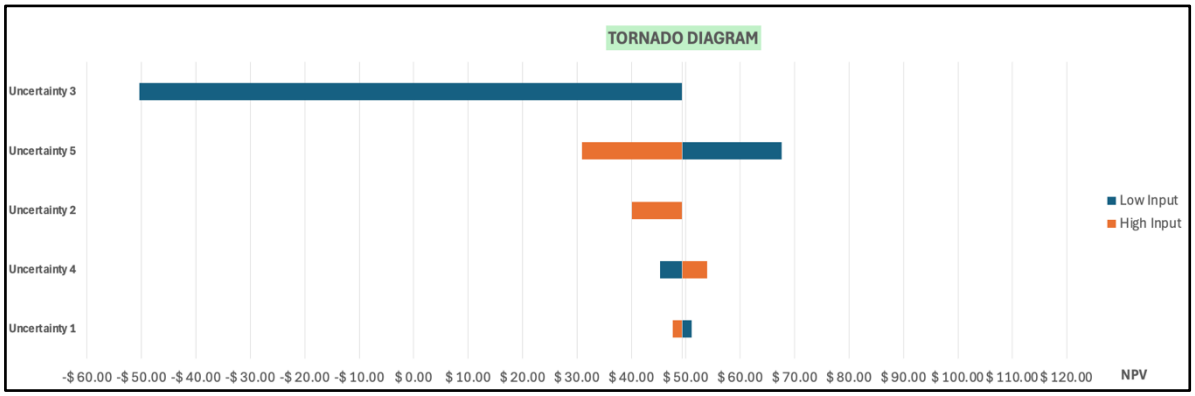

Figure 8: Tornado Diagram for BREATHEBAND.

We can observe that our system is specifically sensitive (in a negative fashion) to Uncertainty #3 (almost - $100M effect on the deterministic NPV). It only affects negatively as the initial demand variability was predicted as smaller than the extremely confident deterministic forecast. The risk factor from startups comes primarily from this – these companies fail to predict product market fit and, hence, demand. Similarly, the variability in materials and manufacturing costs (#5) also greatly impacts the NPV($36M spread), as expected.

- *The Randomized Approach Under Uncertainty*

We created a new financial model. This randomized model is based on the deterministic approach, but that accounts for a variable range of inputs (uncertainties). The Deterministic vs Randomized Demand, Randomized Expenses vs Revenue and Randomized Cashflow Breakeven Projection graphs are now variable (randomized) but also completely different, in general, than the deterministic ones.

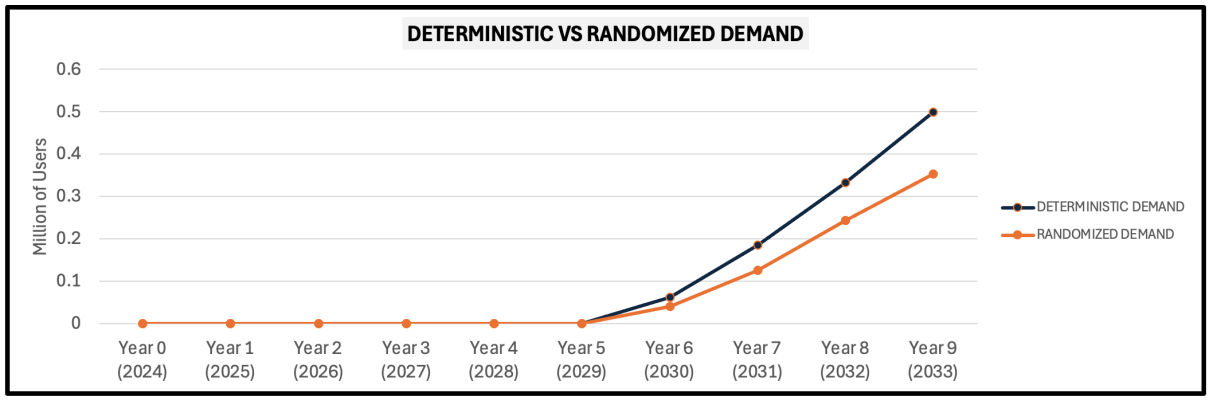

Figure 9: Deterministic vs Randomized (Particular, n=1)Demand Graph

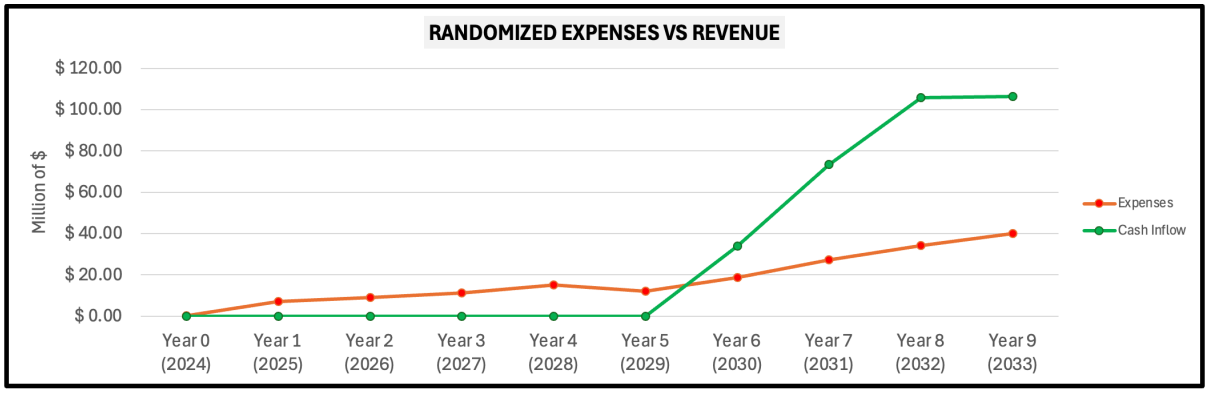

Figure 10: Randomized (Particular, n=1) Expenses vs Revenue.

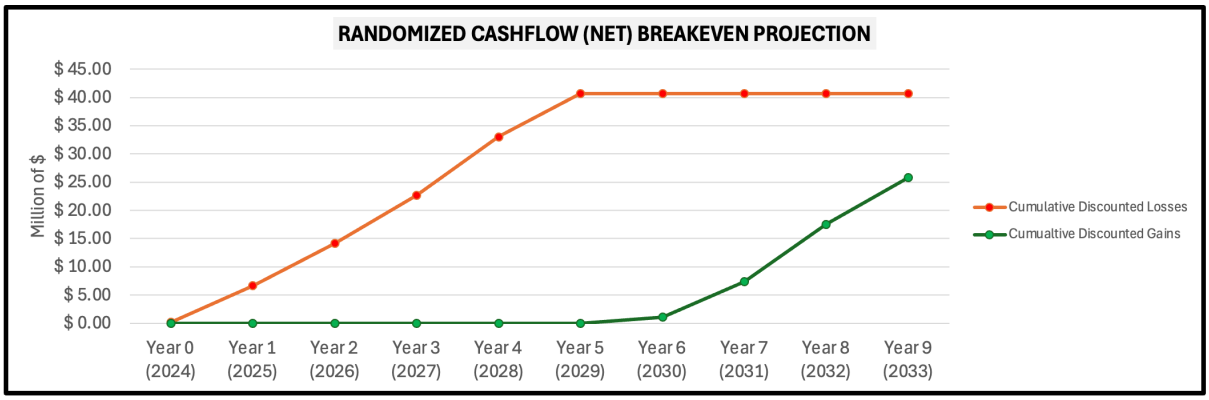

Figure 11: Randomized Cashflow Breakeven Projection (Particular, n=1).

To obtain a statistically significant NPV of the randomized model, we used the Monte Carlo simulation. The combined effect of the 5 uncertainties on the 2000 randomized examples from the MC simulation provides completely different NPV result values. The NPV target curve is nowhere near the deterministic value of $49.31M. We can read from the target curve that the probability of the NPV being $49.31M is closer to 0 (the probability of the NPV being smaller than $49.31M is almost 100%).

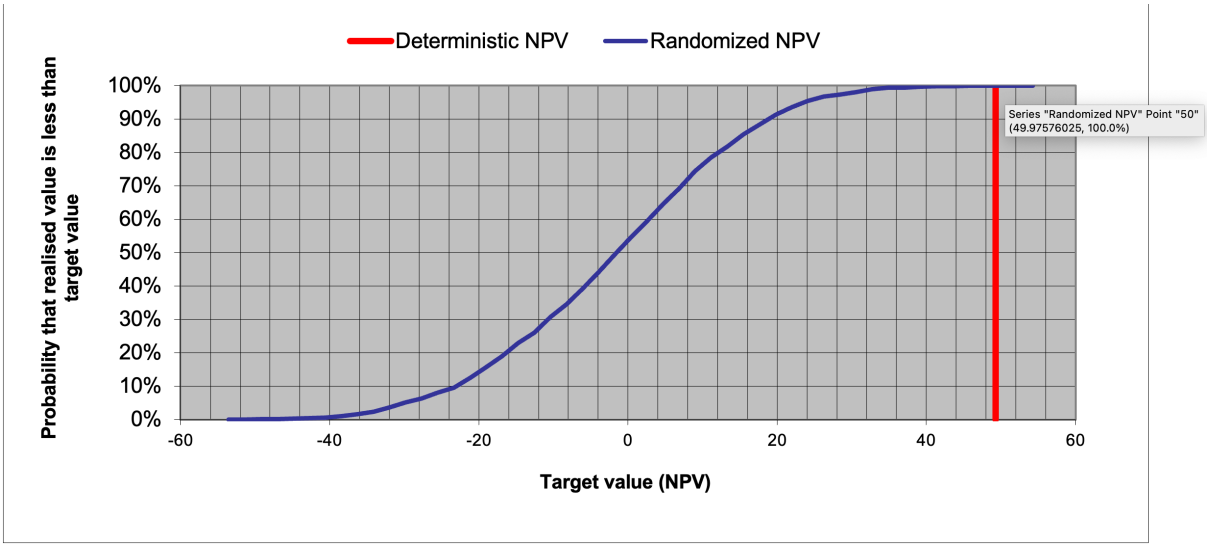

Figure 12: Target Curve Comparison between the NPV Distributions of the deterministic case and the randomized NPV case.

The histogram of the MC simulation for the randomized scenario and its statistical values are the following:

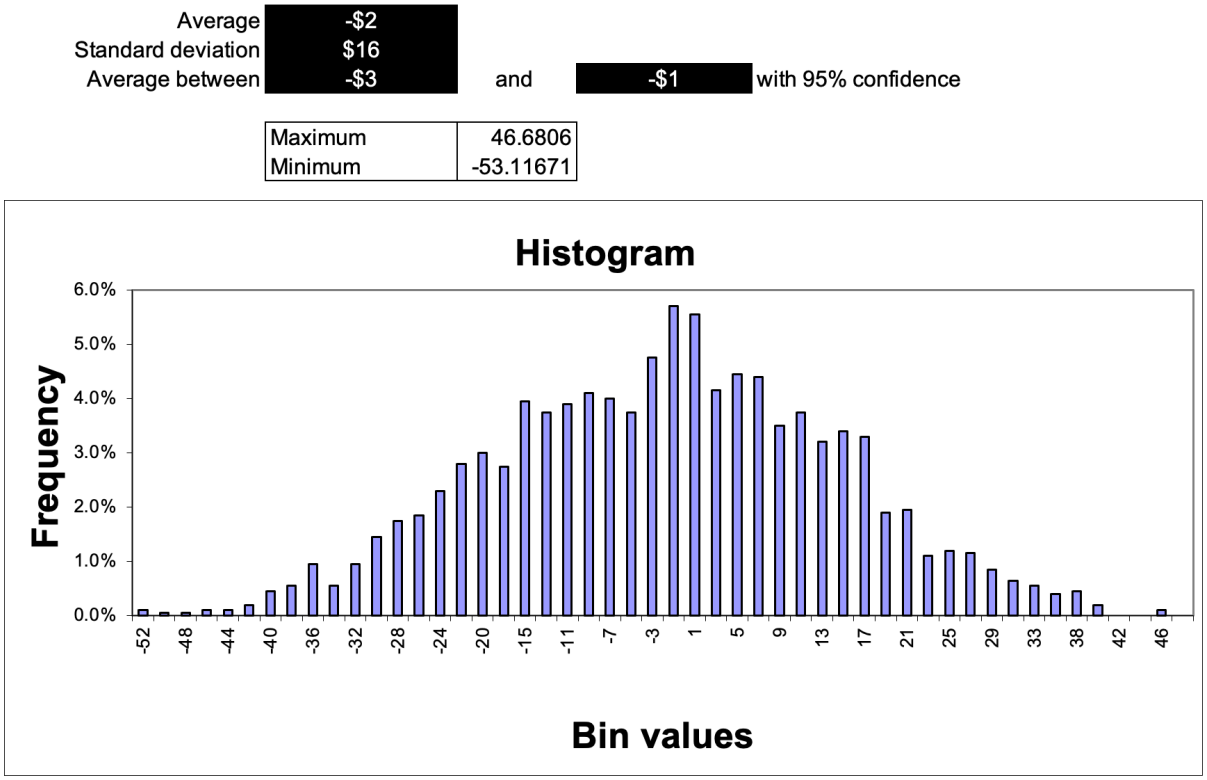

Figure 13: Histogram and Statistical Values for the Randomized Simulation.

The Value at Risk (P5, P10) and Value at Gain (P90, P95) for this NPV distribution are summarized in the following table:

Values	NPV $M)
Value at Risk, P5	- $29 M
Value at Risk, P10	- $22 M
Value at Gain, P90	$17 M
Value at Gain, P95	$24 M

Table 3a: P#s of Randomized Approach.

4. Maximizing the Realistic Case - Flexible Options "in" the Project

To counter the presented uncertainties and maximize our chances of success (optimize the distribution of NPV in the randomized MC simulation, we can include Flexible Options (FOs) in our analysis. As mentioned, these are triggered by pre-set decision rules (DRs). The following table is a summary of the considered FOs and their DRs.

Flexibility Option	Description	Decision Rule (DR)
FO #1	Increase product unit price if development costs are higher than expected.	If Product Development Cost is at least 10% higher than expected, increase Product's Base Price by 10%.
FO #2	Increase manufacturing and raw materials investment when economic conditions are favorable.	If Manufacturing costs are more favorable than the average/predicted cost, invest heavily to cover subsequent years.
FO #3	Cancel the project if early-stage development costs are significantly higher than expected.	If Product Development Cost is at least 25% higher than expected in Year 2 (pre Clinical Trials), cancel the project.

Table 3b: FOs and DRs.

i. Flexible Option #1 (FO #1)

Our first FO implies slightly increasing the product unit price (base option) if the development costs are higher than expected (passing part of the extra cost onto customers). Hence, if the product development cost is at least 10% higher than expected (DR #1), we will increase the product's base price by 10% - $879,99 instead of $799,99 (FO #1). This way, we effectively adapt to the uncertainties concerning increased development and regulatory costs (i and ii).

In the following graph, we can observe how FO #1 under DR #1 shifts the target curve to the right (orange) compared to the randomized base case (blue), with great emphasis in the middle section. The low-end and high-end results are also shifted positively.

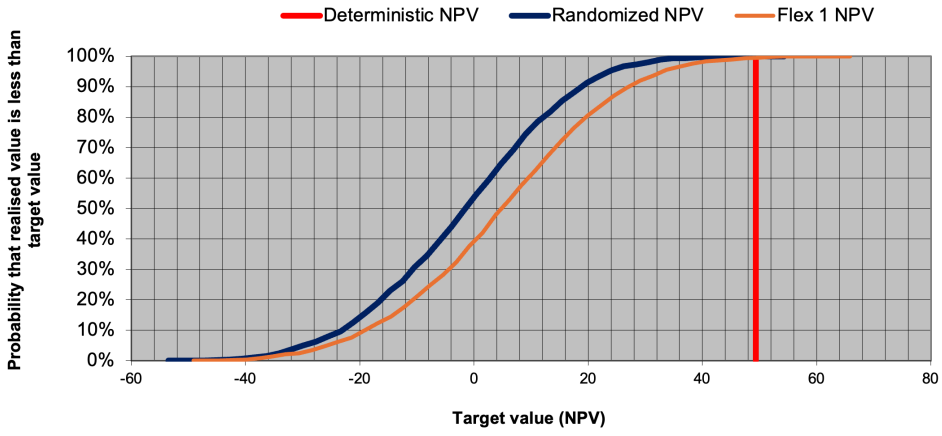

Figure 14: Target Curve Comparison between the NPV Distributions of FO #1, the deterministic case, and the randomized NPV case.

The histogram of the MC simulation for the randomized scenario with the embedded FO #1 and its statistical values are the following:

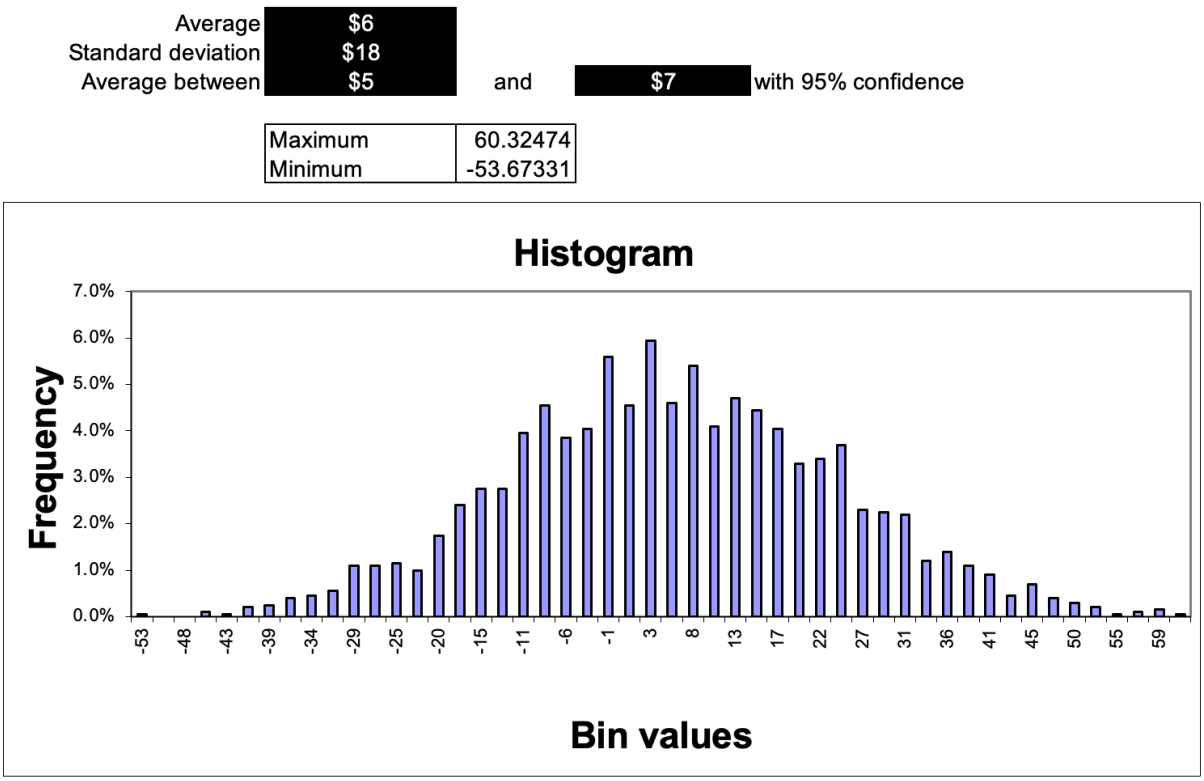

Figure 15: Histogram and Statistical Values for the Randomized FO #1 Simulation.

The Value at Risk (P5, P10) and Value at Gain (P90, P95) for this NPV distribution are summarized in the following table:

Values	NPV $M)
Value at Risk, P5	- $23 M
Value at Risk, P10	- $17 M
Value at Gain, P90	$27 M
Value at Gain, P95	$34 M

Table 4: P#s of FO #1 Simulation.

ii. Flexible Option #2 (FO #2)

FO #2 implies slightly increasing the manufacturing and raw materials investment when the economic situation is favorable for them (favorable COGS). Hence, if the manufacturing and materials costs from the current year are more favorable than the average/predicted cost, invest heavily in them to cover the subsequent years as well. This way, we effectively profit from the uncertainty of dealing with volatile costs during the commercialization stage (v).

In the following graph, we can observe how FO #2 under DR #2 slightly shifts the target curve to the right (maroon) compared to the randomized base case (blue).

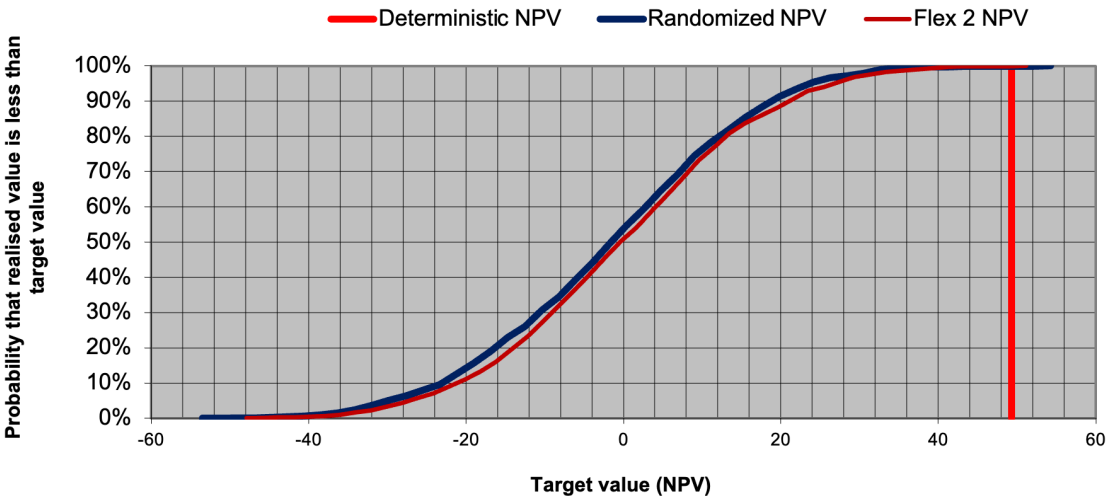

Figure 16: Target Curve Comparison between the NPV Distributions of FO #2, the deterministic case, and the randomized NPV case.

The histogram of the MC simulation for the randomized scenario with the embedded FO #2 and its statistical values are the following:

Average	$1			
Standard deviation	$16			
Average between	$0	and	$1	with 95% confidence

Maximum	52.73993
Minimum	-53.35428

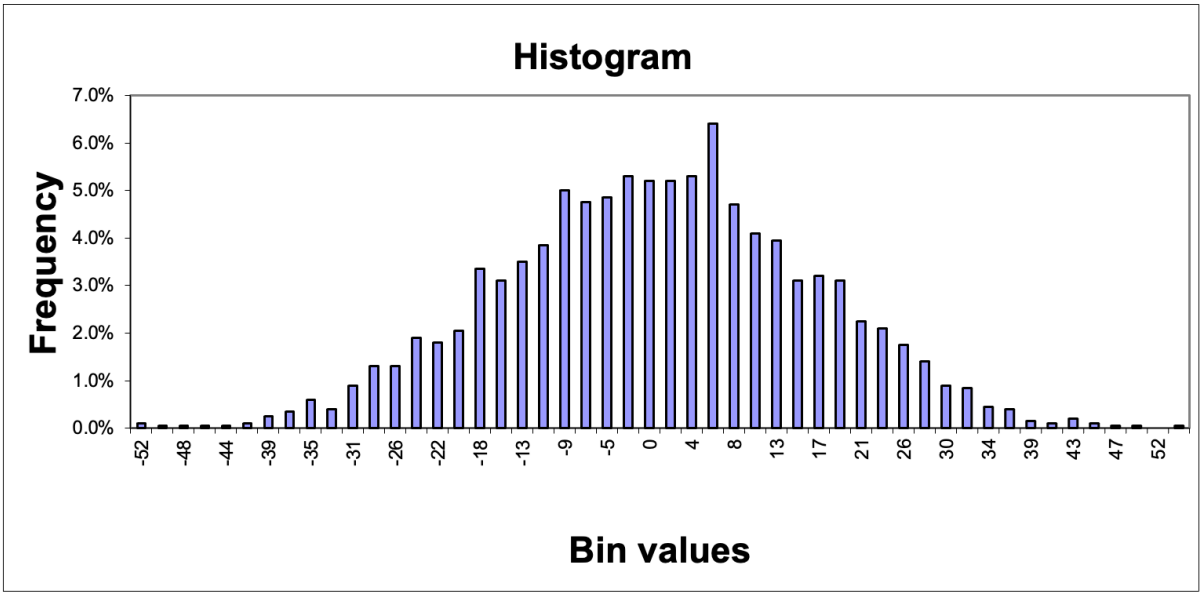

Figure 17: Histogram and Statistical Values for the Randomized FO #2 Simulation.

The Value at Risk (P5, P10) and Value at Gain (P90, P95) for this NPV distribution are summarized in the following table:

Values	NPV $M)
Value at Risk, P5	- $27 M
Value at Risk, P10	- $21 M
Value at Gain, P90	$22 M
Value at Gain, P95	$28 M

Table 5: P#s of FO #2 Simulation.

iii. Flexible Option #3 (FO #3)

FO #3 implies canceling the project if the development costs in the early stages are much higher than expected (unbearable). Hence, if the Product Development Cost is at least 25% higher than expected in Year 2 (critical timestamp, pre-clinical trials), cancel the project. This option is a form of insurance for major losses as a result of increased overall development costs (uncertainties i, ii) and decreased product-market fit (uncertainties iii, iv).

In the following graph, we can observe how FO #3 under DR #3 slightly shifts the target curve to the right (purple) compared to the randomized base case (blue).

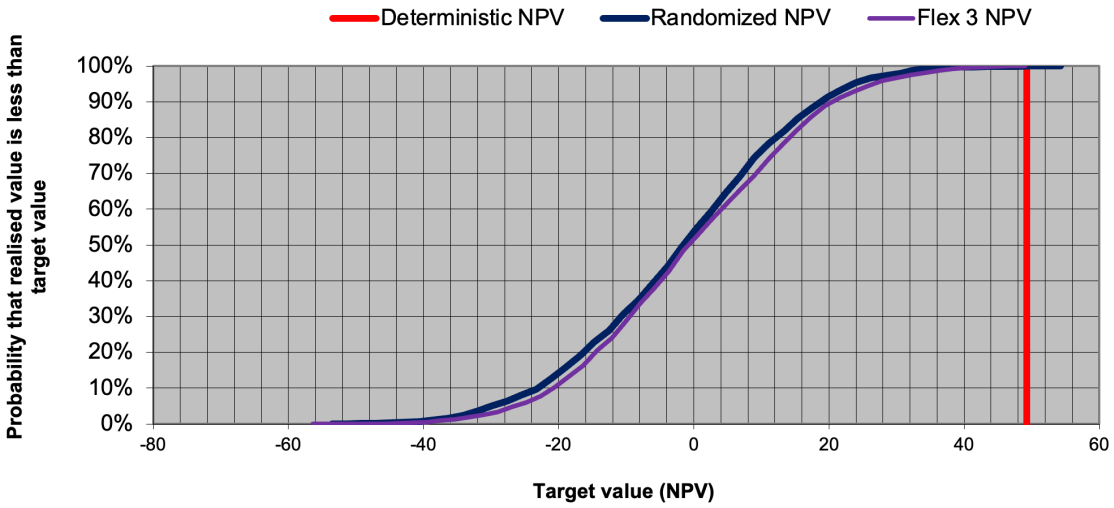

Figure 18: Target Curve Comparison between the NPV Distributions of FO #3, the deterministic case, and the randomized NPV case.

The histogram of the MC simulation for the randomized scenario with the embedded FO #3 and its statistical values are the following:

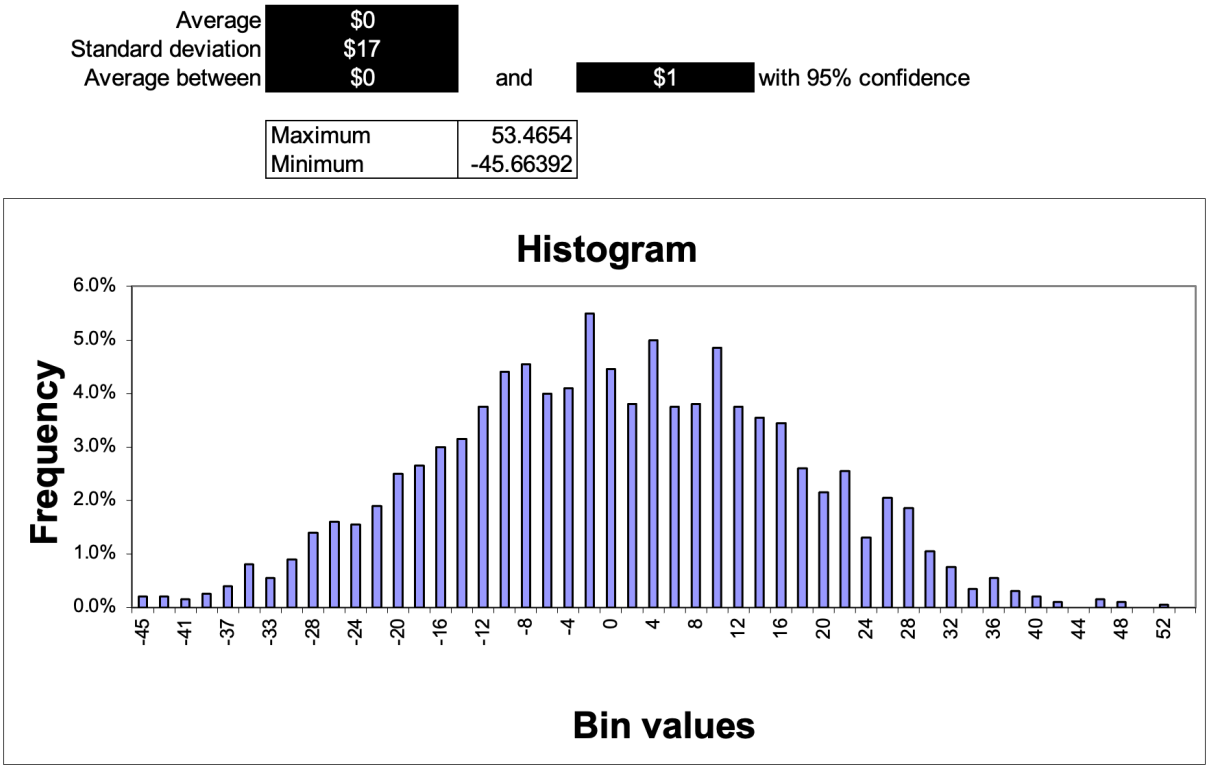

Figure 19: Histogram and Statistical Values for the Randomized FO #3 Simulation.

The Value at Risk (P5, P10) and Value at Gain (P90, P95) for this NPV distribution are summarized in the following table:

Values	NPV $M)
Value at Risk, P5	- $27 M
Value at Risk, P10	- $22 M
Value at Gain, P90	$21 M
Value at Gain, P95	$27 M

Table 6: P#s of FO #3 Simulation.

iv. Comparison of FOs #1, #2, and #3.

The following graph shows a comparison between the expected NPV distributions of the FOs and the non-flexible deterministic and randomized approaches NPVs.

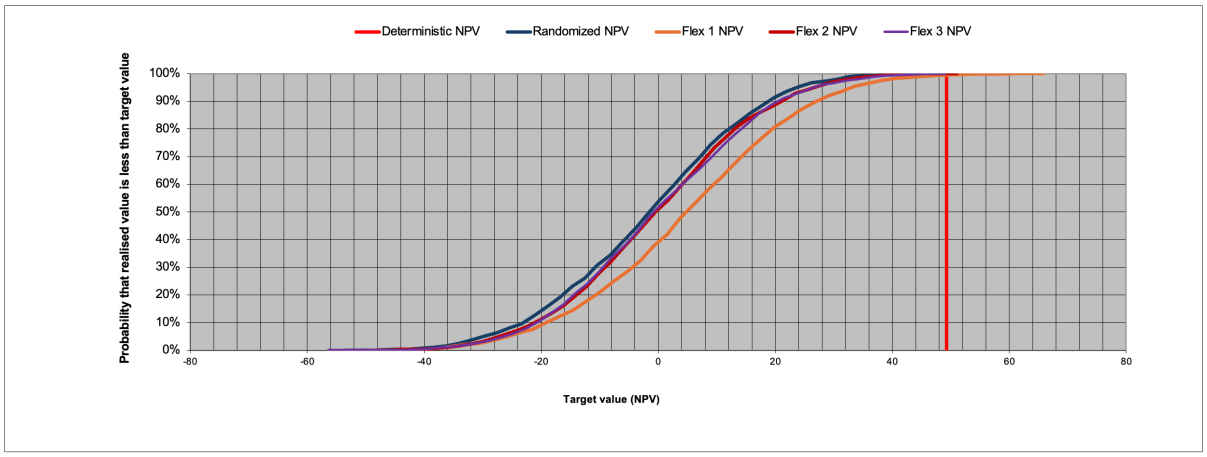

Figure 20: Target Curve Comparison between the NPV Distributions of the FO #1,#2, and #3, and the deterministic and randomized NPV distributions.

v. Flexible Option #4 (FO #4) – Combination of FOs #1, #2, and #3.

Finally, combining the previous three FOs triggered by their respective DR yields the following combined NPV distribution, which is the optimal case. We can observe how FO #4 under DRs #1, #2, and #3 combined shifts the target curve to the right (green) compared to the randomized base case (blue).

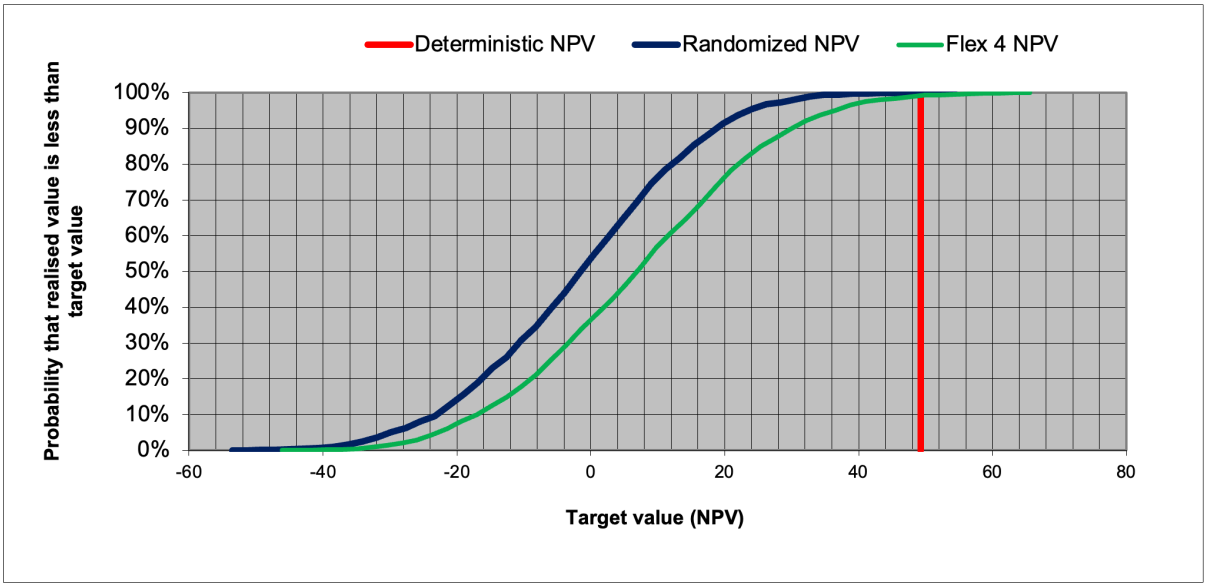

Figure 21: Target Curve Comparison between the NPV Distributions of FO #4, the deterministic case, and the randomized NPV case.

The histogram of the MC simulation for the randomized scenario with the embedded FO #4 and its statistical values are the following:

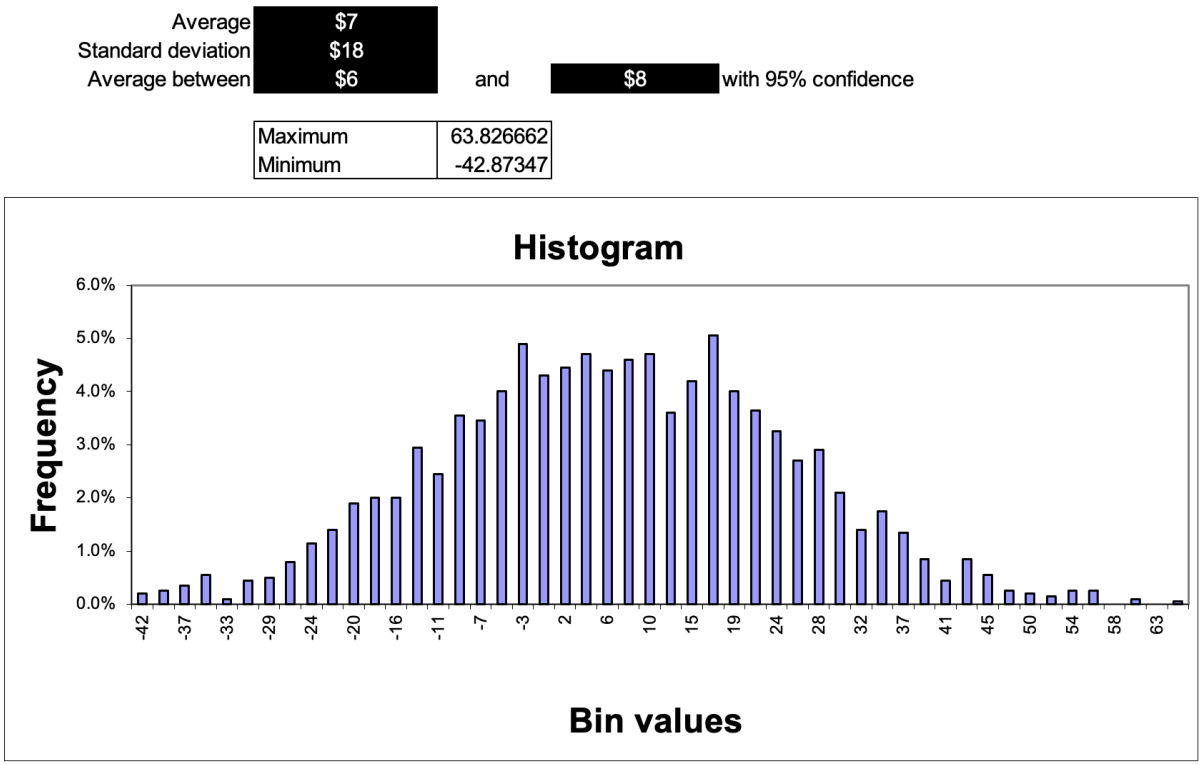

Figure 22: Histogram and Statistical Values for the Randomized FO #4 Simulation.

The Value at Risk (P5, P10) and Value at Gain (P90, P95) for this NPV distribution are summarized in the following table:

Values	NPV $M)
Value at Risk, P5	- $22 M
Value at Risk, P10	- $16 M
Value at Gain, P90	$30 M
Value at Gain, P95	$36 M

Table 7: P#s of FO #4 Simulation.

5. Recommendation and Implementation

Our MC simulations show that a randomized, uncertainty-considering approach yields more realistic outcomes for BREATHEBAND than the solely deterministic one. The CDF of the randomized simulation shows the well-known behavior of startup products – extremely high possible returns (CDF's right tail) but most likely unprofitable outcomes in almost every case (most of the CDF within the negative NPV range).

Once we demonstrated how uncertainties specific to our topic can reduce its deterministic NPV, we introduced the three flexibility options. These are tailored to reduce the effect of uncertainty on NPV and maximize BREATHEBAND'S development and profits. The effect on the system's performance (NPV) of each FO is summarized in the following table:

Values	Base Uncertainty	FO #1	FO #2	FO #3	FO #4
Min	- $53 M	- $54 M	- $53 M	- $46 M	- $43 M
Max	$47 M	$60 M	$53 M	$53 M	$64 M
Average	$-2 M	$6 M	$1 M	$0 M	$7 M
Std. Dev	$16 M	$18 M	$16 M	$17 M	$18 M
Value at Risk, P5	- $29 M	- $23 M	- $27 M	- $27 M	- $22 M
Value at Risk, P10	- $22 M	- $17 M	- $21 M	- $22 M	- $16 M
Value at Gain, P90	$17 M	$27 M	$22 M	$21 M	$30 M
Value at Gain, P95	$24 M	$34 M	$28 M	$27 M	$36 M

Table 8: KPIs Summary from all simulations.

The results of the option-considering MC simulations suggest that option #1 is stronger than options #2 and #3 when considering maximizing BREATHEBAND's NPV. While option #1 clearly shifts the original CDF (randomized, no options) to the right, the other two options do not have a great net effect on BREATHEBAND's NPV. Hence, option #4 (a combination of #1, #2, and #3) is very similar to option #1.

Hence, the recommendations for BREATHEBAND's founding team are:

1. Account for Uncertainty. No startup project in history has ever been free of unexpected situations. Creating a new product is, in the end, creating a new industry, field… The brand-new character of a startup comes with many associated unwanted situations to which BREATHEBAND founders need to react accordingly to profit from them and reduce drastic losses. Accounting for uncertainty in advance helps with this.
2. Introduce Flexibility Option #1 – Adjusted Pricing. FO #1 (adjusting product price to variations in development costs) has been shown as a maximizer of BREATHEBAND's NPV. This looks intuitive: if extra costs are accounted for by the company, the profitability breakeven point will be delayed or never reached. However, there is a limit to the product's price (where demand greatly decreases). This is highlighted in recommendation #4.
3. Introduce Flexibility Option #3 – "Self-destruction mode". Although FO #3 is not a good maximizer of BREATHEBAND's NPV, it reduces its minimum (lower tail). Hence, reduces the possibility of drastic losses. This implication is only applicable as BREATHEBAND's

founders are slightly inclined towards risk-aversion, and BREATHEBAND's fundraising efforts would be maximized with the existence of a "self-destruction mode" (MedTech investors are willing to put some money in at first with the guarantee of a "folding" move if things go wrong, rather than going "all-in" from the beginning).

4. Thorough Market Research is Fundamental. The two observed factors that drive BREATHEBAND's profitability are R&D and regulatory costs, and demand. While the first is barely predictable, the latter can be easily measured through primary and secondary market research. Knowing the sentiments of the customer (parents), the user (kids), the supporter (clinician), and the payer (parents/insurance) beforehand is easy to do and fundamental for the correct development of BREATHEBAND. This helps with setting the correct price for the product, for example.
5. In the case of Including Extra FO, do it in the Product Development Phase. BREATHEBAND is more sensitive to variations during the product development phase rather than during the commercialization stage. This is shown when comparing the effects of FO #1 and #2.

A limitation of our analysis is the fact that it is not extremely specific to the MedTech industry. To solve this, choosing the right partners in investors is key. Investors with Medtech experience can be a valuable asset in, for example, proposing a more accurate model for BREATHEBAND.

The associated risks of the recommendations, leaving aside those natural of a startup product such as BREATHEBAND, are the lack of a team to implement the changes and steer the wheel of BREATHEBANS's direction. In this case, the strength of the founding team and their accuracy with the first hires is the best remedy.

6. Conclusion

BREATHEBAND is a product that promises to disrupt how pediatric asthma is currently treated. Using deep technological advancements, they promise to switch from a reactive to a proactive (anticipation) diagnosis. However, as with every startup product, the road is full of uncertainties and risks. Appropriately considering these and including a flexible design and management of BREATHEBAND's systems is key to its success. Randomization and simulation can provide realistic future scenarios, and including flexible options allows us to profit from them.

In our case, we recommended the BREATHEBAND's founding team to include flexible options that account for variable product pricing and quitting in case of exaggerated initial costs. By doing this, we maximize the expected NPV distribution and reduce potential extreme downsides for the company. By doing so, the BREATEHBAND founding team will be in the best position possible when embarking on this risky health venture.

Lessons Learned

1. Importance of Uncertainty Management: The MedTech industry is inherently uncertain, with factors like regulatory costs, market demand, and manufacturing costs varying significantly. Managing these uncertainties through flexible planning and simulation techniques is crucial for project success.

2. Value of Flexible Options: Incorporating flexible options, such as adjusting product pricing or canceling the project under unfavorable conditions, can significantly mitigate risks and enhance profitability.

3. The Power of Simulations, such as the Monte Carlo one, to simulate uncertainty-prone scenarios.

4. Market Research and Customer Insights: Thorough market research is essential for understanding customer needs and sentiments, which can inform product development and pricing strategies.

List of References

(1) MarketsandMarkets, “Medtech industry to hit USD 694.7 billion by 2025 with ~4% CAGR: MarketsandMarketsTM,” PR Newswire: press release distribution, targeting, monitoring and marketing, https://www.prnewswire.com/news-releases/medtech-industry-to-hit-usd-694-7-billion-by-2025-with-4-cagr--marketsandmarkets-302355063.html (accessed Mar. 17, 2025).

(2) Center for Devices and Radiological Health, “Overview of device regulation,” U.S. Food and Drug Administration, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation (accessed Mar. 17, 2025).

(3) MedTech Intelligence, “Demystifying Regulatory Hurdles: How to Navigate FDA Approval for AI-Enabled Medical Devices,” MedTech Intelligence. [Online]. Available: https://medtechintelligence.com/feature_article/demystifying-regulatory-hurdles-how-to-navigate-fda-approval-for-ai-enabled-medical-devices/. [Accessed: Mar. 7, 2025].

(4) T. Wang and R. de Neufville, “Real Options ‘in’ Projects,” Proc. 9th Real Options Annual Int. Conf., Paris, France, Jun. 2005.

(5) DexCom, Inc., “Annual Reports,” DexCom Investor Relations. [Online]. Available: https://investors.dexcom.com/financials/annual-reports/default.aspx. [Accessed: Mar. 1, 2025].

(6) J. A. DiMasi, H. G. Grabowski, and R. W. Hansen, “Innovation in the pharmaceutical industry: New estimates of R&D costs,” J. Health Econ., vol. 47, pp. 20–33, 2016, doi: 10.1016/j.jhealeco.2016.01.012.