

### **Meet the Founders**





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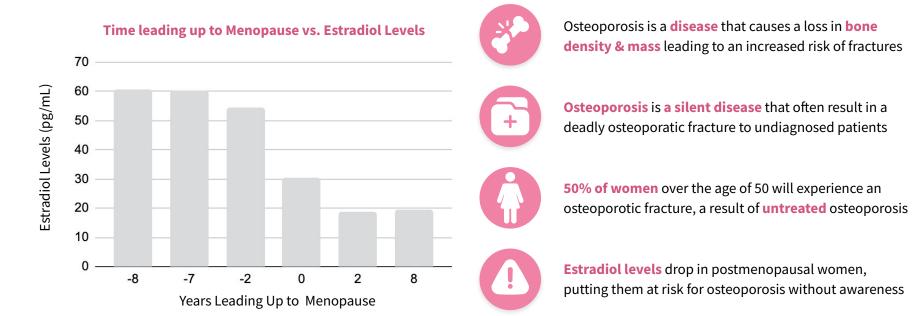


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# osteoX

### Background





Postmenopausal women are at high risk for osteoporotic fracture, but often are unaware until it is too late



Product

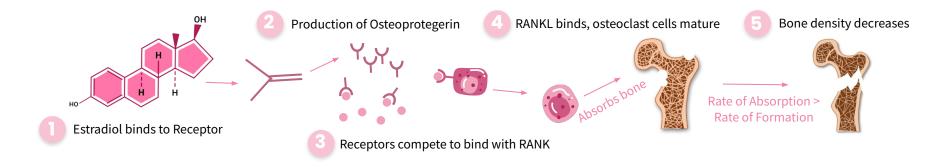
Market Analysis

Marketing

Risks & Mitigations

### Estrogen and Osteoporosis





#### **Estradiol & Osteoclast Mechanism**

- Estradiol binds to a receptor creating Osteoprotegerin
- Osteoprotegerin competes with receptors on osteoclast precursor cell, inhibiting RANKL ligand binding
- Estradiol decreases the level of osteoclasts produced
- Osteoclasts resorb bone cells while osteoclasts create new ones, estradiol keeps the balance between the two

#### **Menopause and Bone Density**

- During menopause, estradiol significantly decreases
- Decreased Estradiol levels increase osteoclast production, leading to increased bone absorption
- Cell absorption and formation of is thrown out of balance, leading to loss of bone mass and density
- Loss of bone mass leads to risk of osteoporotic fracture



Product

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**Risks & Mitigations** 

### **EstroRing**



#### Single-use biowearable ring that monitors estrogen levels in sweat

#### **Mechanism: Competitive Binding**

- In EstroRing, MB-ssDNA (molecules that are similar to estrogen) are partially attached to aptamers (estrogen-specific single-stranded DNA)
- When **estrogen** is present, it competes for the binding site on the **aptamer**, disrupting the connection between **MB-ssDNA** and **aptamers**
- Displacement of MB-ssDNA is captured by a sensor, releasing a signal intensity that corresponds to number of displaced MB-ssDNA molecules
- Signal information is transmitted to an **app** that interprets and displays the **estradiol concentration**, along with an **osteoporotic analysis**









### **Market Analysis**



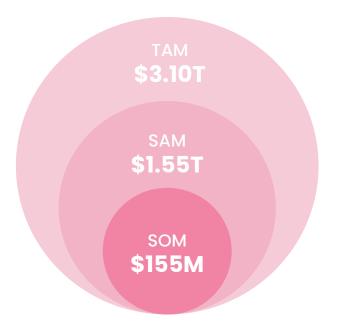
#### **Key Players: Estrogen Trackers**

	Measures	Location	Unit price	Min (pg/ml)
inito	E3	Home	\$3.20	20
	E2	Lab	\$69.95	19
<u>ost</u> eoX	E2	Home	\$4.00*	4

#### **Key Players: Osteoporosis Risk Detection**

	Measures	Location	Unit price	Invasive
<b>ॐ</b> vitall	Vit D	Lab	\$106.80	Υ
BodySpec     BodySpec	BMD	Lab	\$1300	N
<u>ost</u> eoX	<b>E2</b>	Home	\$4.00*	N

#### **TAM-SAM-SOM Analysis**



Background

**Product** 



Marketing

Risks & Mitigations

### **Marketing Strategy**

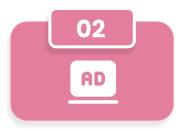




### Trade Show Demonstrations

Introduce **UI** and app feature offerings through live demonstrations

Encourage potential users to try the product with an **Estrogen tracking demo** 



#### Social Media Advertisements

Target women >35 years old through most used Social media apps

Focus on Facebook & Instagram — largest user base of women > 35 years



### Connections in FemTech

Partner with companies that have aligned goals including Flo and Clue

Leverage establishing relationships to reach and target market segment



### Message Beyond the Product

Maintain consistent motif throughout ads promoting women's health

Tie product advertising with campaigns for Osteoporosis awareness



### Risks and Mitigations



#### Risk

#### Mitigation

Have users stay in contact and work

with their healthcare provider to

cover for ring costs which is **significantly** 

less than bi-annual DEXA scans

Frequency of tracking is entirely up to user and they may not maintain consistent use that is most effective

determine the best frequency of use

Partner with insurance companies to

Prevention and measuring is **expensive** as measuring is daily and rings are single use as opposed to reuse

Ensure that data is **securely stored and encrypted** within the app and have strict **guidelines** regarding user privacy

Collecting and storing sensitive data creates the risk of data breaches that could leak user information





## **Q&A Session**

### Appendix - Population with Osteoporosis



#### Why osteoporosis is a problem:

"Osteoporosis is a silent disease with increasing prevalence due to the global ageing population. Decreased bone strength and bone quality is the hallmark of osteoporosis which leads to an increased risk of fragility fractures in elderly. It has been estimated that approximately ~50% of women will suffer during their lifetime from an osteoporotic fracture. This must be considered as a major health concern, as it has previously been established that fragility fracture has been associated with decreased quality of life due to increased disability, more frequent hospital admission and most importantly, osteoporotic fractures have been related to an augmented mortality risk. Anti-osteoporotic drugs are available for improving bone quality. Although there is access to these therapeutic options, there remain multiple unmet needs in the field of osteoporosis and fracture care, for example, the primary prevention of osteoporosis in young individuals (to reach a high peak bone mass), the optimization of the use of imaging techniques [dual-energy X-ray absorptiometry (DXA), vertebral fracture assessment (VFA) and new techniques measuring bone quality], the use of nonmedical treatment options and surgical techniques of fracture healing."

#### Why education and awareness is important:

"The first step is to create awareness of the burden of fracture risk in later life. The next step will be primary prevention of osteoporosis by education programmes for adolescents and young adults, preferably with support of their parents. Implementation of programmes around primary prevention are usually difficult, but certainly worthwhile, given the threat of an enormous increase in the number of fractures in the coming years"

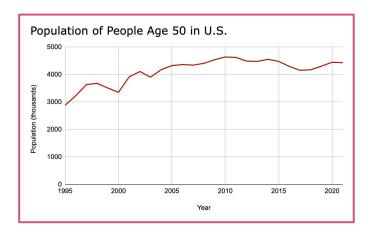






#### Growing world population of postmenopausal women (WHO):

"The global population of postmenopausal women is growing. In 2021, women aged 50 and over accounted for 26% of all women and girls globally. This was up from 22% 10 years earlier.[i] Additionally, women are living longer. Globally, a woman aged 60 years in 2019 could expect to live on average another 21 years.[ii]"



**KEY ASSUMPTION**: If the population of men is growing in the U.S./North American market, then the population of women is also increasing.



### Appendix - Biological Mechanism (Estrogen)

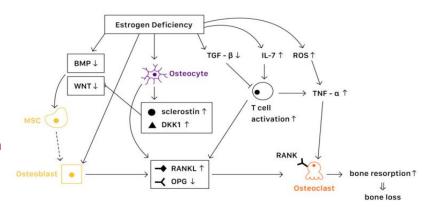


#### In Osteoblasts:

"Several pathways are essential to the activation of osteoblast and bone formation, such as canonical WNT, bone morphogenetic protein (BMP), and TGFβ signaling pathway. Almeida et al. demonstrated that ER complex in osteoblast progenitors activated Wnt/β-catenin signaling, thereby increasing osteogenesis [22]. Estrogen is also known to upregulate BMP signaling, which promotes mesenchymal stem cell differentiation from pre-osteoblasts to osteoblasts, rather than adipocytes. Moreover, estrogens stimulate the production of IGF1 and TGFβ by osteoblasts, enhancing bone formation."

#### In Osteoclasts:

"Various factors are involved in the differentiation and activation of osteoclasts. One key pathway is the NF- $\kappa$ B signaling. The receptor activator of NF- $\kappa$ B (RANK) is expressed on osteoclasts, which is activated when binding with the receptor activator of NF- $\kappa$ B ligand (RANKL) and suppressed when binding with osteoprotegerin (OPG) [23]. Estrogen regulates RANKL and OPG, promoting the expression of OPG and thereby reducing bone resorption. Moreover, estrogen inhibits osteoclast differentiation and advocates osteoclast apoptosis by increasing the production of TGF $\beta$  [19]. In the status of estrogen deficiency, RANKL expression is induced, which leads to osteoclastogenesis."

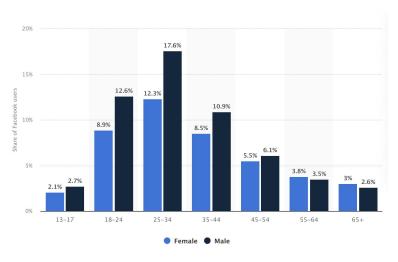




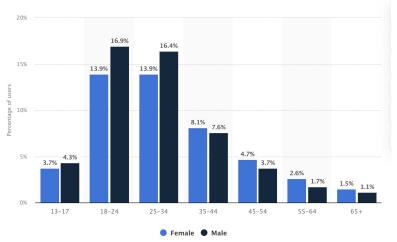
### Appendix - App User Statistics



#### Facebook distribution by age and gender



#### **Instagram distribution by age and gender**





### Appendix - Estradiol Levels and Menopause



#### **Estradiol Levels:**

#### **Graphs explanation:**

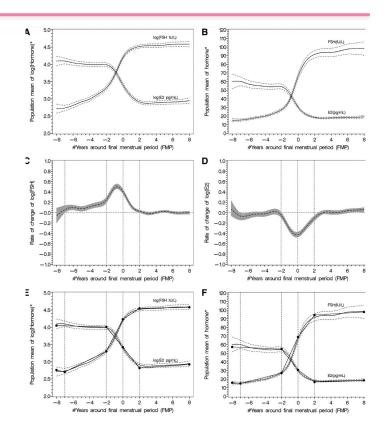
"Adjusted population means (95% CI) for natural logarithm-transformed FSH and E2 (A), back-transformed FSH and E2 (B), rate of change for natural logarithm-transformed FSH (C) and E2 (D), and segmented mean profiles of log(FSH) and log(E2) (E), and FSH and E2 (F) across the FMP (total n = 1215). \*, The y-axis is unitless for A, B, E, and F. The units of hormone are marked in the corresponding curves."

"The strengths of this report include a large sample of diverse women more representative of community-based population groups rather than a selected clinical convenience sample."

#### Note on Estradiol variation across races, ethnicities

FSH and E2 by race/ethnicity

"the mean acceleration in serum FSH levels commenced from 6.72–6.38 yr before the FMP in nonobese women of the four racial/ethnic groups, whereas the mean acceleration occurred at 5.04 and 4.30 yr before the FMP in the obese The decline in serum E2 occurred at 2.01 and 1.92 yr before the FMP in the African-American and Caucasian women, respectively, but at 1.33 and 1.56 yr before the FMP in Chinese and Japanese women, respectively. Mean serum E2 stabilized 1.95–2.03 yr after the FMP in all race/ethnic groups except the Japanese women in whom it stabilized at 1.66 yr."



### Appendix -FLO and Clue User Base and Mission



#### Flo and Clue at both apps with a large user base of people with periods which can serve as a funnel for our product

**From Flo's Website:** "Over **300 million people** around the globe use Flo as their ovulation and period tracker app, fertility calendar, and pregnancy assistant"

Mission statement: "Building a better future for female health"

"We're on a mission to put the **power back in your hands.** Flo helps you harness the power of **your body signals** so you can stay well and live better. Our global community of women, girls and people who menstruate is growing every day."

#### Clue:

"10 million people in over 190 countries rely on our app"

"One of Clue's **co-founders**, **Ida Tin**, **c**oined the term femtech in 2016 to define the group of technologies that are designed to support and **advance women's healthcare**."

"The technologies within this category include fertility solutions, period and fertility tracking apps, reproductive system health care, women's sexual wellness products, pregnancy and nursing care, period care goods, at-home fertility monitoring devices and general healthcare."

"By defining the group of products that are associated with female health, we are creating an entirely new category of technology. Grouping these technologies paves the way for femtech conferences and VC's to invest in femtech and create even more products within this segment that are important and needed in the world."

"Clue helps everyone who menstruates to understand their bodies—and to be empowered by that knowledge. Our vision is to enable women and people with cycles to live in tune with their biology, not in spite of it."



### Appendix - Data Encryption for Health Apps



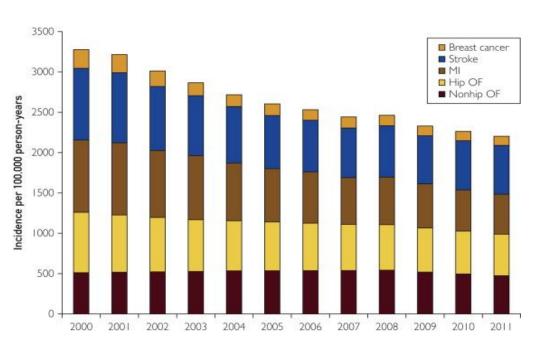
#### Model Data Encryption based on established apps like Flo

- 1. **Servers and networking:** We use AWS to host all production environments. AWS is designed to help us build a secure, high-performing, resilient, and efficient infrastructure for our app. AWS data centers are secure by design and SOC 1, SOC 2, and SOC 3 certified. For added security, we also use additional AWS services such as a virtual private cloud (VPC) and AWS multi-account infrastructure. To secure communication over the network, we use HTTPS protocol encrypted using Transport Layer Security.
- 2. **Encryption:** We use AWS Key Management Service to create and manage keys and control the use of encryption across a wide range of AWS services and our app.
- 3. **Storage:** Flo stores all data such as metadata, activity, original files, and customer's data in different places.
- 4. **System monitoring and alerting:** At Flo, the production application and underlying infrastructure components are monitored 24/7/365 days a year, by dedicated monitoring systems. Critical alerts generated by these systems are sent to 24/7/365 on-call service owners and escalated appropriately to operations management.
- 5. **Vulnerability (penetration) testing:** Flo performs regular penetration tests conducted by industry-leading cybersecurity red teaming companies for network configuration, infrastructure, and application layers. This vulnerability testing includes the use of commonly known web application security toolkits and scanners to identify application vulnerabilities before they are released into production.
- 6. **Traffic management:** Cloudflare security suite allows Flo app to automatically block malicious traffic and ensure app reliability. No matter where our users are located Flo works smoothly on their smartphones thanks to smart traffic routing, and content in the app is now delivered to the user from the closest Cloudflare server.
- 7. **Incident response and data breach notification:** Flo established a process describing the actions to be taken once Flo Health becomes aware of any type of event categorized as an Incident including a Personal Data Breach, according to international guidelines and regulation act.

### Appendix - Burden of Illness for Osteoporosis



#### **Incidences of Osteoporotic Fractures:**



#### **Cost Burden of Osteoporotic Fractures:**

"For example, although our analysis found the mean total inpatient cost of hip fracture per admission to be \$15,845, other studies have shown the mean health care costs (including inpatient, outpatient, and pharmacy) associated with fracture during the first year to be between \$25,332 and \$38,662.28. Concurrently, the annual total fracture costs across all fracture types for US women are projected to be more than 18 billion in 2025. These numbers are significant and further highlight the need for increased focus on prevention of fractures and their associated resource utilization."



### Appendix - EstroRing Mechanism



#### **Competitive Binding Assay**





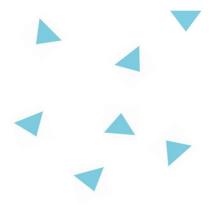
= Aptamer



= MB-ssDNA



= Estrogen



The aptamer has a higher affinity for estradiol than MB-ssDNA, causing MB-ssDNA molecules to be displaced in the presence of estradiol.



### Appendix - DEXA Scan + Frequency



#### Average out of pocket cost of a DEXA scan: \$160 - \$1319 (with insurance) → scanned every 2 years during risk years

"This analysis was limited to women ≥67 years, so different results might be obtained from analyses that included younger postmenopausal women. In addition, 99% of the participants were white. Because the prevalence of osteoporosis of the hip among white women is equal to or slightly higher than it is among nonwhite women, it is likely that the suggested intervals are reasonable estimates for women of all races

#### **FAST TRACT**

The suggested screening intervals are reasonable estimates for women of all races.

In women >80 years, the interval between baseline testing and the development of osteoporosis was shorter than that of their younger counterparts. Thus, it might be reasonable to reduce rescreening intervals by a third for women in their 80s



### Appendix - TAM SAM SOM Analysis: TAM



#### **Total Addressable Market: \$3.10T**

- **2.12B** We assume that the population of women currently undergoing perimenopause (time period between ovulation and menopause where symptoms of menopause have not yet occurred) is equal to the U.S. population of women age 50 in 2022. (Statista)
- \$4 We predict that each unit of single-use EstroRing can be priced at \$4. The average test strip for glucose monitoring costs \$0.22 (Healthline), but costs \$0.05 (Wilson et al.) to produce, which leads to a gross profit margin of 77.27%. Since each estradiol monitor unit costs \$2 to produce (Dai, Chiun-Liu), selling at a price of \$8.80 will achieve a gross profit margin of 77.27%. Since EstroRing is not as established as its competitors in glucose monitoring industry, we believe a starting gross profit margin of 50% is reasonable, taking into account fixed costs.
- 365 days For perimenopausal women whose estradiol levels fluctuate every day, and to a greater extent than any other life stage (Gordon et al.), it is important to collect data about estradiol levels daily, in order to develop a more in-depth analysis of trends.
- [Number of women in perimenopause] x [Revenue per day] x [Days per year] = Total Addressable Market 2,120,000,000 x 4 x 365 = 3,095,200,000 = 3.095T



### Appendix - TAM SAM SOM Analysis: SAM



#### Serviceable Addressable Market: \$1.55T

- 3.10T- Total Addressable Market
- 50% Since approximately 46.8% of women (<u>Siris et al.</u>) will experience an osteoporotic fracture within their lifetime, we predict that osteoX can reasonable target around half of the market.
- [Total Addressable Market] x [Percent available to target] = Serviceable Addressable Market 3,095,200,000,000 x 0.5 = 1,547,600,000,000 = **1.55T**



### Appendix - TAM SAM SOM Analysis: SOM



#### Serviceable Obtainable Market: \$155M

- 1.55T- Serviceable Addressable Market
- 0.01% Currently, risk awareness for osteoporosis is low and women are not motivated to address osteoporosis through preventative measures. Older women are also less likely to use mobile device apps, so we believe that 0.01% obtainable market is a reasonable projection.
- [Serviceable Addressable Market] x [Percent obtainable] = Serviceable Obtainable Market 1,547,600,000,000 x 0.001 = 154,760,000 = 155M

