Duke UNIVERSITY

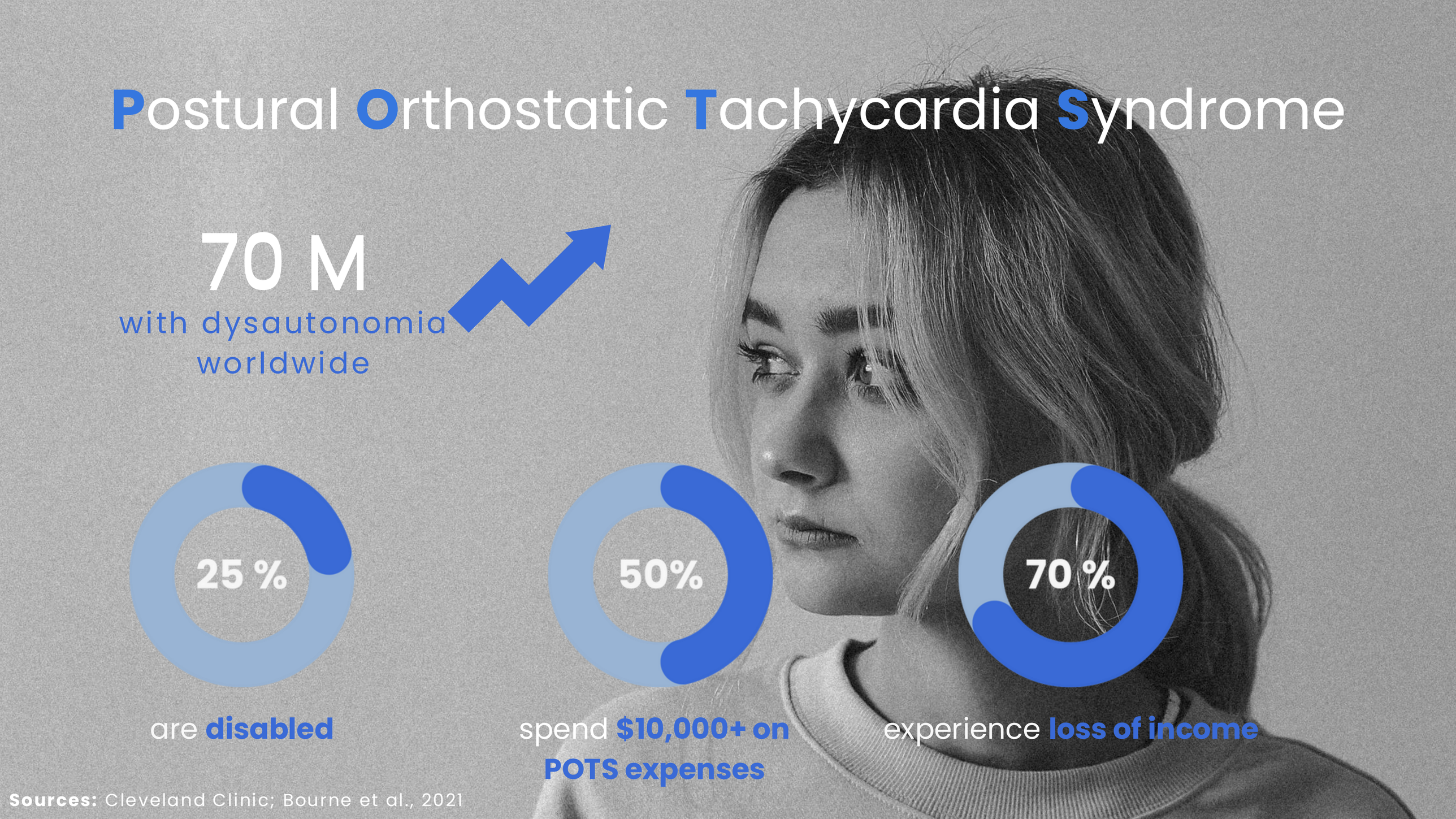
# Uplift

"Adjusting" the future for POTS patients.

Duke INNOVATION & ENTREPRENEURSHIP

Duke design + HEALTH

# Postural Orthostatic Tachycardia Syndrome



**70 M**

with dysautonomia worldwide




are **disabled**



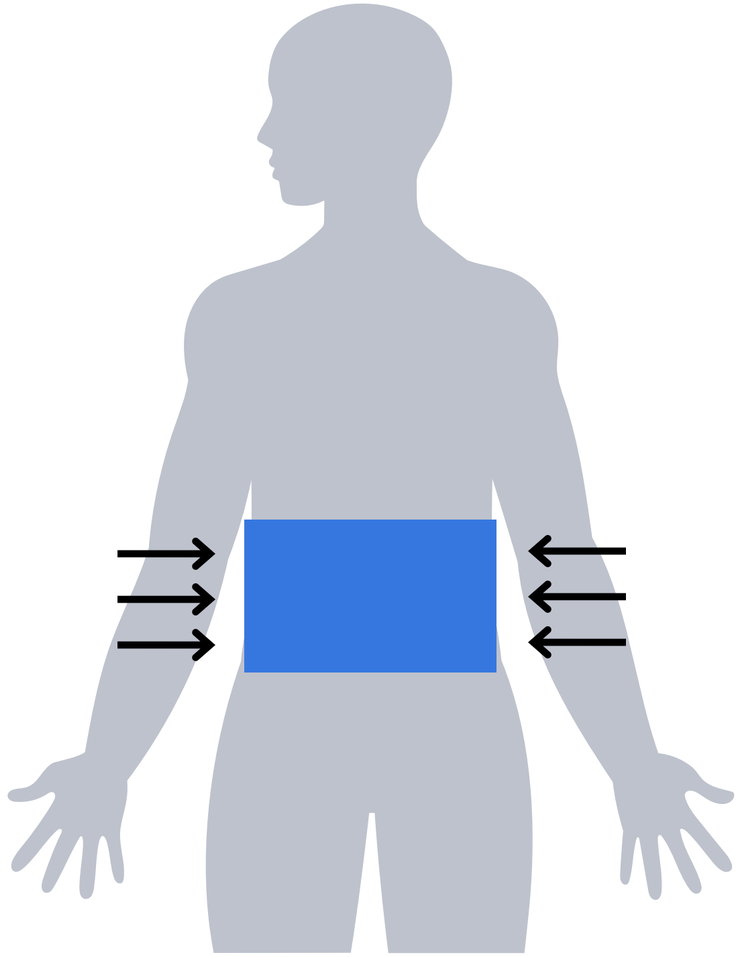

spend **$10,000+ on POTS expenses**




experience **loss of income**

**Sources:** Cleveland Clinic; Bourne et al., 2021

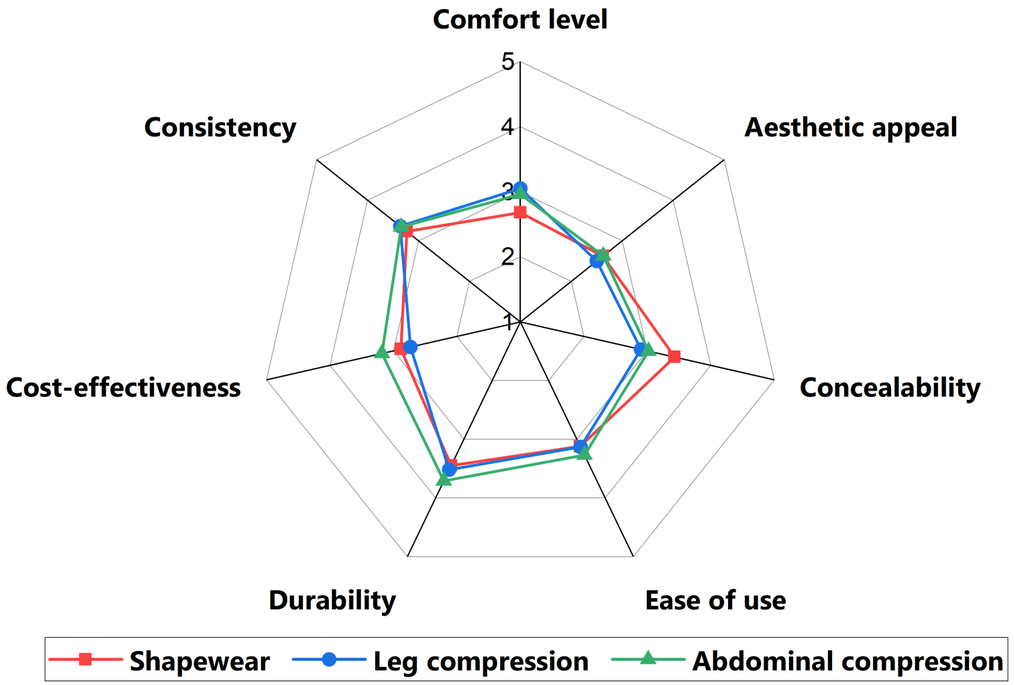
the problem



Abdominal compression has been shown to effectively reduce POTS symptoms....

**... but:**

358 patients surveyed in our peer-reviewed study[1]

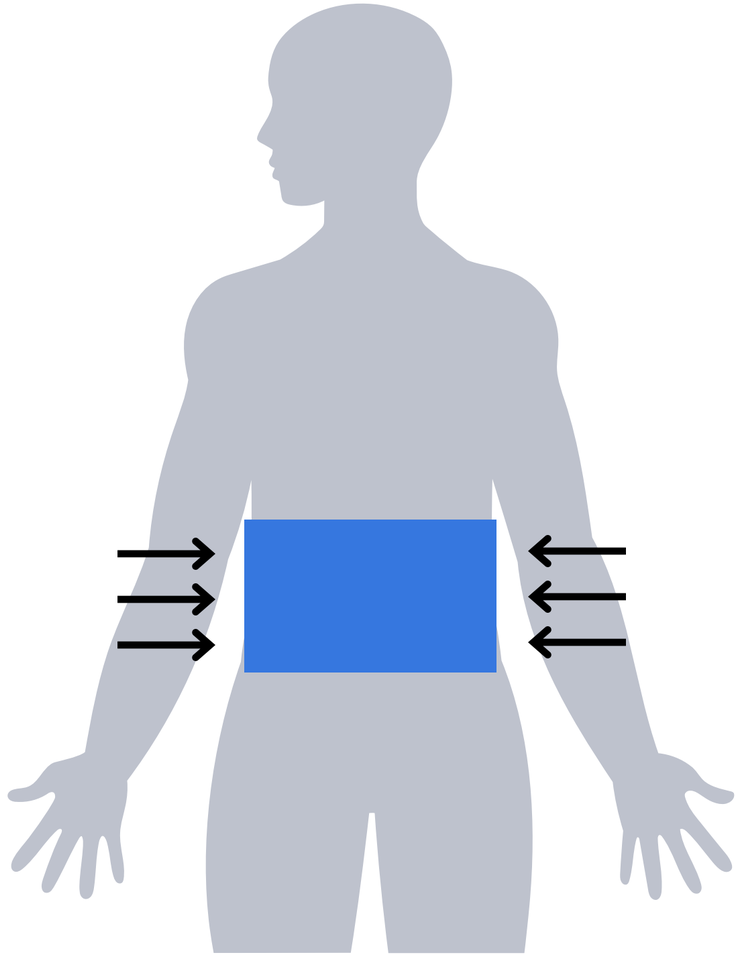



Revealed existing compression products do not fully meet needs.

**Source:** Mitra et al., 2024

[1]Largest sample size of POTS patients to date

the problem



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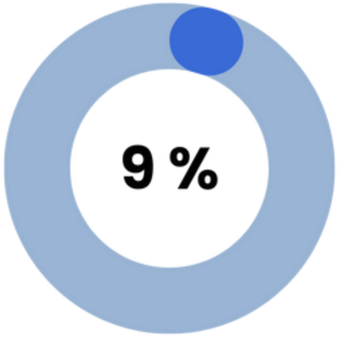



found existing compression solutions effective.

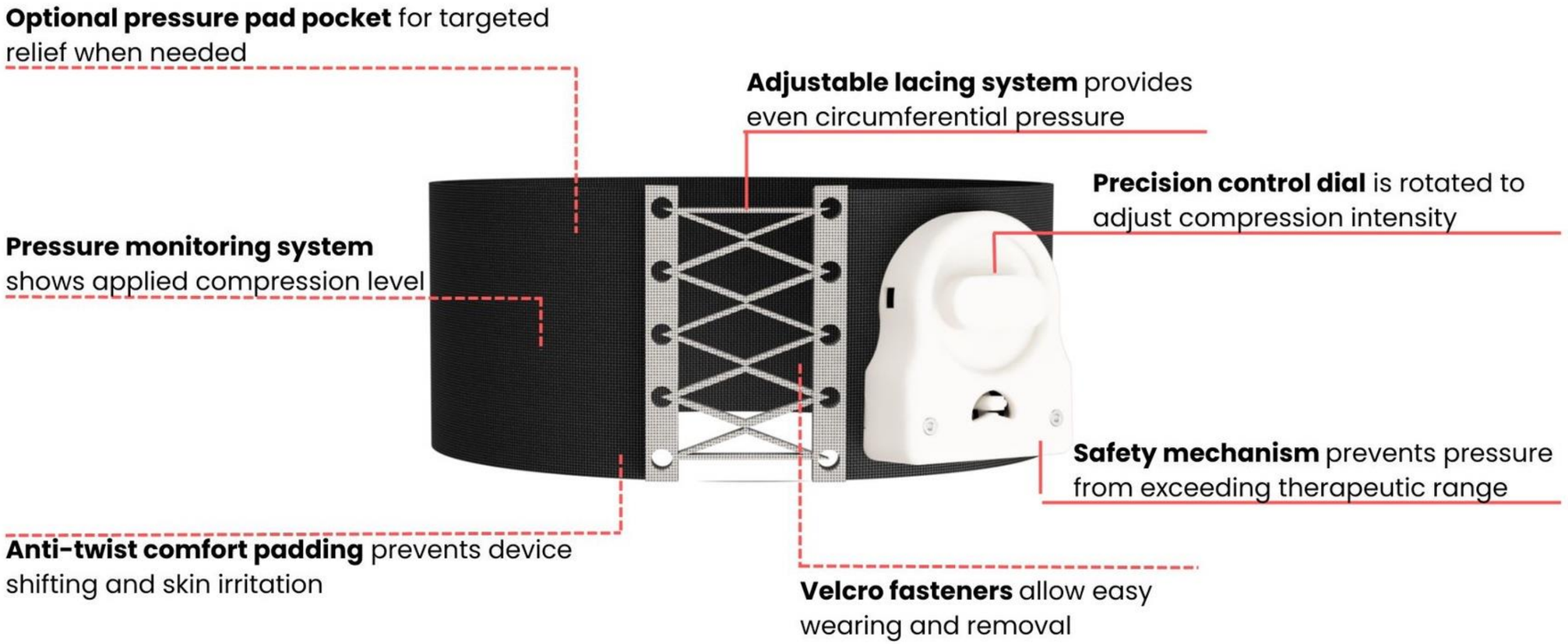
- inconsistent symptom relief
- difficult to use
- uncomfortable to wear

**Source:** Mitra et al., 2024

[1]Largest sample size of POTS patients to date

the solution

# Abdominal compression garment with a **user-controlled** cinching mechanism to apply **therapeutic** pressurel **when** it is **needed**.

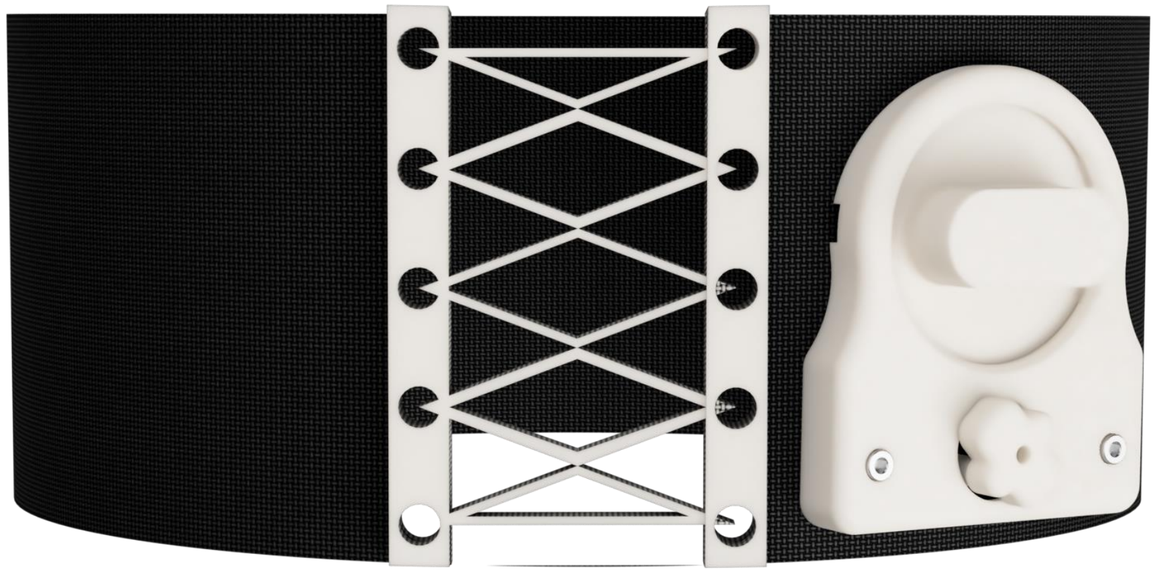



**Sources:** Dahm et al., 2019; Faisal et al., 2018

1Therapeutic pressure (30-40 mmHg) is classified as 'firm' (Class III) compression in medical standards and is clinically proven to reduce venous pooling in POTS patients.

the solution

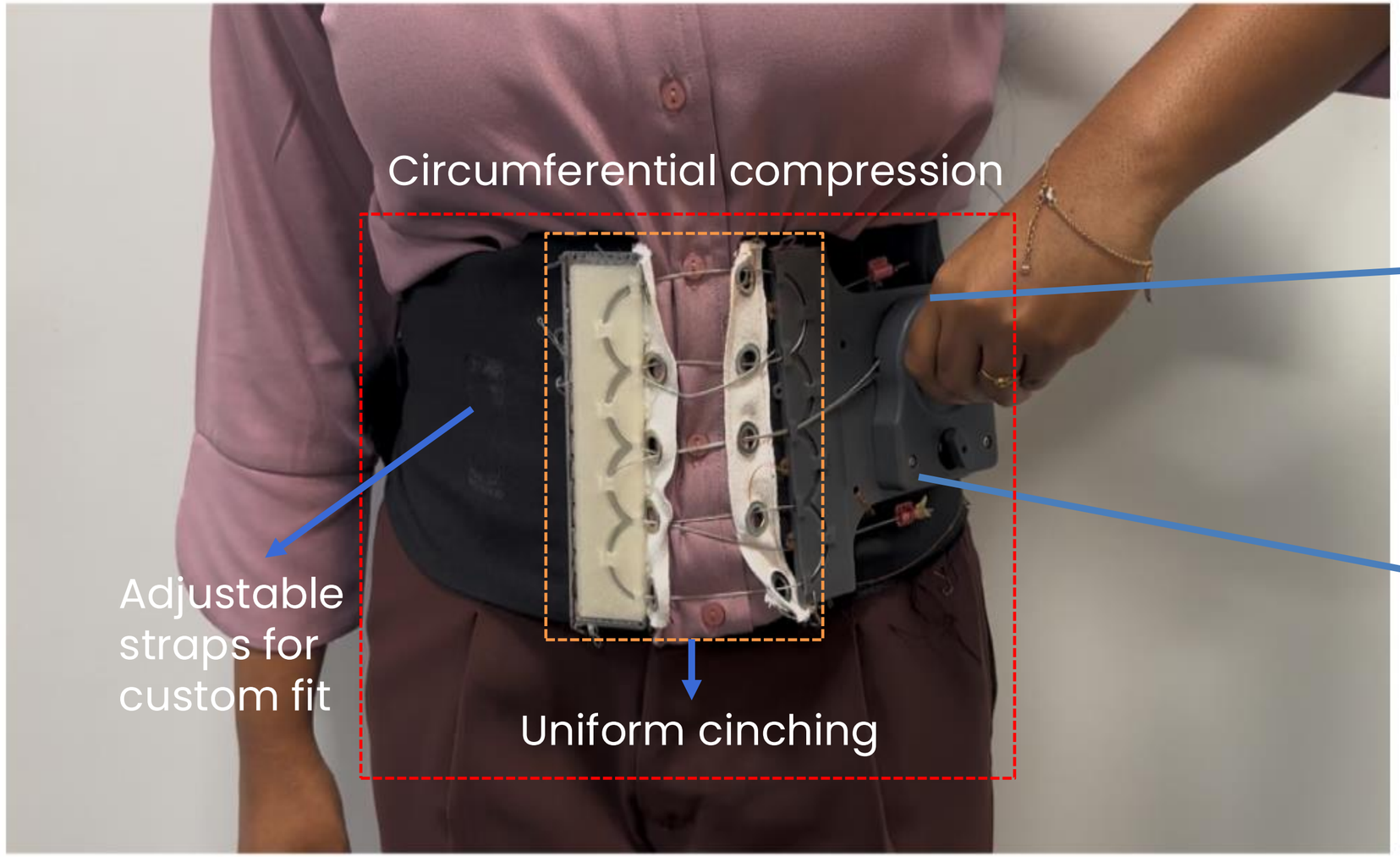
Abdominal compression garment with a **user-controlled** cinching mechanism to apply **therapeutic** pressure **when** it is **needed**.



- **patent-pending** design
- **therapeutic** pressures of 30-40 mmHg
- **intuitive control system** with easy-to-use rotational dial
- **on-demand compression** for maximum comfort

Initial human testing with **significant positive effects** on relevant vital parameters

the solution

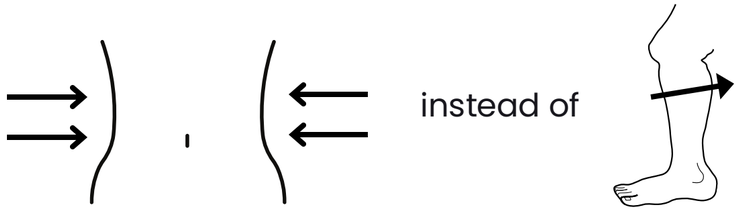



Dial mechanism

unique selling points

## EFFECTIVE

employs abdominal rather than leg compression




## THERAPEUTIC

operates within therapeutic ranges of pressure

30-40 mmHg

instead of

10-20 mmHg

## EASY TO USE

thanks to an intuitive rotational knob design

## COMFORTABLE

(dis-)engagable to apply compression only when needed

ON

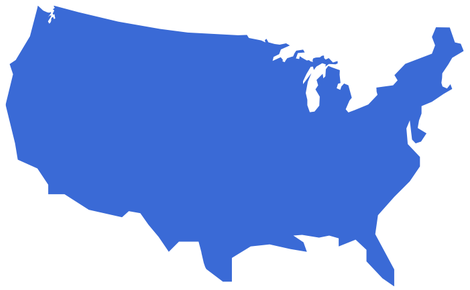
OFF

instead of

always **ON**

market validation

## Market opportunity:



**3-6 M**

people with POTS in the US alone

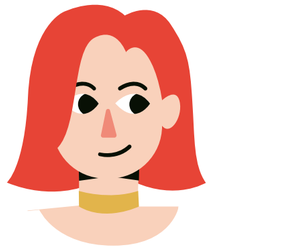
Target retail price: **$300.00**

**$1.35 B** Market size

**Sources:** Grubb, 2008; Dysautonomia International; Harris, 2022
1Based on midpoint US POTS patient population estimate and retail price

## Target customer:

15-50 year old, predominantly female POTS patients



Does **not** account for:

- increasing POTS prevalence
  13.8% CAGR in the US from 2007 to 2024
- adjacent markets
  e.g., other forms of dysautonomia, anxiety management, etc.
- global market potential
  the number of people affected by dysautonomia is estimated to be 70 M worldwide

# competitive landscape

| | Uplift | Consumer Shapewear | Medical Compression | Abdominal Binders |
|---|---|---|---|---|
| | | SPANX BY SARA BLAKELY, MAIDENFORM | LEONISA, Juzo | COPPER fit, BELLY BANDIT |
| Effective symptom management | ★★★★★ | ★☆☆☆☆ | ★★★☆☆ | ★★☆☆☆ |
| Targeted abdominal compression | ★★★★★ | ★★☆☆☆ | ★★☆☆☆ | ★★★★★ |
| User-controlled adjustment | ★★★★★ | ☆☆☆☆☆ | ☆☆☆☆☆ | ★★☆☆☆ |
| Cost | ★★★☆☆ | ★★★★☆ | ★★★★☆ | ★★★★★ |

**Source:** Mitra et al., 2024

operational plan

# Strategic Development Roadmap

2025

## Prototype Validation

- Design optimization & mechanical testing
- Corporate formation & initial team building
- First in-patient POTS pre-clinical study
- Market research expansion & competitive analysis

**$50K**

2026 2027

## Commercial Preparation

- FDA Class I registration & quality system implementation
- Patent issuance & Duke IP licensing
- Execute pilot production (100 units) and contract manufacturing setup for 2,500 units
- Build initial sales and marketing team (3 FTEs)

**$750K**

2028 2029

## Market Expansion

- Patient registry implementation & data collection for 510(k) submission
- Scale manufacturing while reducing COGS
- Launch direct-to-consumer channel with targeted marketing
- Grow operational team across functions

**$1.5M**

marketing and distribution

# Go-to-market Strategy

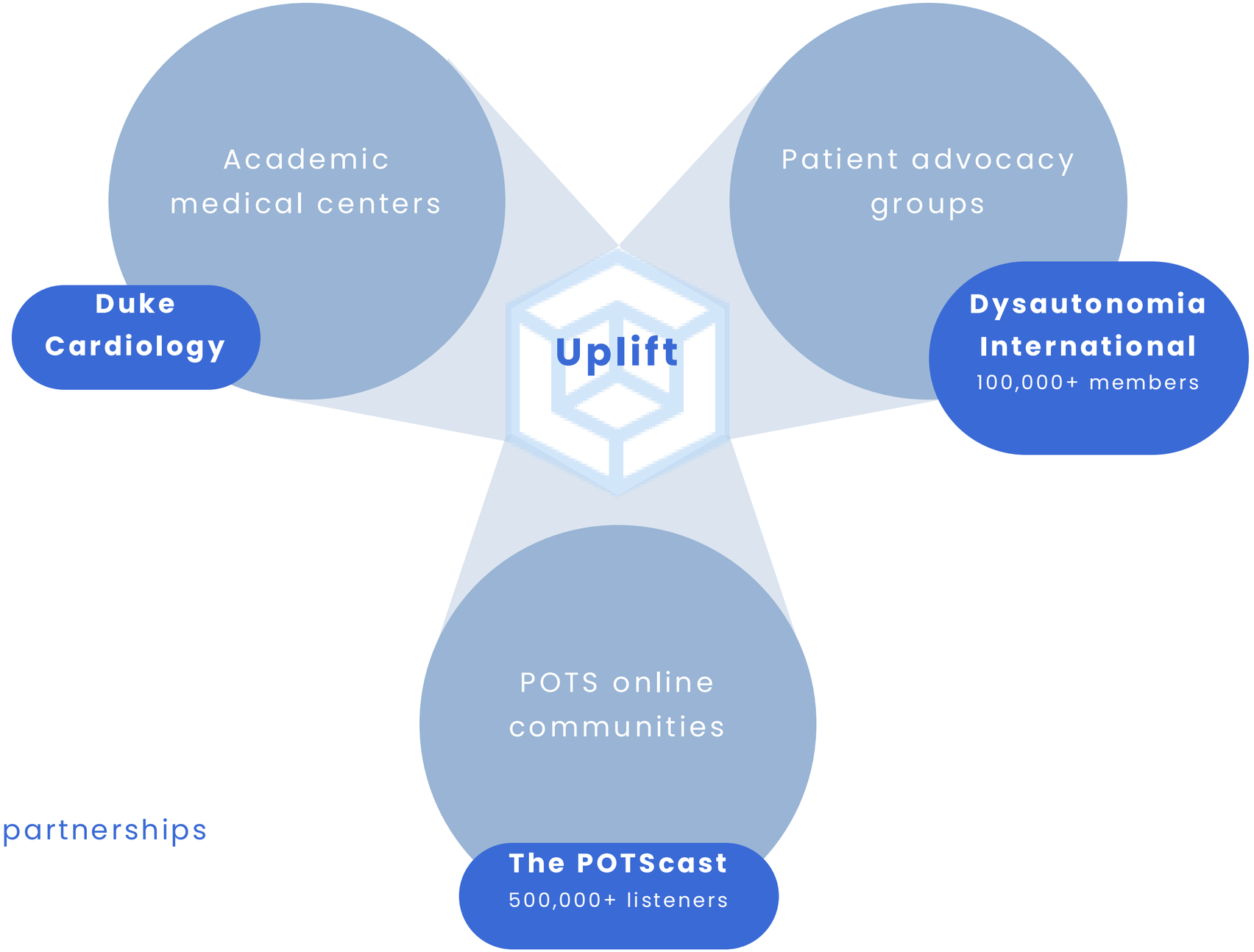
## Clinical Partnerships (2026+)

- Direct distribution through Duke Syncope Clinic and 10+ specialty centers
- Physician-directed recommendations
- Real-world evidence collection through structured feedback protocols

## Direct-to-Consumer (2028+)

- E-commerce platform with physician verification option
- Patient education portal and community support
- Subscription model with replacement options

marketing and distribution

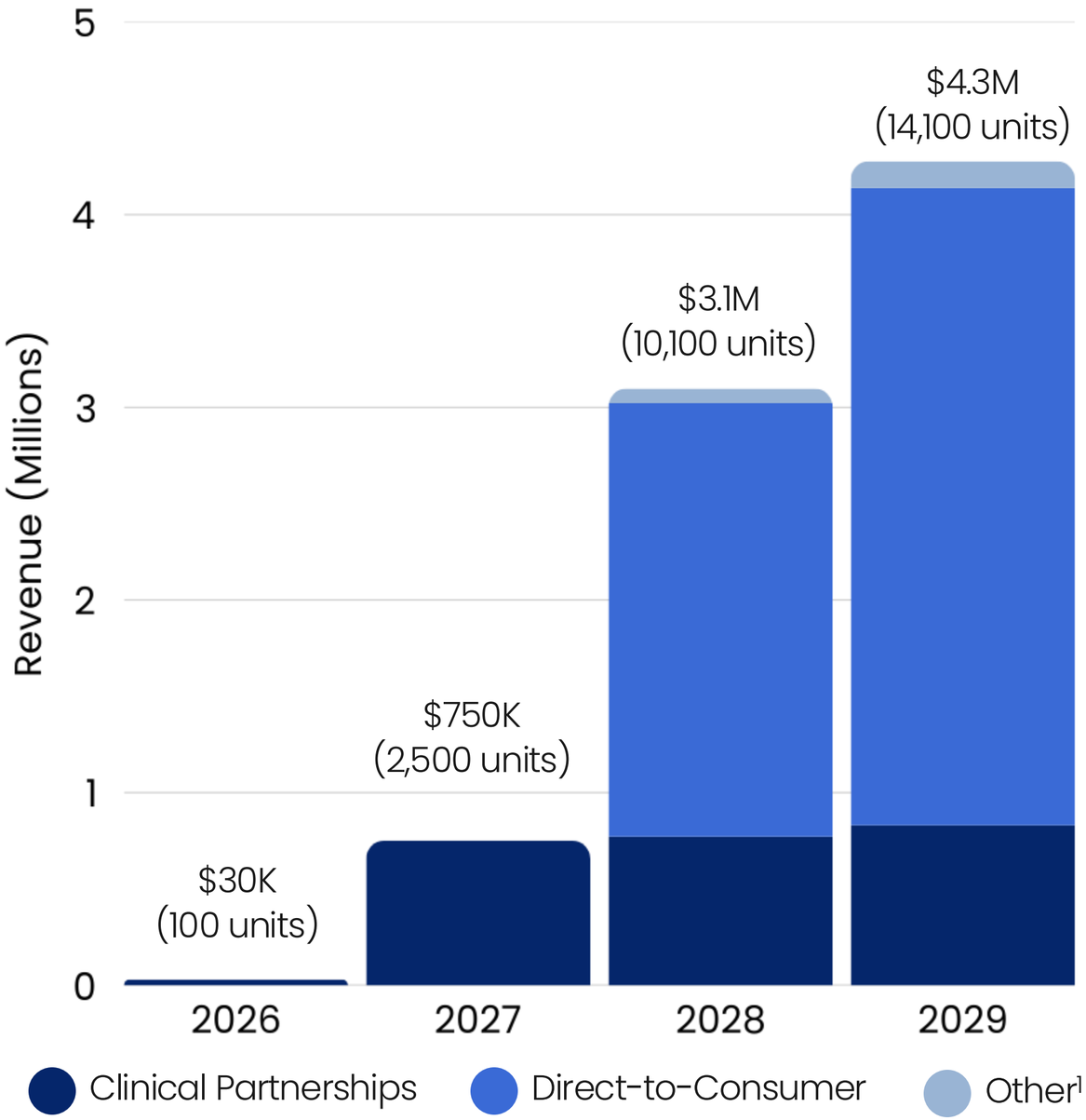



established partnerships

financials

**$300**
conjoint analysis suggests low price sensitivity

| | 2026 | 2029 |
|---|---|---|
| COGS[2] | **$160** | **$111** |
| Gross margin | **33.3%** | **53.7%** |
| Operating margin | **-81.5%** | **18.0%** |




**Source: Levita Health Financial Model**
[1]'Other' includes educational materials starting 2028
[2]COGS reduction driven by manufacturing scale and supply chain optimization

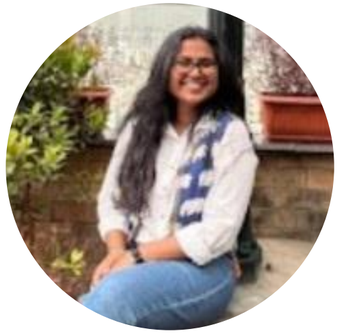
team

## Founders

**Kishen Mitra**
Co-Founder

**Sara Taube**
Co-Founder

## Leadership



**Shruthi Parameswaran**
Head of Product

**Lokesh Manivannan**
Head of Engineering

**Sameer Kunte**
Head of Research

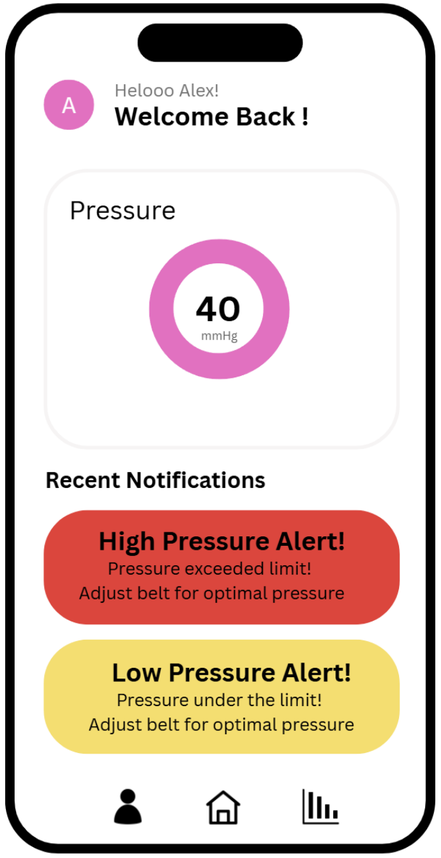
## Advisors

**Joseph Knight, PhD, MBA**
CEO at Simpson Interventions;
Executive-in-Residence at Duke University

**Eric Richardson, PhD**
BME Professor & Director of Design
Health at Duke University

**Marat Fudim, MD, MHS**
Cardiologist at Duke; Health Technology
Advisory Group Member at AHA

# next steps




## Product Maturation

- sourcing and testing appropriate garment materials
- designing refinements for extended wearability
- Building mobile application for pressure monitoring and user notifications

# Appendix

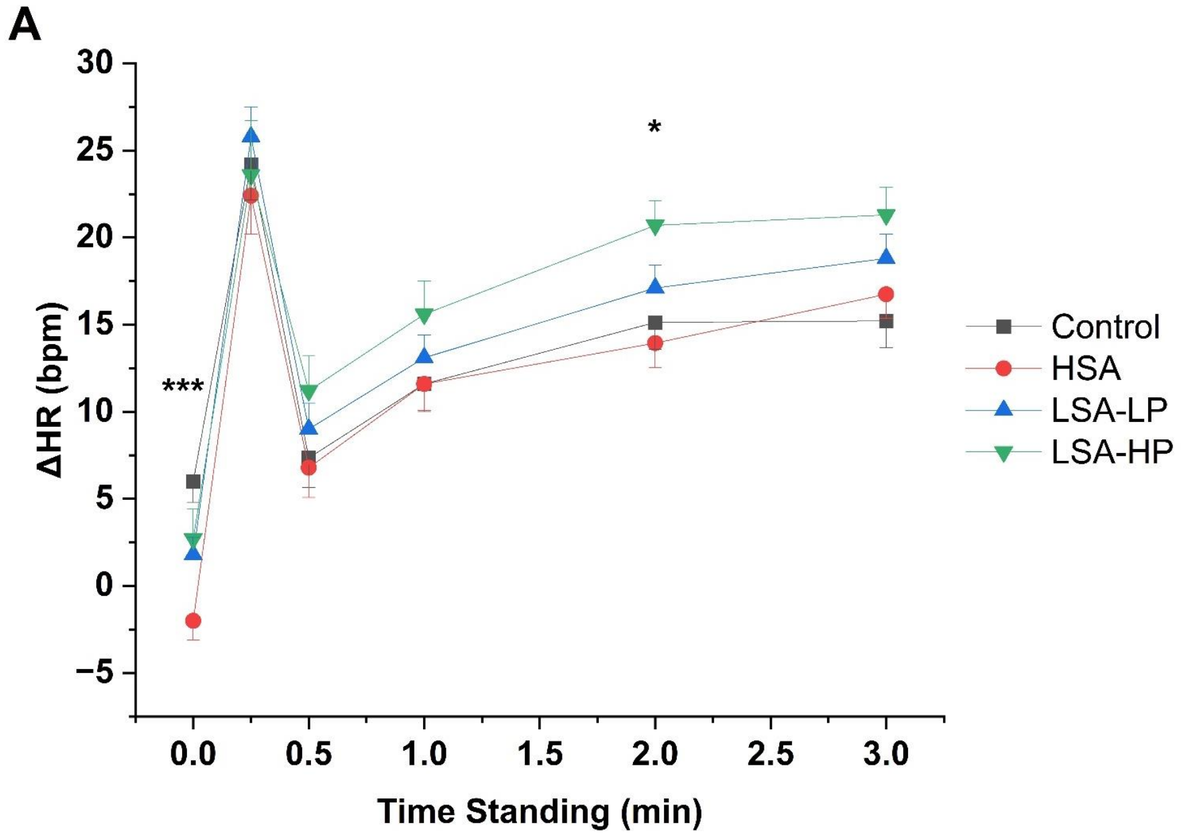
**Regression Statistics**

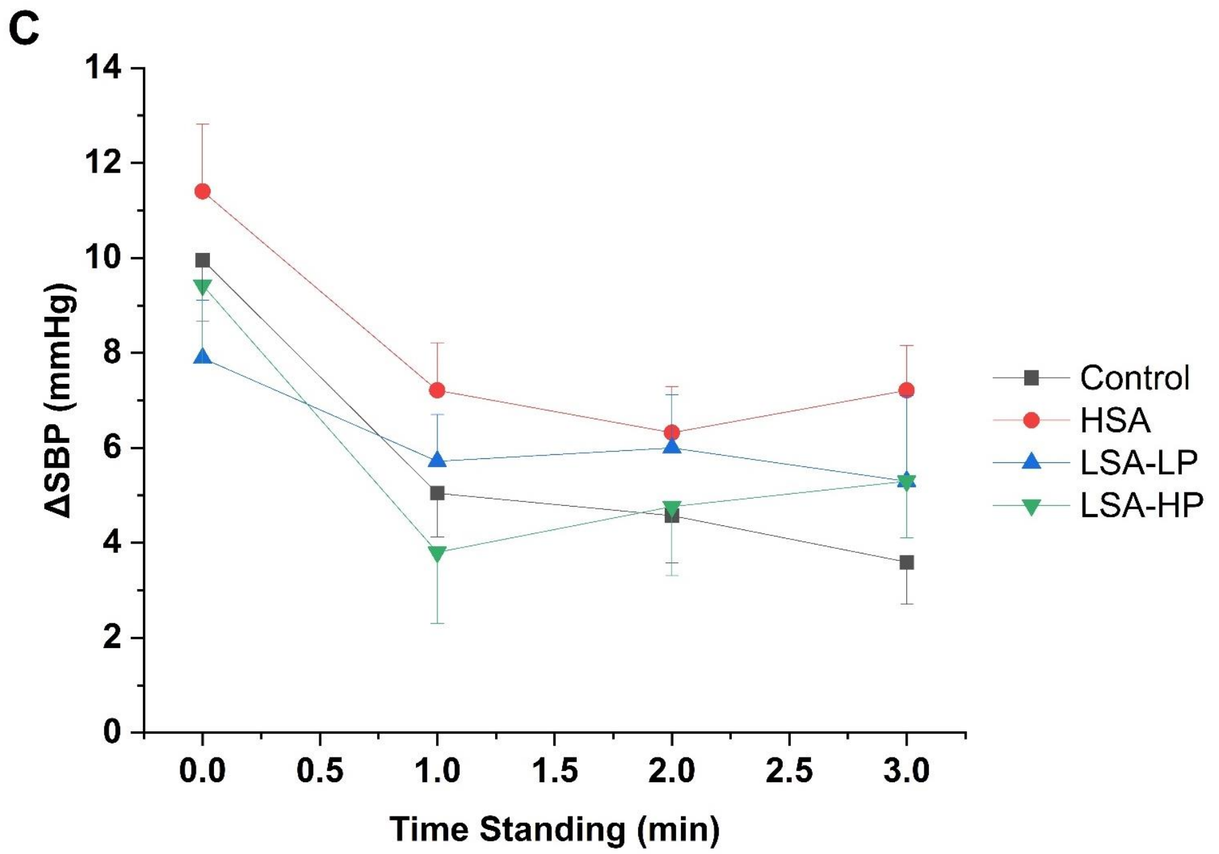
| R Square | Adj.RSqr | Std.Err.Reg. | # Cases | # Missing | t(2.5%,12) |
|---|---|---|---|---|---|
| 0.559 | 0.154 | 0.660 | 24 | 0 | 2.179 |

**Summary Table**

| Variable | Coeff | Std.Err. | t-Stat. | P-value | Lower95% | Upper95% |
|---|---|---|---|---|---|---|
| Intercept | -2.711 | 3.736 | -0.726 | 0.482 | -10.850 | 5.429 |
| Consistency | 0.470 | 0.284 | 1.655 | 0.124 | -0.149 | 1.088 |
| Ease of Cleaning | 0.377 | 0.266 | 1.415 | 0.182 | -0.203 | 0.956 |
| Ease of Use | 0.088 | 0.426 | 0.206 | 0.840 | -0.840 | 1.016 |
| Flexibility | -0.172 | 0.236 | -0.729 | 0.480 | -0.686 | 0.342 |
| General Comfort | 0.153 | 0.198 | 0.772 | 0.455 | -0.279 | 0.585 |
| Lifecycle | -0.006300 | 0.379 | -0.017 | 0.987 | -0.831 | 0.819 |
| Noise in Operation | 0.270 | 0.272 | 0.993 | 0.340 | -0.323 | 0.863 |
| Price | -0.060 | 0.240 | -0.251 | 0.806 | -0.584 | 0.463 |
| Symptom Reduction | 0.554 | 0.351 | 1.578 | 0.140 | -0.211 | 1.318 |
| Temperature Control & Breathability | 0.083 | 0.257 | 0.321 | 0.753 | -0.478 | 0.644 |
| Weight | -0.123 | 0.249 | -0.493 | 0.631 | -0.665 | 0.420 |

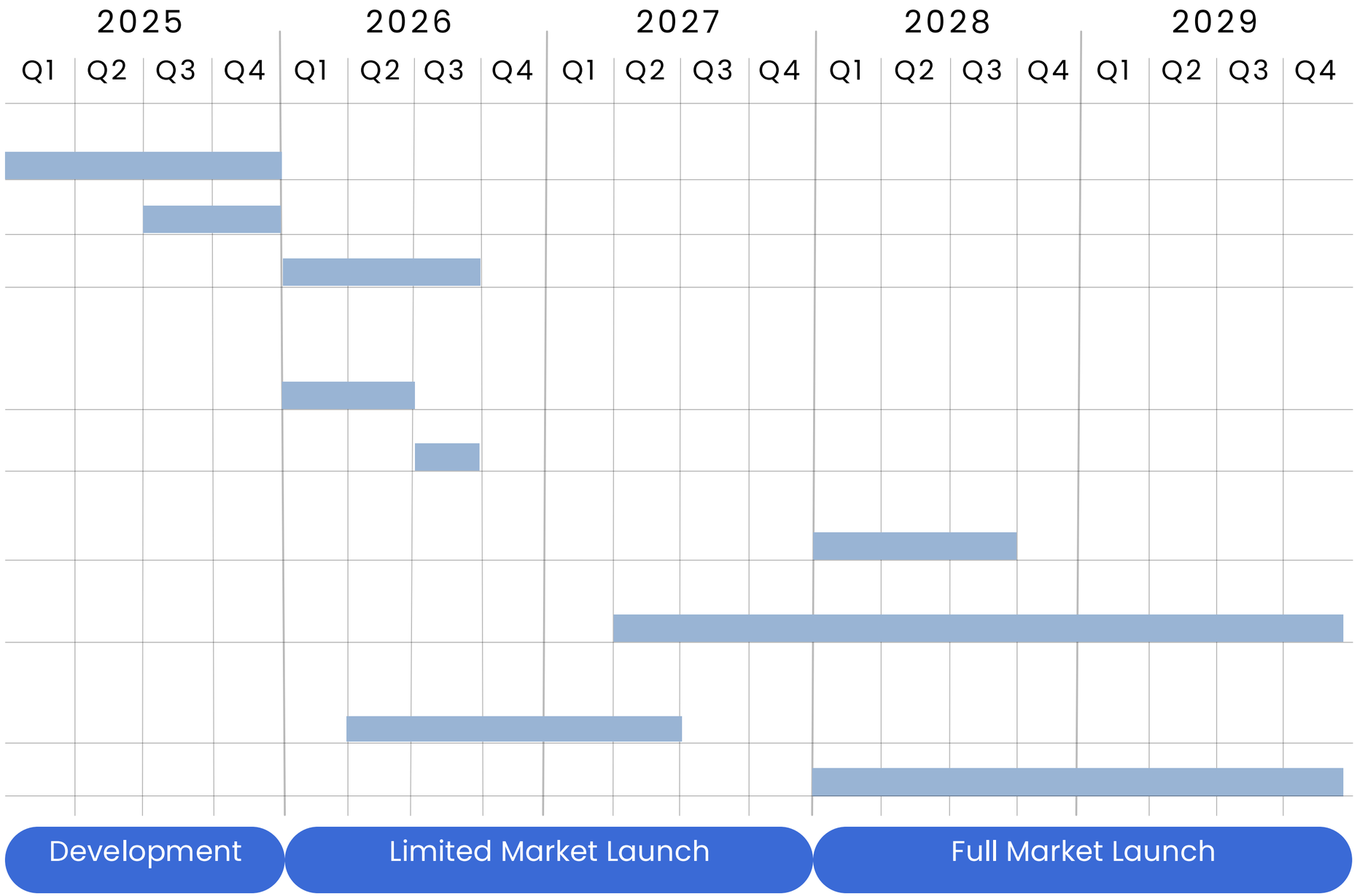
# healthy participant trial results



operational plan

# Strategic Development Roadmap



# regulatory pathways

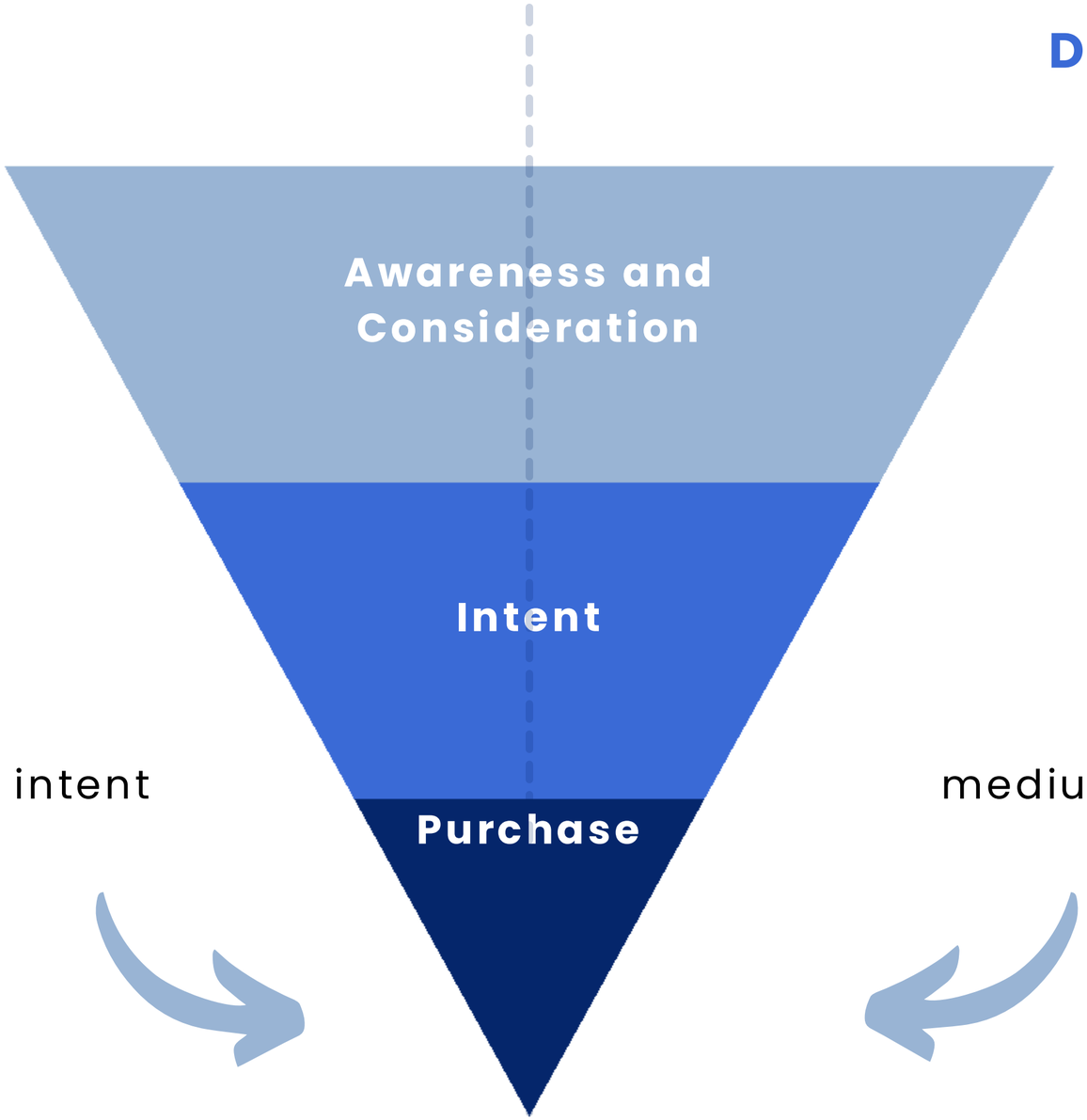
| | *Q-Submission (Pre-Sub) – Regulatory Pathway Assessment* | *Class I* | *Class II - 510(k)* | *De Novo (If No Predicate Exists)* |
|---|---|---|---|---|
| ***FDA Classification*** | Determines if Class I or II is appropriate | General controls | Special controls + General controls | New classification request (risk-based) |
| ***Approval Pathway*** | FDA provides **non-binding feedback** on classification & pathway options | Exempt from 510(k) premarket notification | Requires 510(k) submission to demonstrate substantial equivalence | Establishes a new Class II category |
| ***Claims Allowed*** | FDA advises on **acceptable claims under each pathway** | Limited to general support, comfort, and mild compression | Can claim POH management with supporting clinical evidence | Can establish POH treatment claims if successful |
| ***Market Entry Speed*** | Adds **75-90 days upfront** for FDA feedback | Fastest (self-registration and listing) | Moderate (510(k) review required) | Slowest (De Novo review takes longer) |
| ***Regulatory Risk*** | Reduces **uncertainty** before committing to a pathway | Potential FDA pushback if seen as an active medical device | Moderate – requires predicate & performance data | High – subject to full FDA review for classification |
| ***Clinical Data Requirements*** | FDA provides feedback on **testing expectations for each pathway** | Minimal (safety, basic performance) | Bench testing, biocompatibility, some clinical data | Full clinical validation required |
| ***Target Market*** | FDA clarifies **claim limitations for each pathway** | OTC consumer, wellness, general support | Medical professionals, hospitals, POH specialists | Medical professionals, hospitals, POH specialists |
| ***Annual FDA Registration Fee (FY 2025)*** | **$9,280** (required for all pathways) | **$9,280** | **$9,280** | **$9,280** |
| ***Other FDA Fees (FY 2025)*** | No fee for Q-Submission | N/A | 510(k) Standard: **$24,335** / Small Business: **$6,084** | De Novo Standard: **$162,235** / Small Business: **$40,559** |
| ***Timelines*** | **75-90 days** for FDA feedback | **1-2 months** (self-registration, labeling review) | **~90 days** for 510(k) review (can be longer if additional info is requested) | **~150+ days** (longer review due to classification process) |
| ***Post-Market Requirements*** | FDA guidance on compliance expectations | General controls (labeling, recordkeeping) | General + special controls (post-market surveillance, adherence to performance standards) | Same as Class II once approved, with post-market requirements |
| ***Q-Submission Consideration*** | **Recommended first step** to assess pathway | Optional; can seek FDA feedback on classification and intended use | Recommended; obtain FDA input on testing protocols, clinical study design, and predicate selection | Highly recommended; discuss risk classification, necessary evidence, and submission strategy |

marketing and distribution

## Clinical Partnerships

Academic medical centers/ Physicians/ Providers recommend Uplift

high intent

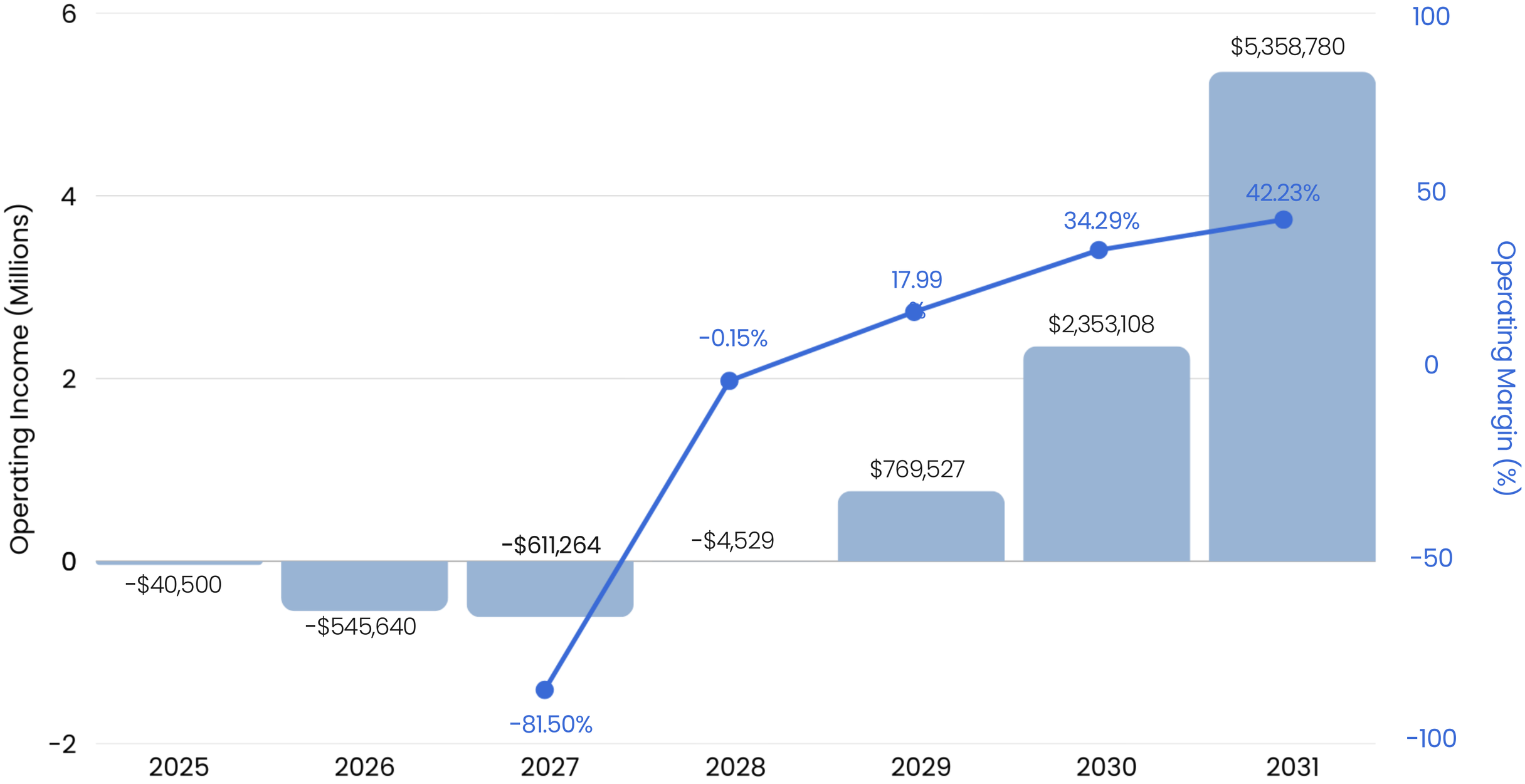


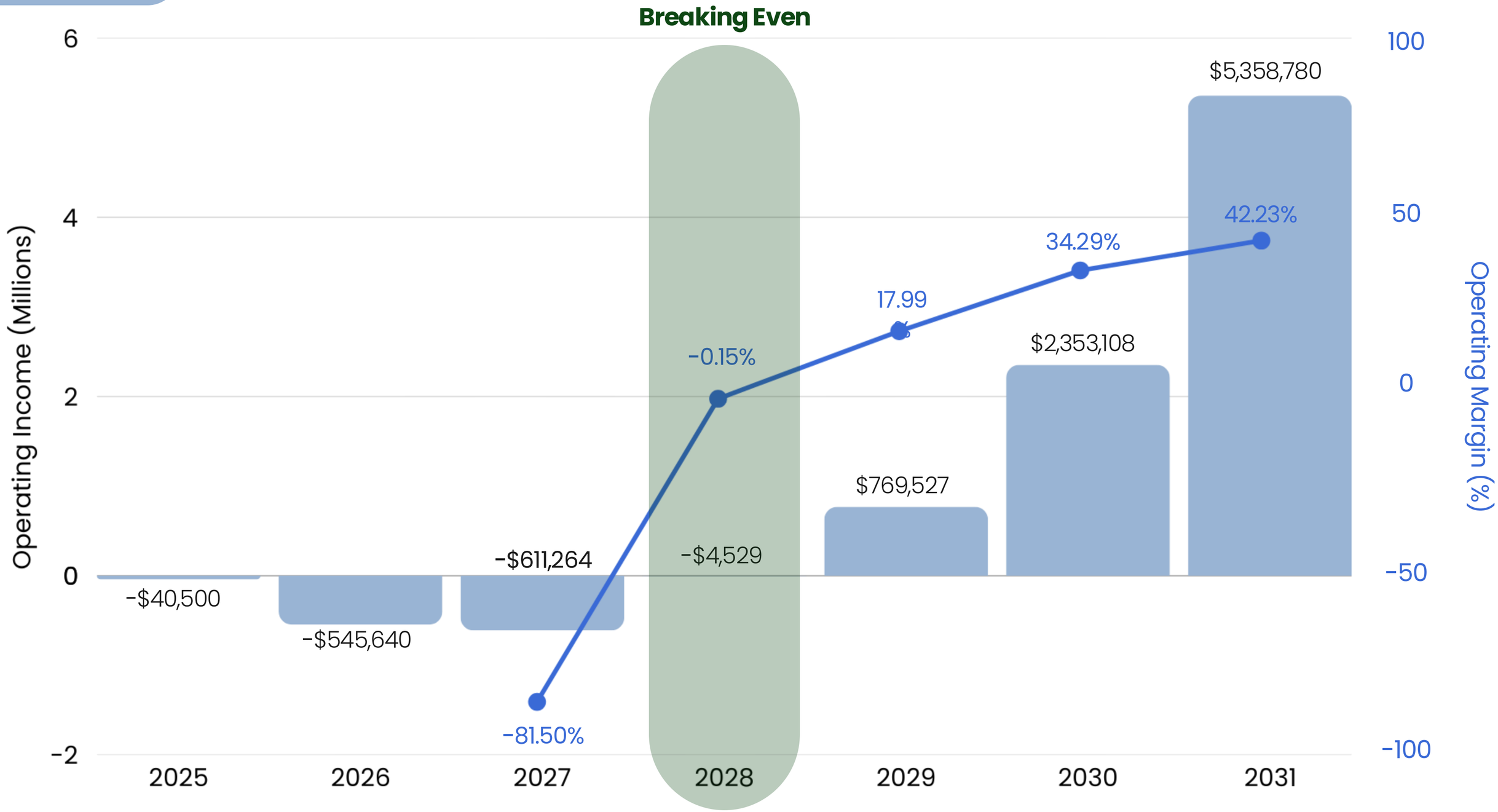

## Direct-to-Consumer

- Online POTS groups and word of mouth
- Patient advocacy groups
- Paid Search (SEO)

medium intent

financials


6
4
2
0
-2
Operating Income (Millions)
100
50
0
-50
-100
Operating Margin (%)
-$40,500
-$545,640
-$611,264
-$4,529
$769,527
$2,353,108
$5,358,780
-81.50%
-0.15%
17.99
34.29%
42.23%
2025
2026
2027
2028
2029
2030
2031


Breaking Even
Operating Income (Millions)
Operating Margin (%)
6
4
2
0
-2
100
50
0
-50
-100
-$40,500
-$545,640
-$611,264
-$4,529
$769,527
$2,353,108
$5,358,780
-81.50%
-0.15%
17.99
34.29%
42.23%
2025
2026
2027
2028
2029
2030
2031