

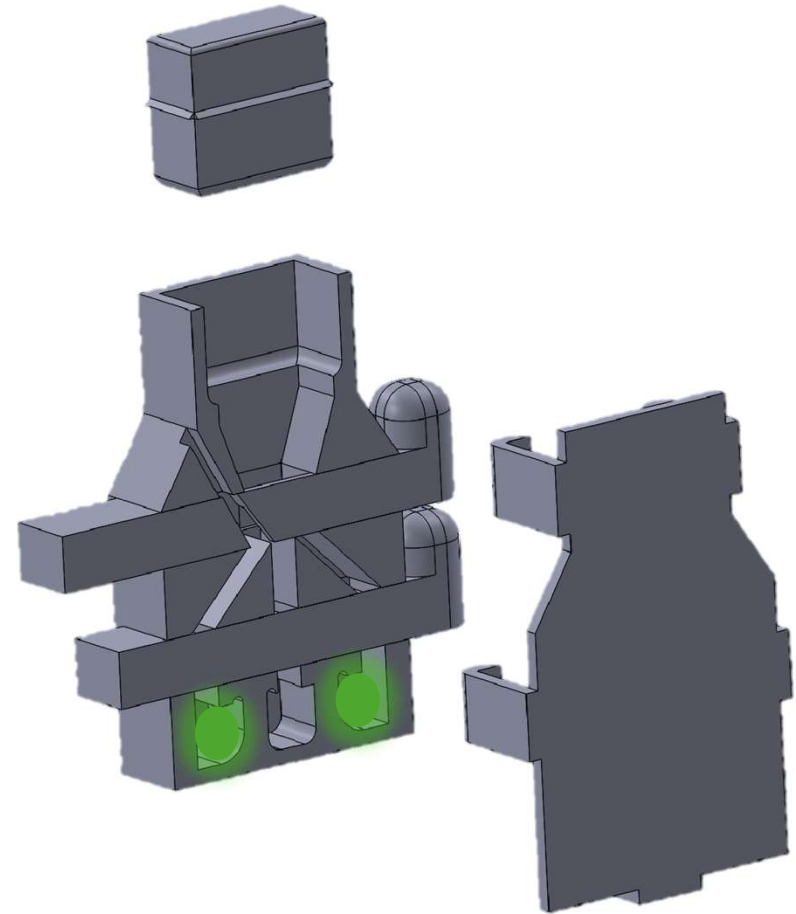


CuraLux

Strategy info.

**Precision you can count on.
Access everyone deserves.**

CuraLux.Health



**An at-home diagnostic for chlamydia
and gonorrhea.**

The Hidden Epidemic

Who isn't getting tested — and why it matters

45% of new STI infections are ages 15–24

Kreisel et al., Sexually Transmitted Diseases, 2021 (CDC model)

24% of 18–24 year olds tested for CT/NG annually

... The other 76% are actively waiting for a better way

Correlates of STI Testing, Prevention Science, 2021

THE TESTING GAP

The highest-risk group is the least-tested.

Cost Barrier

At-home tests cost \$50–\$149. The uninsured and underinsured simply don't test.

Access Gap

Most testing occurs at OB-GYN & primary care facilities — settings young men almost never visit.

Stigma & Privacy

STI stigma runs deep. A generation that texts rather than talks won't walk into a clinic to ask.

Silent Disease

Up to 70% of CT and most NG infections are asymptomatic. No symptoms = no reason to test.

The Solution

Built for the people the system forgot.

<\$50

target retail price
vs. \$50–\$149 competitors

**Same
Day**

results, at home
no lab, no appointment

**Phone
App**

From result to treatment — without
leaving the app

THE ANSWER

We built the test the system forgot to make.

For the cost barrier →

Under \$10 to produce

Priced to make routine screening realistic for the uninsured, underinsured, and cost-conscious.

For the access gap →

No clinic. No appointment. No waiting room.

Instrument-free device works anywhere — at home, in a dorm, or in a clinic.

For stigma & privacy →

Completely private. No conversation required.

Order online. Test alone. Get your answer.
Designed for a generation that self-serves everything.

For silent disease →

Catches what you can't feel

Simultaneous CT + NG detection with PCR-equivalent sensitivity — finds infections before symptoms appear.

The Science

Built for accuracy, reliability, affordability, and a digital world.

10-copy

Detection Limit

PCR-equivalent sensitivity

**US-2024
0085406-A1**

2 Patent Applications

Instrument-free point-of-care diagnostic integrating reactions and detection in a hand-held device

3-Track

CT · NG · Human Control

Simultaneous detection, one sealed device

THE SCIENCE

Diagnostics keeping up with a generation on the move.

PCR-LEVEL SENSITIVITY, NO INSTRUMENT REQUIRED

Isothermal amplification at room temperature.

No thermal cycling. No instrument. Accurate results at room temperature — no lab required.

PATHOGEN-SPECIFIC DETECTION WITH FLUORESCENT READOUT

Triggers only on the exact pathogen sequence.

Fluorescent result readable by anyone — no training, no technician, compatible with a phone.

CuraLux DEVICE — FROM LABORATORY TO HOME

Lab-grade molecular biology in a consumer format.

Lyophilized reagents. Ambient shipping. 12+ month shelf life. Under \$10 to produce. No cold chain. No prescription. Off the shelf.

Accurate

Reliable

Affordable

Digital-first

The Market

A \$1.2B market today.
3.2M untested Americans not yet in it.

TAM

\$10.6B

Global STI Diagnostics

→ \$16B by 2030 · 7.1% CAGR

Grand View Research, 2024

SAM

\$1.2B

US At-Home STI Testing

→ \$2.3B by 2033 · 8.5% CAGR

Grand View Research, 2025

SOM

\$76M

Untested 15–24 · 10% Capture

3.2M untested · \$40 retail · Year 3–5

CDC 2024 + CuraLux bottom-up model

MARKET OPPORTUNITY

A market we displace. A market we create.

THE MARKET WE DISPLACE

Mail-in testing: proven demand, broken experience.

\$1.2B US at-home STI market — consumers already paying \$50–\$149 and waiting 3–5 days. CuraLux: same privacy, same accuracy, same day, under \$50.

THE MARKET WE CREATE

3.2M Americans with CT/NG who get nothing.

76% of the highest-risk demographic goes untested annually. Cost, stigma, and access lock them out of every existing solution. CuraLux is built specifically for them.

THE MARKET WE UNLOCK

Clinic avoiders — a behavioral shift already happening.

~9M CT/NG tests performed annually in the US – 80% in clinics. <\$50 with same-day results, many of those patients would choose Amazon over a waiting room.

CDC/Tao et al. Sexually Transmitted Diseases, 2025; Mass General Brigham

82M global NG/yr

129M global CT/yr

8.85% at-home CAGR

\$0 serving the 76%

The Competition

A validated market.
A clear gap.

\$149.99

Visby retail price

3x CuraLux target price

3–5 days

Wait time for Mail-in tests

No same-day answer.

No same-day treatment.

3 steps

Sherlock platform

RPA + T7 transcription + Cas13a many steps + equipment

vs. CuraLux: 3 step

COMPETITIVE LANDSCAPE

The market is being validated. The gap is ours.

	Mail-in (Everlywell etc.)	Visby Medical	OraSure / Sherlock	CuraLux
Price	\$50–\$149	\$149.99	Undisclosed	<\$50 target
Same-day results	X	✓	✓	✓
Instrument-free	✓	✓	✓	✓
CT + NG detection	✓	✓	✓	✓
Human control	X	X	X	✓
All genders	✓	X	TBD	✓
Mfg. complexity	Low	High	Medium-High	Low

Visby validates the FDA pathway. OraSure validates the market. **CuraLux wins on price, simplicity, and coverage.**

BUSINESS MODEL & MARKET APPROACH

Transactional today. Platform tomorrow.

<\$10

Production cost

Lyophilized · Ambient shipping · No cold chain

<\$50

Retail price

No insurance · No prescription · FSA/HSA eligible

60-80%

Gross margin

Subject to final device design & mfg. scale

REVENUE MODEL & GO-TO-MARKET

Meet them where they are. Capture the market.

STREAM 1 — D2C RETAIL

Post-FDA

Amazon · CVS · Walgreens · CuraLux.Health

Under \$50 cash pay. No prescription. No insurance.

Self-checkout generation buying health the way they buy everything else.

STREAM 2 — UNIVERSITY HEALTH CENTERS

Validation + post-FDA

4,000+ US campuses · exact 15-24 demographic

Institutional B2B sales. No insurance billing.

Clinical validation partnerships convert directly to purchase agreements post-clearance.

STREAM 3 — RESEARCH COLLABORATION & LICENSING

Active now → licensing

Active 1-year agreement · mail-in STI company

Mail-in incumbents face disruption.

CuraLux platform is their natural evolution — licensing or white-label as market shifts to real at-home testing.

STREAM 4 — PLATFORM EXPANSION

Year 2-3

Modular device · swap pellets · new targets

Same device architecture. New lyophilized reagent pellets = new pathogen targets.

Each new indication opens a new revenue stream.

The Financial Projections

3.2M Americans with CT/NG untested annually

Milestone-based · All revenue contingent on FDA 510K clearance · Conservative to base-case ranges

PRE-CLEARANCE

Investment Phase

\$0

Product Revenue

Clinical validation
\$200-500K cost

20-30K units manufactured
\$200-300K cost

FDA Q-Sub & 510K process
Ongoing

Research collaboration
Active — samples + data

Market penetration
0%

YEAR 1 POST-CLEARANCE

Three Channels Activate

\$5-10M

Total Revenue

University health centers
\$3-5M

D2C / Amazon
\$2-4M

Mail-in licensing
\$0.5-1M

Gross margin
~75%

Market penetration (15-24)
1-2% → ~64K people

YEAR 2 POST-CLEARANCE

Scale & License

\$20-35M

Total Revenue

University health centers
\$8-12M

D2C / Amazon
\$8-15M

Mail-in licensing
\$4-8M

Gross margin
~77%

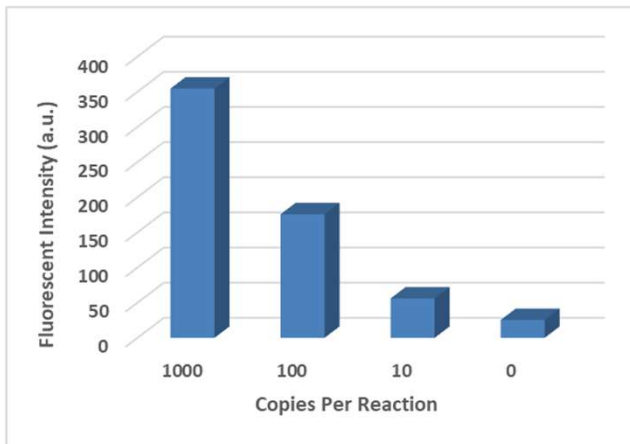
Market penetration (15-24)
5-10% → ~320K people

Year 1: 1-2% capture · Year 2: 5-10% capture · 60-80% gross margin · TAM \$10.6B global STI diagnostics

The science is proven. The platform is validated. The market is ready.

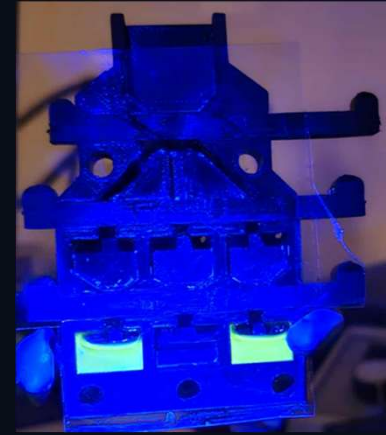
10-Copy Detection Limit

Fluorescent detection — preliminary data



Working Prototype

Fluorescent signal confirmed in device wells



FOUNDATION INVESTMENT

\$800K — NIH contracts, NIH grant + internal investment

- P1 Contract: 75N93023C00056
- P2 Contract: 75N93025C00031-0-9999-1
- P1 Grant: 5R43AI179513-02

PEER-REVIEWED PUBLICATION

Wiggins TJ et al. (2024)

"Instrument-Free Point-of-Care Diagnostic for Leishmania Parasites" *Diagnostics* 14(23):2744 · doi:10.3390/diagnostics14232744

TEAM & ADVISORS

Deep scientific expertise. Built to execute.

FOUNDING TEAM

You?

Currently Seeking

Chief Executive Officer

- Diagnostic or Medical Device Commercialization Experience
- Capital Raising and Investor Relations
- Strategic Partnerships and Business Development
- Ability to Lead a Technical Team Without Being the Scientist



Taralyn J. Wiggins, MS

Chief Operating Officer

- Molecular biology, immunology & commercialization
- PhD candidate, Univ. of Miami
- 14+ years, Biological Mimetics Inc.
- NSF I-Corps — customer discovery & strategic planning



Stephen J. Dollery, PhD

Chief Scientific Officer

- Molecular structure, micro/immunology, genetics
- NIH & industry diagnostics experience
- Vaccines & translational discovery
- Multiple molecular detection platforms



Gregory J. Tobin, PhD

Chief Technical Officer

- Molecular biologist & immunologist
- 27 NIH & DoD grants/contracts
- 40 peer-reviewed publications
- 8 patents & applications

ADVISORY BOARD — INFORMATION



Regulatory Advisor

FDA 510K / Diagnostic Device

Seeking: Regulatory affairs expert with demonstrated experience navigating FDA clearance for molecular diagnostic devices.



Clinical Advisor

Sexual Health / Infectious Disease

Seeking: OB-GYN, ID physician, or STI clinic director to guide clinical validation design and champion institutional adoption.



Commercial Advisor

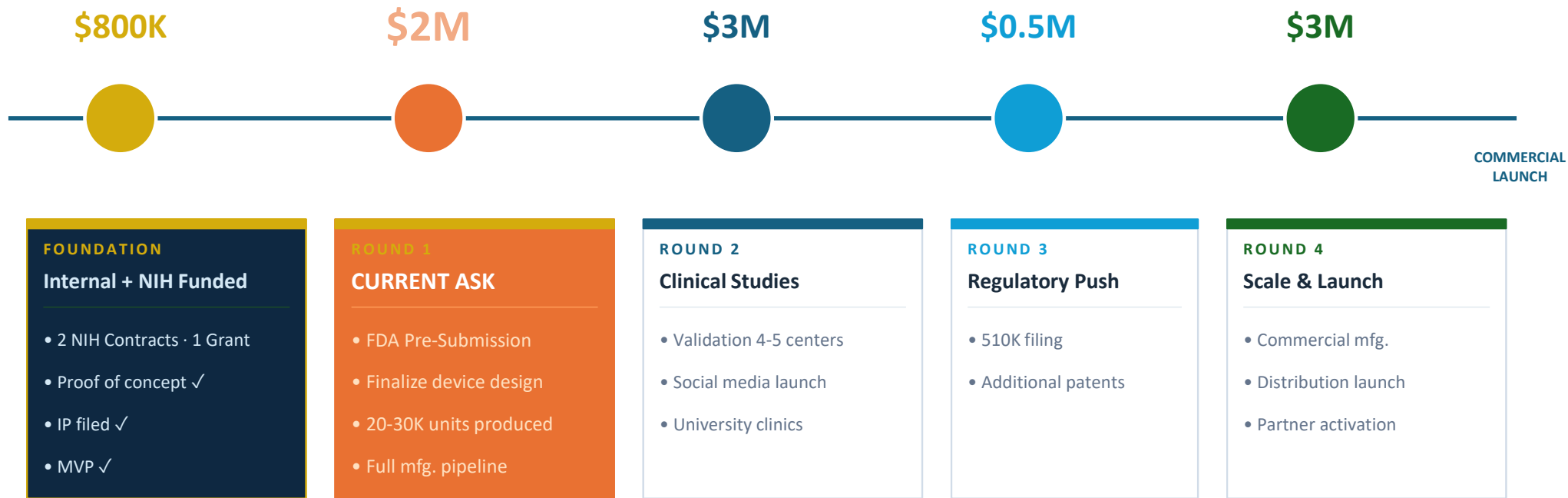
Consumer Diagnostics / Retail Launch

Seeking: Executive with demonstrated success launching consumer diagnostic products through retail and D2C channels.

INVESTMENT OPPORTUNITY

\$800K NIH-validated foundation. ~\$8.5M to market.

510K PATHWAY
Visby + Sherlock predicates



KEY RISKS & MITIGATIONS

FDA timeline slippage

510K pathway de-risked by Visby + OraSure predicates. Q-Sub targets alignment before trials begin.

Competitive timing

OraSure/Sherlock lacks human control, all-gender validation, and modular platform. CuraLux differentiators hold post-clearance.

Clinical validation

Platform peer-reviewed and NIH-validated across multiple pathogens. Technology risk substantially de-risked.



Precision you can count on. Access everyone deserves.

**Every person deserves the same standard of care.
Invest in the technology to make that possible.**

WEB CuraLux.Health

EMAIL info@curalux.health

PHONE [301-378-2551](tel:301-378-2551)

\$2M Seed Round — Now Open

