

bioZhen Corporation

A Breakthrough in Women's Healthcare

Fort Collins, Colorado 80535, USA Founder CEO Vaclav Kirsner PhD



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Company Contact

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Problem:

Women's reproductive healthcare needs a definitive diagnostic tool for self-care and for providing menstrual cycle data to healthcare professionals.

Current Market Size (US):

62.5 M reproductive-age women (initial target is 48 M women): \$21B initial Serviceable Market (fertility-impaired plus off-label birth control users). Worldwide \$168 B.

Products:

See Products on the right for the first two: [prototype FDA-cleared](#), and see the list in [ref. 4](#) for anticipated next products.

IP Protection:

10 patent cases in all stages of prosecution: fully issued, applied for, and applications waiting to be submitted when funded. See [ref. 7](#). Trade secrets are separate.

Core Team:

[Vaclav Kirsner, PhD](#)– Founder CEO

President/COO/new CEO – TBD

Chief OBGYN [Kim Langdon MD](#)

CMO – TBD or [Sara Harms MBA](#)

CTO–TBD or [ShannonCampbell PhD](#)

Controller –TBD

Board of Directors

Use of Funds:

Hire the core staff, conduct large-scale pre-launch clinical trial, and file for additional patents and FDA clearances. Finalize first product fabrication, scale-up and retailing to generate revenues with the FDA-cleared Ovulona. Prepare for Smart Ovulona™ and Halo™ launches. Launch Ovulograph™. Ovulona chip production to be in-house but manufacturing scale-up at third parties. Clinical trial design in-house, monitoring/analyses by third party.

Pro forma financial projections: [ref. 10](#)

Company

bioZhen provides women a personal reproductive life management tool with essential healthcare benefits. A fertility tracking electronic device that records and makes available to consumers and physicians unprecedented evidentiary records of menstrual cyclic profiles as they change over time. In the process, the monitor will inconspicuously capture data about the patients' cervical health, screening for early signs of cervical cancer and other sexually transmitted diseases. The first app is an FDA-cleared fertility monitoring for easy use by women at home, with data sharing for doctors. Note: It will automatically and instantly detect pregnancy - planned or accidental - and it will enable couples to try pre-selecting their planned baby's gender.

Problem

An increasing number of women are struggling to conceive. **Solution:** Simple self-monitoring of folliculogenesis via admittance of outer cervix tissues to assess ovarian function. See [ref. 1](#) - an overview **for people who know women's health**. With the Smart Ovulona™, the user will not need to engage in any data interpretation ([ref. 2](#)). This is important for many US women who are interested in fertility awareness, which is also used for non-hormonal contraception. Medical professionals and the OBGYN community in particular ([ref. 3](#)) need our cervix-monitoring diagnostic method to better serve their patients who present with reproductive and related health problems. Menstrual cycle is a newly recognized vital sign, and we provide the only means of recording its signature profile for better diagnosis. There is no competitive technology platform vs. our Folliculogenesis-In-Vivo™ ([ref. 5](#)) and Ovulograph™ ([ref. 6](#)). No fertility monitor can do what Ovulona does: Tracking the end-organ effects of brain - ovary interactions, it works with the frequent irregular menstrual cycles, and offers the only solution to managing the effects of stress (incl. disease) on a woman's fertility.

Market Opportunity

Our **initial** Serviceable Addressable Market size estimate ranges from \$21 Billion in the U.S. to \$168 Billion worldwide: Fertility-impaired plus off-label birth control users (~50% of ovulation tests are bought by women who DON'T want pregnancy). This estimate does not consider applications other than the initial personal reproductive management (fertility/sex-life management) use of the Ovulona. See [ref. 8](#).

Products

- Ovulona™ Fertility Monitor - inserted like a tampon with a digital display - will be offered later as an internally worn telemetric cervical ring Halo™ for effortless monitoring. Anticipated initial pricing of the Ovulona is below \$300, better than those monitors that require monthly refills (Clearblue) or those that are sold at significantly higher prices (e.g. DuoFertility, BabyComp). <https://biozhena.files.wordpress.com/2017/05/single-slide-comparative-matrix.pps>
- Ovulograph™ SaaS Patient Management System for healthcare providers (clinical and insurance payers), which will receive patients' data when needed.

Plan

- Seeking \$6 million for 20% equity (v.gd/fdBJRy).
- Have raised and invested well over \$1M from our own resources.
- May seek further funding for larger-scale commercialization ([ref.4](#)).
- Exploring strategic marketing partnerships. See Full Value Scenario: [ref. 9](#).

Pro Forma Financial Summary (\$000)	Year 1	Year 2	Year 3	Year 4	Year 5	Cumulative
Revenues	218	23,954	64,108	102,941	133,804	325,026
EBITDA	(4,079)	2,086	17,803	34,943	53,194	103,948
Free Cash Flow	(3,976)	(210)	17,522	33,133	52,330	98,800
Unit Sales (Ovulona™ only – thousands)	1	136	310	575	838	1,859