



OvulonaTM

A revolutionary women's health product & technology platform

Transforming female reproductive health management

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Click the up- and down-arrow keys seen in upper left to navigate back and forth.

bioZhena Overview

- Breakthrough technology addressing significant market need and opportunity
- bioZhena has competitive advantages and barriers to entry, incl. FDA clearance
- Regulatory approval and technology risks largely minimized/removed
- Solid business model - profitability projected within 1 year of market launch
- Management team in progress pending funds



Cervical tissue monitor - the Ovulona™ bioZhena's core product

The Ovulona™ is a personal fertility monitor for women.

Similar to a tampon, it tracks electrochemical signals of the cervix to anticipate and also to detect ovulation.

The Ovulona quickly and accurately defines the woman's daily fertility status.

The electronically recorded data can be forwarded to healthcare providers to better diagnose and treat conditions, and to provide correct timing for tests and procedures.

See how the Ovulona does it [in detail here](#) or quicker [here](#).

What does the Ovulona™ do?

It tracks folliculogenesis in vivo (FIV™).

No other product does that.

Folliculogenesis is central to women's health,
well-being and lifestyle.

Tracking its course generates menstrual cycle
Vital Sign® signatures for physicians and payers.



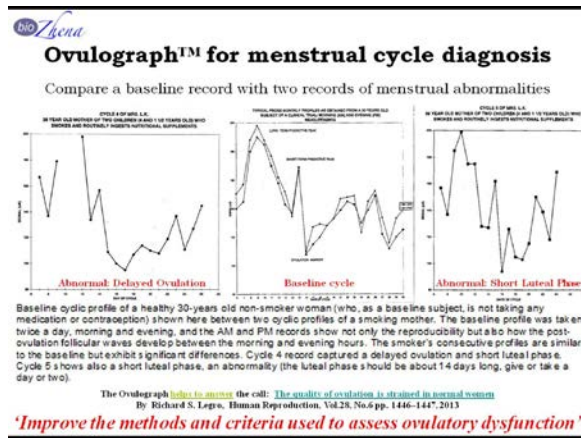
Click the up- and down-arrow keys seen in upper left to navigate back and forth.

Pause to click on link to connect. Hover over the link to read about it . Return here by closing the linked window.

Friendly Technology

Data From Home To Healthcare Providers

From patients' Ovulona™ units to a physician's Ovulograph™
 – when needed



Helping to answer the challenge:

'Improve the methods and criteria used to assess ovulatory dysfunction'

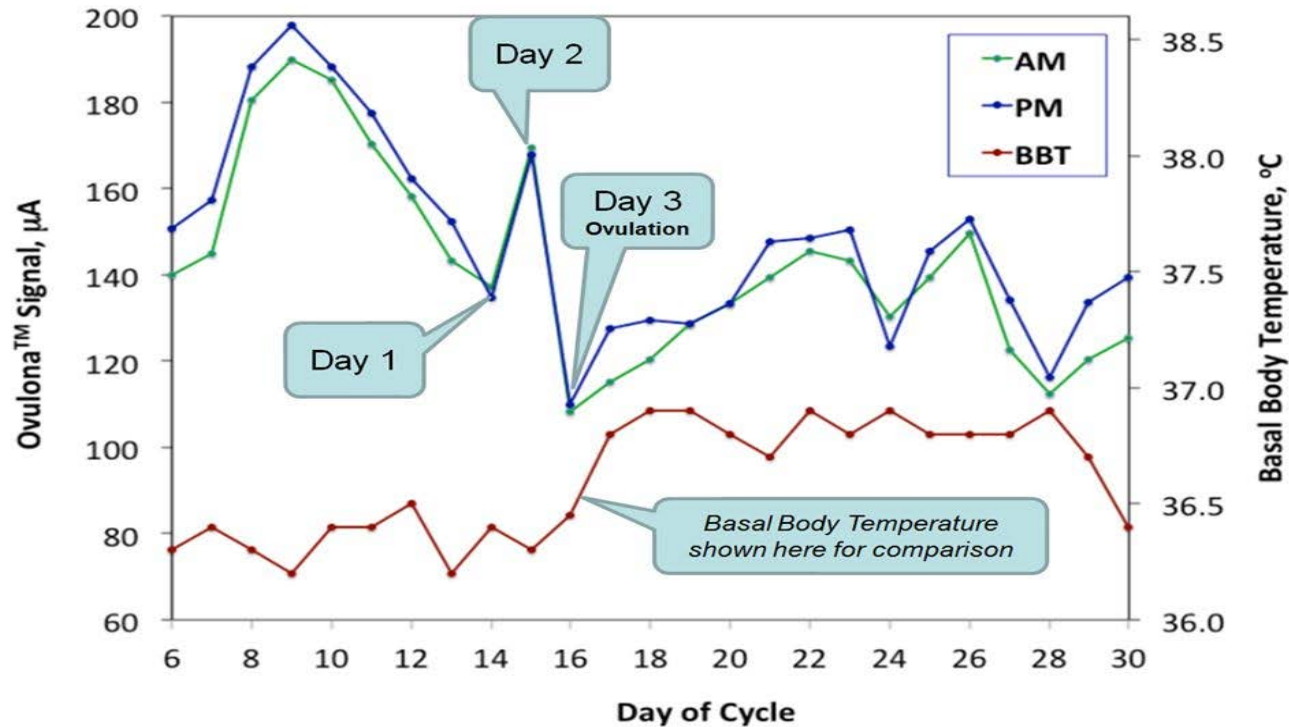
The quality of ovulation is strained in normal women - Human Reproduction 2013

How the Ovulona™ will help physicians to better help their patients

- Review of menstrual profile data recorded over time will help doctors to better diagnose patients ([ref. 1](#)) & progress of treatment ([2](#), [3](#)).
- Ovulona **anticipates failure to ovulate** in a healthy woman ([see 4](#)). This avoids disappointment and the cost of treatment had the doctor not have the patient's Ovulona data **warning that her current menstrual cycle is infertile** (note: not the patient).
- Ovulona detects **delayed ovulations** in asynchronous⁵ cycles that happen to many healthy women. This – when undetected - interferes with planned conception and/or with pregnancy avoidance by fertility awareness ([see 6](#)).

⁵ [Fertility and Sterility report](#): 36% of menstrual cycles (and 45% in another referenced report) were found abnormal due to asynchrony of ovarian and brain pacemakers. Ovulona pilot study [revealed 45% of abnormal \(“challenged”\) cycles](#).

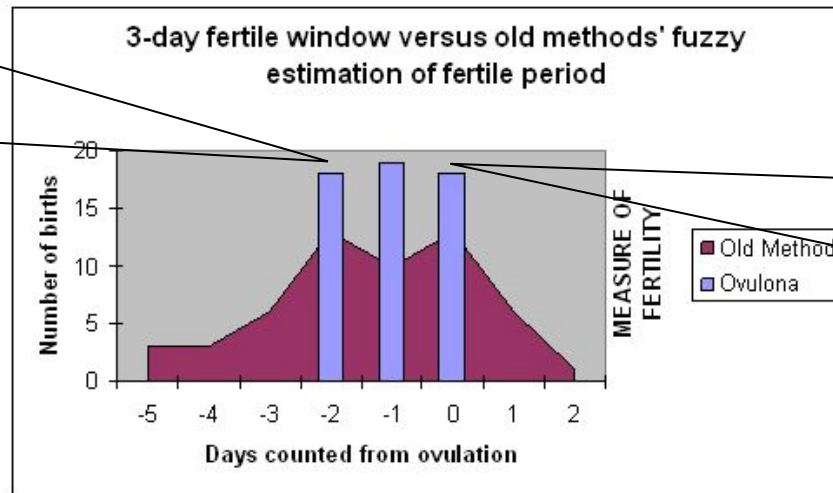
The FDA-cleared first application



Citing from FDA 510K Letter Number K973860: ... *The Monitor serves as an independent information aid to the woman by helping her to define the fertile window... whereby she may choose the proper timing for vaginal intercourse. ... The Monitor may serve to provide the user and her physician with data to better time artificial insemination or other interventional techniques.*

Breakthrough For Trying-To-Conceive Women

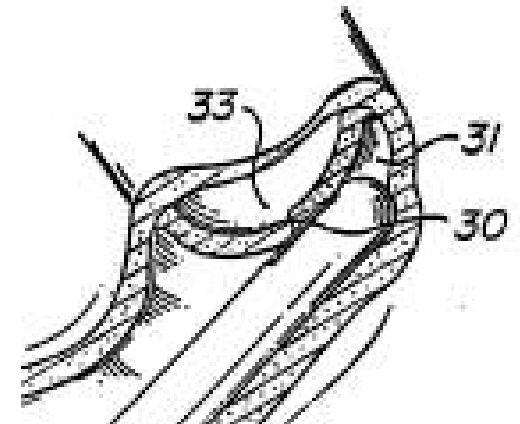
**MOSTLY
BOYS
BORN
77%**



**MOSTLY
GIRLS
BORN
69%**

FERTILE DAY 1 2 3

J.T. France et al., "Characteristics of natural conception cycles occurring in a prospective study of sex preselection...", *Int J Fertility* 37 (4), 224 - 255, 1992



- Precise determination of the 3-day fertile window
- Clear daily indications: FERTILE DAY # or mostly INFERTILE
- Easy to use Smart Ovulona™ and next generation Halo™ telemetric cervical ring
- Requires no chemical work, no graphing, no interpretation of data by the user

Male spermatozoa (Y-chromosome-bearing sperm) live longer than female spermatozoa (X-chromosome-bearing sperm)
G.D. Hodgen et al., *Andrologia* 33,199 (2001)

Trying-To-Conceive Plus Off-Label Use

Market Size At Launch Of The Ovulona™

“About Half Who Use Tests Do Not Want Pregnancy” (marketresearch.com)

“A growing trend among women to use apps to prevent pregnancy” (Mhealth. 2018)

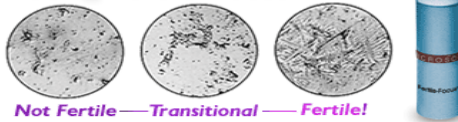
“Up to 60% of women express interest in natural fertility awareness-based methods to prevent pregnancy” ([J Am Board Fam Med](http://JAmBoardFamMed). 2016)

- US Serviceable Available Market (SAM): 17 million Trying-To-Conceive (TTC)
- 31 million Natural Family Planning (Fertility Awareness) Users to avoid pregnancy
- US women with impaired ability to get pregnant or carry a baby to term: 8.2 million women (CDC 2015)
- Worldwide Number of Women off-label users SAM upon device launch: 41.8 million (per UN 2015 Report) - out of 222 million who “want to avoid pregnancy, but are not using a contraceptive method... because of concerns about side effects associated with most available methods” ([JMIR Res Protoc](http://JMIRResProtoc) 2017)

Ovulation prediction products



Using Fertile-Focus



“Only worn during the night, the [Ava](#), a fertility-tracking wearable device” is [an IT adaptation](#) of the old approach to estimating ovulation via numerous variables, here “9 parameters [to] detect the beginning of a woman’s fertile window ... including breathing rate, sleep quality, pulse rate, heart rate variability, temperature [etc]”. For people “deserve to enjoy the baby-making process”.

Two recent IT products do not determine the 3-day fertile window - [like the others](#), merely predict ovulation, 6 days assumed



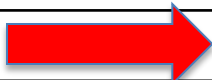
A very expensive IT adaptation of the old BBT technique that does not (cannot) anticipate ovulation. Their counselors help infertility sufferers to practice “focused intercourse” aiming to avoid or at least minimize the high costs of Artificial Reproductive Technologies (ARTs).



Comparison of technologies

in the Trying-To-Conceive self-help market

This is Ovulona monitor's first application, [FDA-ready](#) for market

Characteristics	Ovulona™	BBT Thermo meters	LH kits urine chemistry	Saliva magnifying glasses	Body fluid Conductivity
Precision	High	Low	Low	Low	Low
Reliability	High	Low	Low	Low	Low
Immediacy of results	Yes	Yes	No	Yes	No
Convenience of use	Yes	No	No	Yes	No
Low cost of ownership	Yes	Yes	No	Yes	Yes
Information content 	High	Low	Low	Low	Low
Can be used for birth control?	Yes	No	No	No	No
Can be used to preselect baby's sex?	Yes	No	No	No	No
Can it do built-in pregnancy check?	Yes	No	No	No	No
Can it compute date of delivery?	Yes	No	No	No	No
Folliculogenesis profile for healthcare?	Yes	No	No	No	No
Multi-purpose long-term use?	Yes	No	No	No	No

bioZhenal Startup First Year Timeline: Launch of Basic-Profiling Ovulona

TASKS VS. MONTHS AFTER FUNDING	01	02	03	04	05	06	07	08	09	10	11	12	
Ovulona™ Repackage & Pilot Run			HWI contractor										
FDA 510(k) re-certification													
Ovulona manufacturable and marketable, 10 units tested													
Manufacture and test 50 Ovulona units													
Pilot manufacturing run, 500 units													
Clinical trials and promotion, 3-5 centers													
3,525 units available for sale									budget proposed				
First shipments for sales revenue													



Manufacturing Engineering Contractor's Budget Proposal

Phase	Description	Total est. cost per phase
1	Engineering/Design of Ovulona product	\$316,000
2	Prototype Build (10 units)	\$72,000
3	Engineering Build (25 units)	\$92,000
4	Pilot Run (500 units)	\$222,000
5	First Year Production: 3,525 units ready for sale	\$886,000
	Documentation throughout	\$58,000
	Pre-production Subtotal: Phases 1 to 4	\$702,000
	First Year Production Subtotal: Phase 5 plus Documentation	\$944,000
	Grand Total	\$1,646,000

Ovulona™ product genesis in our plan

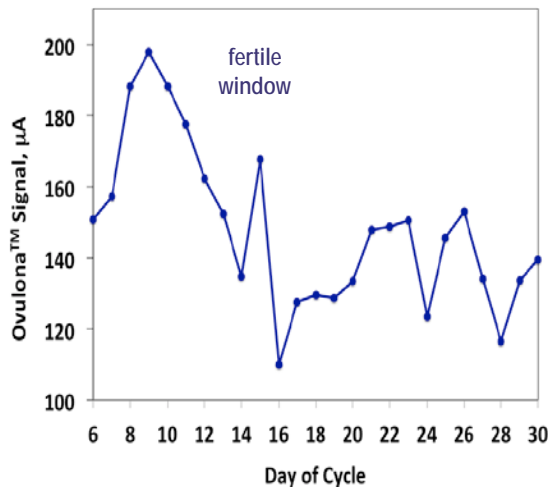
Basic-Profiling Ovulona (launch in yr 1)
 Commercial concept rendition of previously tested and FDA approved pre-production prototype



Smart Ovulona™ (launch in year 3)
 Commercial concept rendition of Smart Ovulona™ which will interpret data for the woman user



Woman generates graph for herself and her physician:



- Immediate readout: INFERTILE or FERTILE DAY 1, FERTILE DAY 2 or FERTILE DAY 3
- Possible to try conceiving a boy on DAY 1 or a girl on DAY 3
- Instant pregnancy detection readout: PREGNANT!
- Abnormal cervical screen readout: SEE DOCTOR
- Wireless transfer of **Ovulona™** data to computer or smart phone
- Transfer data securely to physician for expert assessment using our Ovulograph™ (SaaS, Software as a Service)

Financial Projection – 5 Year Plan

PRO FORMA SUMMARY	Year 1	Year 2	Year 3	Year 4	Year 5	CUMULATIVE
Units Sold (Ovulona - 000)	1	136	310	575	838	1,859
Revenues (\$000)	\$ 218	\$ 23,954	\$ 64,108	\$ 102,941	\$ 133,804	\$ 325,026
EBITDA (\$000)	\$ (4,079)	\$ 2,086	\$ 17,803	\$ 34,943	\$ 53,194	\$ 103,948
EBITDA Margin	--	9%	28%	34%	40%	32%
Capex (\$000)	\$ 76	\$ 192	\$ 354	\$ 421	\$ 421	\$ 1,463
Free Cash Flow (\$000)	\$ (3,976)	\$ (210)	\$ 17,522	\$ 33,133	\$ 52,330	\$ 98,800



10-Year Financial Pro Forma

Financial planning starts with US market only and the Minimum Viable Scenario, MVS, from which we build the Full Value Scenario, FVS. Rest of the World models are built from the US-only models. All assumptions are listed in the Excel financial spreadsheets. We seek to finance the Full Value Scenario, which calls for \$21.1 million (in defined tranches).

Full Value Scenario (FVS) takes the MVS and adds a birth control (BC) capability; promotion via 66 sales reps to all physicians who prescribe BC, and through the internet.

Minimum Viable Scenario (MVS) - the commercial model using only the current 510(k) clearance; promotion via 22 reps to OBGs and through the internet; the TTC use is non-Rx.

	MVS	FVS	
Total Global NPV (\$M)	\$334	\$1,353	total global net present value (detailed US model plus rest of world estimate)
Total Global Women using Ovulona	12.2	46.5	millions of women using Ovulona GLOBALLY by the 10th year
Model Summary (US Only)			
NPV (\$M)	\$106	\$523	net present value, calculated based on the NPAT (net profit after taxes) minus t
Investment (\$M)	\$18.1	\$21.1	the amount of money needed to execute this model
10-year GS (\$M)	\$1,088	\$4,235	10 year cumulative gross sales in millions
Initial Sales (month)	16	16	the first month that the business generates revenue
Profitability: 1st positive Cash Flow (month)	32	33	the first month that the business becomes profitable
NPAT/GS @10YR (%)	39.1%	46.2%	the percentage of our gross sales converted into profit
Gross-to-Net @10YR (%)	82.2%	85.3%	the impact of discounts and returns on gross sales (doctors and patients referring
Women using Ovulona @10YR (M)	3.67	13.8	millions of women using Ovulona by the 10th year
Total Women in Target (M)	16.6	62.2	millions of women in target for this indication
% of Women Using Ovulona @10YR	22.1%	22.2%	% of the target women using Ovulona
Total Doctors Using Ovulona @10YR	6,810	22,558	cumulative number of doctors using Ovulona by the 10th year
Earnings/Doctor @10YR (\$/year)	\$4,760	\$8,817	the annual average incentive payments doctors receive
Sales Force (FTEs)	22	66	total number of full time equivalents (FTEs) in the sales force
Model Summary (Rest of World Estimate)			
RoW NPV (\$M)	\$229	\$830	rest of world net present value, calculated based on the NPAT's shown on the I
Women using Ovulona @10YR (M)	8.6	32.7	millions of women using Ovulona by the 10th year

Health insurance payers are expected to benefit from the use of patients' Ovulona profiling, and from Ovulona impact on management of various conditions, including course of pregnancy.

Press the ctrl key and click on the summary table above to view Full Value Scenario xls spreadsheet. To return here, close the xls spreadsheet window.

Ovulona™ patent portfolio

8,821,407	Fertility Status Diagnosis System
8,152,735	Diagnosis of fertility status
7,771,366	Vaginal fertility probe
7,427,271	Diagnosis of fertility status by folliculogenesis monitoring in the vagina
5,916,173	Methods and apparatus for monitoring fertility status in the mammalian vagina
D393,311	Mammalian fertility probe
4,753,247	Method and apparatus for monitoring redox reactions

WHY HAS THIS NOT BEEN DONE BEFORE?

Management Team

Vaclav Kirsner PhD – Founder CEO

EVP/President/COO/new CEO – TBD

Chief OBGYN Kim Langdon MD

CMO – TBD or Sara Harms MBA

CTO –TBD or Shannon Campbell PhD

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 (see [slide](#)).
- Exploring commercial marketing partnerships.
See Full Value Scenario ([xls, summary tab](#)).

*We of course know of related women's health tech M&As: Conceptus to Bayer \$1.1B (invasive contraception Essure); Diagene to Qiagen \$1.6 B (cervical cancer diagnosis).
Our technology is better than those two.*

Recap and Thank You for your attention!
Ovulona™ for assessment of reproductive health:
Reliable and uniquely user-friendly

- Accurately detects the female fertile window
 - Aids in achieving pregnancy
 - Allows hormone-free birth control
- Will detect pregnancy immediately, automatically
- Will detect reproductive health anomalies and cervical tissue aberration from teen age to menopause
- Has FDA 510(k) clearance for conception-aiding prototype
- Multiple patents issued and several in process
- Substantial market that can lead to \$1B revenues

