Ovulona™

A revolutionary women’s health product & technology platform

Transforming female reproductive health management

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bioZhena Overview

• Breakthrough technology addressing significant market need and opportunity

• Products have 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.

You can see how the Ovulona does it [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).

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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.
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

- 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

Mostly boys born 77%

Mostly girls born 69%

Male spermatozoa (Y-chromosome-bearing sperm) live longer than female spermatozoa (X-chromosome-bearing sperm)

G.D. Hodgen et al., Andrologia 33,199 (2001)

“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. 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 2017)
Ovulation prediction products

Two recent IT products do not determine the 3-day fertile window - like the others, merely predict ovulation, 6 days assumed.

“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".

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

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Ovulona™</th>
<th>BBT Thermometers</th>
<th>LH kits urine chemistry</th>
<th>Saliva magnifying glasses</th>
<th>Body fluid Conductivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precision</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Reliability</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Immediacy of results</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Convenience of use</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Low cost of ownership</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Information content</strong></td>
<td><strong>High</strong></td>
<td><strong>Low</strong></td>
<td><strong>Low</strong></td>
<td><strong>Low</strong></td>
<td><strong>Low</strong></td>
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<tr>
<td>Can be used for birth control?</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Can be used to preselect baby’s sex?</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Can it do built-in pregnancy check?</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Can it compute date of delivery?</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Folliculogenesis profile for healthcare?</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Multi-purpose long-term use?</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

### bioZhena Startup First Year Timeline: Launch of Basic-Profiling Ovulona

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

**HWI contractor budget proposed**
# Manufacturing Engineering Contractor’s Budget Proposal

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

- 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)

Clarification of our SALES AND MARKETING STRATEGY
# Financial Projection – 5 Year Plan

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

<table>
<thead>
<tr>
<th></th>
<th>MVS</th>
<th>FVS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Global NPV ($M)</td>
<td>$334</td>
<td>$1,353</td>
</tr>
<tr>
<td>Total Global Women using Ovulona</td>
<td>12.2</td>
<td>46.5</td>
</tr>
</tbody>
</table>

**Model Summary (US Only)**

- NPV ($M) $106 $523
- Investment ($M) $18.1 $21.1
- 10-year GS ($M) $1,088 $4,235
- Initial Sales (month) 16 16
- Profitability: 1st positive Cash Flow (month) 32 33
- NPAT/GS @10YR (%) 39.1% 46.2%
- Gross-to-Net @10YR (%) 82.2% 85.3%
- Women using Ovulona @10YR (%) 3.67 13.8
- Total Women in Target (%) 16.6 62.2
- % of Women Using Ovulona @10YR (%) 22.1% 22.2%
- Total Doctors Using Ovulona @10YR 6,810 22,558
- Earnings/Doctor @10YR ($/year) $4,760 $8,817
- Sales Force (FTEs) 22 66

**Model Summary (Rest of World Estimate)**

- RoW NPV ($M) $229 $830
- Women using Ovulona @10YR (M) 8.6 32.7

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 use
• Multiple patents issued and several in process
• Substantial market that can lead to $1B revenues