



## **BIOZHENA MISSION:**

### **A HEALTH TOOL FOR EVERY WOMAN**

Far more than a tool to aid achieving pregnancy

Our vision is to create a product that practically every woman will want to use. The woman of the 21st century is envisaged to become accustomed to using her daily Ovulona self-check about as routinely as she is using her lipstick or her toothbrush.

The Ovulona™ will be useful to the point of becoming an essential tool of women's health management, both at home and, if need be, for the provider in the doctor's office. Accordingly, the Ovulona will be supremely user-friendly and affordable for everyone.

These are two important attributes because "discontinuation of use of a reversible contraceptive for a method-related reason is very common" in the U.S., and "the risk of failure during typical use of reversible contraceptives" is too high: Overall, 9% of women become pregnant within one year of starting use", and the high contraceptive failure rates "reflect imperfect use because most reversible methods are difficult to use correctly". The high discontinuation rates are believed to reflect dissatisfaction with available contraceptive methods [Family Planning Perspectives, 1999, 31(2):64-72 & 93; <http://www.agi-usa.org/pubs/journals/3106499.html> ].

Women's health and well-being revolve around the hormone-driven menstrual cycle, from birth control and family planning concerns, through such aspects of health care as the estimated timing of baby's birth and/or such ills as the premenstrual syndrome or clinical depression, all the way to preparing for the individualized management of menopause.

bioZhenalogo Corporation will introduce a high-tech version of the natural family planning method that is widely used in many countries. Scientific studies have

**bioZhenalogo Corporation**

83 Davis Ranch Road, P.O. Box 122, Bellvue, Colorado 80512, USA

Vaclav Kirsner, Ph.D., Chairman and CEO

[vaclavkirsner@yahoo.com](mailto:vaclavkirsner@yahoo.com)

970-484-1272



concluded that natural family planning is a perfectly acceptable approach to birth control, with well-defined advantages for individual well being and for public health. While we have large markets in the developing countries, we aim to offer particularly the American and Western women a new alternative for their birth control. Many of them want a method that does not introduce chemicals into the body, a birth control method that does not interfere with the natural course of the menstrual cycle.

Public health surveys in the mid- and late nineties found that more than 20% of US women, who do not currently use it, are interested in natural family planning/fertility awareness. Proponents of the natural family planning methods have proffered statistics showing comparable efficacy with chemical contraception. Despite that, the medical and lay public perception of method effectiveness continues to favor the chemical approach and irreversible surgical sterilization. Public health studies have found that most physicians underestimate the effectiveness of NFP and consequently “do not give information about modern methods to women” [Obstet. Gynecol. 1999 Nov; 94 (5 Pt 1):672-8].

We are introducing a technology that removes the subjective, demanding and imprecise aspect out of the natural method of birth control. This renders NFP or Fertility Awareness readily accessible to any woman, not only to the better educated ones who currently tend to be the majority among the users of the method in the industrial countries. This is the cornerstone of our philosophy.

We are also idealistic enough to allow for the possibility that an increase in the prevalence of this approach to birth control may have desirable effects on public health. To mention just two such possible positive consequences, the incidence of unwanted pregnancies and of complications in pregnancy could be lowered, and the divorce rate and moral standards may improve as a consequence of the discipline inherent in the natural method of family planning. Even institutions that are at best impartial to NFP, such as the American Academy of Family Physicians, advise the public that “natural family planning methods require partners to share the responsibility for planning or avoiding pregnancy.

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Typically, couples who use these methods notice an increase in communication and in cooperation” [ <http://www.familydoctor.org/handouts/126.html> ].

The medical profession’s bias toward chemical contraception is not surprising. Yet, it is known that about half of the unwanted pregnancies in the U.S. result from contraceptive failure. It is understood that contraceptive failure is “the result of the difficulties that individual women confront in incorporating the task of contraceptive use into their everyday lives; over half of all women practicing contraception use a method that requires ongoing attention [including] oral contraceptives as well as intercourse-related methods such as the condom and the diaphragm” [ <http://www.alanguttmacherinstitute.org/pubs/ib19.html> ].

bioZhená Corporation will work with the medical profession to introduce the NFP-assistive technology and make it as useful for the health care providers as for the women. The plan is to build on the fact that many facets of women’s health are linked with the menstrual cycle. We will introduce the technology as a more broadly applicable diagnostic tool for the medical profession, and make them used to the idea of a high-tech approach to natural family planning/fertility awareness.

The first clinical application will be for the accurate determination of the post-ovulation phase in premenstrual syndrome management, combined with electronic reporting of the daily PMS symptoms. We shall also give the infertility specialists a convenient alternative to the presently used hormone kits and/or the BBT charts. This will provide previously unavailable information about the patient’s menstrual history, so as to improve on the effectiveness of the infertility treatments. These clinical applications will introduce the technology to the medical profession well before we enter into the birth control arena, so that by the time we do, the medical community will have become used to the technology and will logically anticipate its use as a birth control aid.

In the course of the clinical studies that are an integral part of the bioZhená business plan, several applications of the technology will be investigated, in addition to the main use as fertility monitor. Firstly, there are potential applications closely related to the family planning purpose, such as early

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detection of pregnancy, and the calculation of the more reliably projected date of delivery from the actual history of the prospective mother's menstrual cycles as stored in the electronic memory of the device. Then there are potential applications of the tissue-biosensor as an end-organ effect monitor of the steroid hormones as they change throughout the woman's life, leading to breast examination alarm, and pre-menopausal monitoring with a view to designing an individualized hormone replacement therapy.

Last but not least, there is the speculatively expected capability to detect early stages of cervical cancer, and the diagnosis of pelvic inflammatory disease. The speculation is based on the mode of operation of the technology, which may be expected to generate telltale signatures for the pathological conditions. These may be sufficiently distinct from the normal cyclic profiles so as to yield an early warning for the woman, bringing her into the physician's office and again providing history of menstrual cycle data to assist in further diagnosis and treatment.

Developments in the animal use of the technology for birth alarm may also lead to analogous fundamental improvements in human obstetric care, to save expectant mothers and the healthcare system from premature trips into the maternity ward.

Other applications may in due course be proposed by the physicians as they get used to the technology and the data it generates.

It is certainly encouraging that the American College of Obstetricians and Gynecologists advises the public that "periodic abstinence is quite an effective means to prevent an unwanted pregnancy"

[ [http://www.medem.com/search/article\\_display.cfm?path=n:&mstr=/ZZZH6QKJ27C.html&soc=ACOG&srch\\_typ=NAV\\_SERCH](http://www.medem.com/search/article_display.cfm?path=n:&mstr=/ZZZH6QKJ27C.html&soc=ACOG&srch_typ=NAV_SERCH) ].

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