



MEMORANDUM REPORT

To: (A Group of Angel Investors)
Date: January 29, 1998
Subject: **THE OUTLOOK FOR AN OVULATION PREDICTION INSTRUMENT**

INTRODUCTION

This is a report of a market research project to assess the potential market for an ovulation prediction instrument developed by Dr. _____.

To reach the conclusions reported here I made an extensive survey of the business and medical literature, interviewed human health and agricultural science practitioners, and interviewed marketing personnel in companies presently selling fertility and contraceptive products to those markets. I have given you reports of the interviews I have made, and copies of the significant articles and competitive literature which I found.

CONCLUSION

There is some evidence in my research supporting Dr. _____'s belief in his product, and I believe there are opportunities for him to proceed with development on a smaller scale than proposed in his business plan, with funding through joint ventures and research grants. But sales of \$100 million per year as projected in the business plan are fanciful. Sales of \$3 million to \$5 million by the end of year five might be attainable.

GENERAL OUTLOOK

Commercial products to predict or time ovulation, in humans and in animals, have been available in the U.S. for at least 25 years, both as aids to fertility and for natural family planning. During that time a great variety of devices have been developed and marketed, with little or no success. I estimate that total sales in the U.S. of all ovulation prediction products, for both humans and animals, is less than \$35 million, with most of that accounted for by sales of Ovulation Prediction Kits (OPKs).

Although none of the devices and methodologies used for ovulation prediction are without operational problems, and none are completely reliable, the principal barrier to sales is lack of demand. The benefits of the devices are recognized by a very small segment of the potential buyer populations or are seen as less convenient than the available alternatives.

A superior product might increase demand slightly, but there is no sound basis at this time for projecting a substantial increase in demand.

If Dr. _____'s instrument can overcome the operational and reliability problems of present ovulation prediction devices, and can be competitive in price, it could capture a share of the existing fertility aid market segment for animals, and, perhaps, expand the market somewhat. Capturing any share of the human contraception market appears unlikely.

AGRICULTURE

There is absolutely no doubt at all that animal breeders could benefit enormously from better estrus detection. Article after article in the business and scientific literature point out that dairymen lose as much as \$300 million per year or \$10 per month per cow from poor estrus detection. Smaller, but still significant breeding losses are experienced by breeders of beef cattle, milk goats, sheep, and horses.

There have been devices on the market for about 25 years which can improve estrus detection. Currently, there are pressure sensors and chalk markers which identify which cows are standing in heat and being mounted, vaginal wands which measure electrical resistance of mucus, vaginal inserts which slowly release progesterone, progesterone measurement in milk, and pedometers which measure increased activity associated with estrus. All of the devices work, in that they measure or sense what they claim to measure or sense. And what they sense is related to the onset of estrus.

But all of the devices have weaknesses. They generate false positives and negatives, they come off and become lost, they cause infections, they are too labor intensive, and they require the time and attention of dairy managers.

For biophysical or biochemical sensors, a further weakness is that, even within species, there are differences from one animal to another which, so far, cannot be accommodated by any estrus detecting device. Animals cannot, as humans can, follow instructions, and learn to adjust for individual differences in using medical devices.

Animal breeders have therefore been slow to adopt any of the devices. They resist spending money on anything but frozen semen. If they miss estrus on a cow for one cycle, they are not greatly concerned, because they do not track that cost element. An inherent characteristic of farming is to be at risk of nature. A farmer will accept that risk, which he understands, more readily than he will spend money on a new technology which gives him less than certain control or takes time and attention from other tasks to which he assigns a higher value.

One of the leading estrus detecting devices presently on the market is the *HeatWatch* system developed and marketed by Ddx, Inc., Denver, CO. This device employs a pressure sensor glued to the animal's tail head and connected by telemetry to a central computer. *HeatWatch* has been

used in several dozen experiments by University animal science and reproductive biology specialists, and has been found to have acceptable performance. Ddx has been selling *HeatWatch* since 1991. Sales in 1997 were about \$1 million.

Improvements in estrus detecting devices is possible. Clinical tests to support FDA certification of implantable sensors which can do more than just estrus detection may be underway soon.

But another technique offers greater promise than estrus detection devices, and that is the use of hormones to synchronize estrus so that it does not need to be detected, it can be programmed or induced. In the long run, this technique is likely to prove more cost-effective and more acceptable to farmers than the use of instruments and computer systems.

THE HUMAN FERTILITY MARKET SEGMENT

There are about 60 million women in the U.S. of child-bearing age. Each year, about 5% of them, 3 million women, enter into a conception stage of life and bear a child, only half of them, 2.5%, intentionally.

It is widely estimated in the literature that one out of six women in the U.S. of child-bearing age have difficulty conceiving, a population segment of about 10 million. Assuming that the same percentage of those women as fertile women try to conceive in any one year, 2.5%, or about 250,000, would be seeking some sort of aid. Because of the difficulty they experience in conceiving, it is reasonable to assume that perhaps the number is twice that, or 500,000 in any one year.

About one out of five women with conception difficulty undergoes medical intervention in any one year, and, of those, only about 20,000 are successful in producing a child. That is not a lot of encouragement for companies selling fertility products and services.

U.S. sales of over-the-counter fertility aids for women using medical intervention, and those using only OTC methods, is about \$25 million per year at the manufacturers' sales level according to reports of manufacturers and of retail survey organizations. That is an average of \$50 per woman, or \$70 at retail.

According to women's fertility support groups and medical fertility practitioners, the OPKs are 95% reliable in predicting a woman's cycle when used over several cycles. The most popular brand of OPK, *ClearPlan Easy*, sold by Unipath, a division of Unilever, is rated easy to use and of the highest value by a consumer rating organization. Private label OPKs, which have a 65% market share, are virtually equal in performance to *ClearPlan Easy*, and sell at about half the price.

In contrast, sales of pregnancy test kits, which are similar to OPKs in technology, operation, and price, and which are offered by some of the same companies which offer OPKs, is about \$300 million, about ten times the total for fertility aids.

The demand for pregnancy detection kits is split among those who are trying to become pregnant - about 1.5 million women - and those who are worried that they might have unintentionally become pregnant, about another 3 million, according to the manufacturers. The potential market

for pregnancy detection kits thus is 4-5 million women, 10 times the number who are in the market for fertility aids. If Dr. _____'s instrument can be used to detect pregnancy in women as well as the onset of ovulation, the instrument might then be able to capture market share in this larger segment.

The suppliers of OPKs are consolidating. Heavy price resistance by consumers and fertility specialists, and the increasing market share of private label kits, has eroded the price and the margin, and brought about an overall decline in gross sales. Some brands, which have been purchased by competitors from manufacturers exiting the market, may disappear over the next several years.

It is unlikely that the appearance of a superior, or less expensive, ovulation prediction instrument will increase the market for fertility aids, because the existing demand is already satisfied. Instead, it will simply take share from OPKs, further erode margins, and, if priced lower, reduce the value of the total market.

THE HUMAN CONTRACEPTION MARKET SEGMENT

The target population is nearly 20 times larger for this segment than for fertility aids. Moreover, the population is willing to spend considerably more per person for contraception products than for fertility aids.

Sterilization is the most popular method of birth control, relied upon by 42% of contraceptive users. Among the 58% practicing reversible contraception, the birth control pill is by far the most popular method, used by half of the women in this group. Despite the continued warnings about side effects of oral contraceptives, the percentage of women who take this medication continues to grow. Oral contraceptives are used most used by those who are affluent and well-educated. Condoms are the next most popular reversible method, with 18% of the women in this group relying on them.

Fewer than 1 million women use fertility awareness methods with periodic abstinence.

There are two problems with fertility awareness methods. One is that there is not a completely reliable method of predicting when a woman must abstain, and the other is that it requires discipline on the part of the woman and her partner during the fertile periods.

Dr. _____ addresses the first problem, but not the second. Because his instrument is less convenient to use than the pill, and requires discipline, it is unlikely to take a substantial market share from the pill. Because condoms are used mostly by teenagers and unmarried women, his instrument is not likely to take market share from this segment, either.

With extensive market education and development over a 5-10 year period, Dr. _____'s instrument, if it proves reliable in clinical tests, and achieves FDA certification, might be purchased by some percentage of the 1 million women practicing fertility awareness. It also is possible that the instrument could double the number of women practicing fertility awareness. There are no reliable data available to estimate the potential sales. A reasonable assumption might be 25% of the old and new fertility awareness segment, 500,000 women, or 50,000 to 100,000 units per year if there is no competition. At \$25 each at the manufacturers level, that

would mean average yearly sales of \$1.5 million to \$3 million, starting as low as \$100,000 the first year.

Unipath has developed an electronic ovulation prediction instrument for contraception, the *Persona*, which it has introduced in Europe and Canada, and it is beginning clinical trials in the U.S. As noted earlier in this report, Unipath sells the most popular OPK and pregnancy detection kits.

Dr. _____ describes his market entry strategy as depending on UniPath or another manufacturer to pioneer this market segment, including FDA certification. If he enters the U.S. market with a contraceptive device based on that assumption, it will face substantial competition from the *Persona*. Unipath has established distribution in the market, has a recognized brand name, and has substantially more resources than BioSense.

Moreover, the *Persona* requires the user periodically to purchase consumables, which increases the revenue for the product at what are traditionally high margins. That will enable Unipath to expend more effort on market and distribution development than Dr. _____ will be able to do. It therefore is unlikely that he will be able to capture more than 30% market share, or an average of \$500,000 per year. That does not seem adequate to finance an FDA application and consumer education campaign.

But Unipath may decide in the end not to go to market with the *Persona*. In clinical tests in Europe, which were considerably less stringent than those planned for the U.S., 6 out of 100 women using the instrument *correctly* (emphasis mine) became pregnant unintentionally. That may prove too high a percentage for a high market penetration in the U.S.

Although the *Persona* is described in Unipath's sales literature as being easy to use, many women buying it in the U.K. did not find it so. An organized campaign by women's health groups forced Unilever to open its help line 24 hours per day, and also to allow phone calls by prospect buyers which, if required in the U.S., too, will increase sales and support expenses.

RECOMMENDATIONS

I recommend that Dr. _____ withdraw from seeking venture capital to support an unrealistic business plan, and, instead focus on research, licensing, and the sale of custom instruments to research and development laboratories. For funding, he should pursue research and development contracts, grants, cost-sharing projects with industrial partners, licensing, consulting, and the sale of custom instruments.

To support that work, Dr. _____ should write scientific papers and attempt to establish a reputation as a scientist in the field of ovulation detection. In a search of 150 scientific literature databases I was unable to find any references to publications by Dr. _____.