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BioNovo: Women's Health And Cancer

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Small Emeryville Company Has Some Truly Novel Compounds

Editor's Note: This article is a result of Dr. Eeckman's and Greg Scott's interview with the founders of BioNovo, Isaac Cohen, O.M.D., and Mary Tagliaferri, M.D., at their offices on November 10, 2005. The Centient Biotech Investor™ will also cover BioNovo's upcoming announcement on December 8th regarding their BZL 101 drug for cancer.

November 14, 2005 -- BioNovo ([BNVI](#)) is a small, Emeryville, CA-based pharmaceutical company focused on drugs for women's health and cancer, especially breast cancer. The company works on agents derived from plants and natural sources. Using a systems biology approach, which looks at multiple effects and pathways simultaneously, the company has managed to develop some unique compounds aimed at large, growing markets.

BioNovo's founders hail from UCSF and have many top contacts in the research community. That means that the company, despite its small size, has access to very well-known cancer researchers and premier cancer centers to run its clinical trials. With all the recent attention to cancer compounds, getting trials done at reputable centers is fast becoming a major threshold to entry in this exciting field. Another outside validation lies in the several millions of dollars of grant money that the company pulls in on a yearly basis, much of it from the National Institutes of Health (NIH) R01/R03 programs, which are very selective.

But BioNovo is not just about great research. The company has two drugs in mid-stage trials. BioNovo's lead compound, MF101, is designed for the treatment of hot flashes and night sweats in the peri- and post-menopausal period. This is a large market, which is growing rapidly as more and more baby boomers enter their silver years. The leading drug, Premarin from Wyeth ([WYE](#)), is effective here but has recently been shown to seriously increase the risk of major, life-threatening side-effects. That has led to rather significant decline in its market. Without Premarin, hot flashes and night sweats are essentially an unmet medical need.

Hot flashes affect most women for extended periods of time between the ages of 47 and 51. They can be as frequent as 5-10 times daily and lead to a major decrease in the quality of life. A smaller group of about 20% of women have very severe hot flashes that last for years or decades beyond the peri-menopausal period. Such severe hot flashes are a real quality of life issue, according to company founders.

MF101 is a selective estrogen beta agonist. BioNovo has shown that selectivity for estrogen beta receptors yields a compound with good efficacy that is virtually free of side-effects, like breast cancer, endometrial cancer, cardiovascular problems, and dementia. These side-effects are largely mediated through estrogen-alpha receptors. MF101 may also be protective for osteoporosis, another major problem in older women.

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BioNovo's second compound, BZL101, is an apoptosis-inducing drug that uses a novel mechanism to kill cancer cells. BZL101 circumvents the regular apoptosis mediators such as Bcl and others that are often defective or missing in tumors. It also escapes the multi-drug resistance pumps that make most chemotherapies ineffective after a few months. BZL101 just completed a Phase I study, the results of which will be reported in the upcoming Breast Cancer meeting in San Antonio on December 8. (*Editor's Note: The Centient Biotech Investor™ is receiving a full copy of the study and will be analyzing the results on December 8 or 9.*)

BioNovo has a robust pipeline, with two other compounds that are about to enter the clinic, and expects to file at least two INDs early next year. Also planned for next year are two major Phase II trials. Additionally, the company has entered into discussions with major pharma companies for the late-stage development and commercialization of some of its compounds. The only apparent hitch is that investors are hanging on to their stock in anticipation of the pending announcement, so the trading activity is relatively light.

All in all, it looks like good things are happening in Emeryville, CA.

Disclosure: None.