



## Corporate Fact Sheet 2012

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Bionovo Inc. is a drug development and discovery company, founded in 2002, focused on developing safe and effective drugs for the treatment of unmet medical needs in women's health and cancer. Bionovo's unique business model is focused on developing women's health therapies based on botanical extracts from plants with a history of efficacy in traditional Chinese medicine.

Of the 40 million women in America who are of menopausal age, an estimated 75% to 85% experience significant and unpleasant side effects due to declining and fluctuating hormone levels. These problems include hot flashes, vaginal dryness, cognitive impairment, depression, mood swings, and infections, as well as weight gain. Existing therapies represent a multi-billion dollar market but are, unfortunately, ineffective, unsafe, or both. Due to the lack of safe and well tolerated treatment options, 80% of menopausal women turn to some form of botanical dietary supplement to control their symptoms of menopause. Bionovo is striving to fill this gap by providing a safe, reliable, and clinically proven therapy to fill this unmet need for the 40 million women transitioning through menopause.

## Lead Product Candidates



Menerba (MF101) is a first-in-class non-hormonal, botanically-derived, orally delivered drug for the treatment of hot flashes and night sweats. Menerba's mechanism of action is to decrease hot flashes by selectively regulating the estrogen receptor beta ( $ER\beta$ ) pathway while leaving the estrogen receptor alpha ( $ER\alpha$ ) pathway unaffected. Its unique ability to selectively regulate the  $ER\beta$  pathway gives it a more favorable safety profile than hormone therapy. Estrogens in hormone therapy are non-selective and the activation of  $ER\alpha$  by estrogens results in the increased breast and uterine cancer risk. Menerba is the first multi-species botanical drug product to advance to Phase 3 in the FDA's rigorous approval process. This accomplishment is paramount to the future commercial viability of Menerba and Botanical Drug Products in general.

Menerba's positive Phase 2 clinical trial results confirmed its status as a first-in-class drug. The Phase 2 study concluded that treatment with Menerba significantly reduced the frequency of hot flashes in healthy postmenopausal women and had no significant side effects. Bionovo launched the first of two Phase 3

clinical trials in October 2011. The randomized, placebo controlled trial is currently underway at 50 clinical sites across the US and total enrollment will include 1,200 patients. The primary aim of the study is to measure the safety and efficacy of Menerba compared to placebo in reducing the frequency of moderate to severe hot flashes among healthy postmenopausal women after 12 weeks of treatment.



Bezielle is an oral drug designed for the treatment of solid tumors, initially for metastatic breast cancer. Bezielle induces necrotic and apoptotic cell death selectively in tumor cells by interrupting glycolysis, the process utilized by tumor cells for energy production. Because normal cells do not primarily rely upon glycolysis for energy production, Bezielle can selectively kill cancer cells while leaving normal cells intact. Therefore, Bezielle offers patients diagnosed with cancer an effective treatment option with minimal toxicity.

In clinical studies in women with refractory metastatic breast cancer, Bezielle showed excellent tolerability, minimal toxicity and encouraging clinical activity in two heavily pre-treated populations. To date, a total of 48 women with advanced breast cancer have been treated with Bezielle in two early phase clinical trials. We have early signs that Bezielle has a preferential effect on HR- breast cancers that do not express receptors for either estrogen or progesterone. Bezielle also shows promising potential to treat patients with Her2/neu negative breast cancer. To this end, Bezielle may be very effective in the adjuvant setting as a multiple year treatment for women diagnosed with early stage breast cancer and for women with late stage, triple negative breast cancer.



Seala, a non-steroidal vaginal suppository selective to the estrogen receptor beta (ER $\beta$ ), has been developed to treat the symptoms associated with vaginal atrophy. Due to concerns about the side effects of systemic and local estrogen therapy, there is growing interest in new treatments for vaginal dryness which Bionovo is seeking to meet through Seala.

Seala selectively targets ER $\beta$  and we have previously shown that ER $\beta$  acts as a tumor suppressor, inhibiting the proliferative effects mediated through ER $\alpha$  in breast cancer and uterine cell lines. The vaginal canal expresses both estrogen receptors, ER $\alpha$  and ER $\beta$ . In animal models, our estrogen receptor beta selective drug, Seala, was effective at treating vaginal atrophy without causing any untoward cancerous effects in the uterus.

### Recent Corporate Highlights

- ❖ Bionovo launched the Phase 3 trial for Menerba (MF101) at 50 approved U.S. clinical trial sites. Enrollment is expected to be complete in Q4 2012 with final Phase 3 trial results released in Q2 2013.
- ❖ In a tolerability trial investigating higher doses of Menerba, Bionovo reported results that after 4 weeks of treatment with Menerba 10g/day, the reduction in moderate to severe hot flashes was 60% (with a p-value of 0.003). This level of efficacy at 4 weeks is comparable to estrogen-based hormone therapy.
- ❖ Bionovo completed a series of safety and tolerability trials of Menerba in women and two animal species investigating much higher doses than will be used in the Phase 3 trial. The drug was well tolerated and safe in all studies to date with no reports of serious adverse events.

## Product Pipeline

Drug	Indication	Mechanism of Action
Women's Health		
	Pre-Clinical	Phase 1
		Phase 2
		Phase 3
Menerba	Postmenopausal Vasomotor Symptoms	Estrogen Receptor Beta Agonist
Seala	Postmenopausal Vaginal Atrophy	Estrogen Receptor Beta Agonist
Cancer Therapy		
Bezielle	Breast Cancer	Pro-apoptotic Agent
Bezielle	Pancreatic Cancer	Pro-apoptotic Agent
BN107	Breast Cancer	Pro-apoptotic Agent
BN108	Breast Cancer	Pro-apoptotic Agent

### Forward Looking Statements

This release contains certain forward-looking statements relating to the business of Bionovo, Inc. that can be identified by the use of forward-looking terminology such as "believes," "expects," or similar expressions. Such forward-looking statements involve known and unknown risks and uncertainties, including uncertainties relating to product development, efficacy and safety, regulatory actions or delays, the ability to obtain or maintain patent or other proprietary intellectual property protection, market acceptance, physician acceptance, third party reimbursement, future capital requirements, competition in general and other factors that may cause actual results to be materially different from those described herein as anticipated, believed, estimated or expected. Certain of these risks and uncertainties are or will be described in greater detail in our filings with the Securities and Exchange Commission, which are available at <http://www.sec.gov>. Bionovo, Inc. is under no obligation (and expressly disclaims any such obligation) to update or alter its forward-looking statements whether as a result of new information, future events or otherwise.