

Bionovo Inc. (BNVI)

UPDATE REPORT

March 21, 2011

Rating Target

Strong \$7.50

Speculative Buy

Analysts

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CEO – Isaac Cohen
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- ◆ High-Dose® Menerba Safety Trial Commencing
- ◆ U.S. Phase IIIa Enrollment Starts Q2 with Dosing Q3
- ◆ Menerba® Could Be First Botanical Blockbuster Drug

1.) **Bionovo Completes High-Dose Manufacturing:** Bionovo completed the manufacture of Menerba® drug material at the higher potency paving the way for the required animal toxicity testing and human safety trial.

2.) **High-Dose Safety Trial:** Bionovo will first conduct a 40-patient 28-day Phase I safety trial of high-dose Menerba® (3x higher than tested in Phase II) which will initiate late-Q1 and is expected to be completed in Q2.

3.) **Phase IIIa Trial Enrollment Starting Q2 and Dosing Starting Q3:** Bionovo has already received clinical trial guidance from both the FDA and the European Medicines Agency (EMA) and anticipates initiating dosing for the Phase IIIa trials in Q3. There will be 5 safety reviews by the Data Safety Monitoring Board during the Phase IIIa trial with data expected Q4 2012.

4.) **New Funding could Re-Start Bezielle® Development:** Bionovo completed Phase Ia and Ib trials of Bezielle® in 48 advanced breast cancer patients, but the program was put on hold due to financial constraints. With the new funding we believe Bionovo could begin enrolling the Phase II trial which has already been approved by the FDA and several IRBs.

5.) **Menopause Market – Large and Underserved:** With approximately 80 million women in the U.S. and Europe transitioning through menopause and at least 70% experiencing hot flashes, night sweats and associated insomnia, **we estimate the worldwide market at approximately \$10 billion.** Current hormone replacement therapy (HRT) carries warnings for increased risk of breast cancer, strokes, heart attacks, and blood clots while alternatives to HRT, such as antidepressant drugs, are not FDA approved and can cause significant side-effects as well.

Market Data

Price	\$0.57
52-Week	\$0.52-\$3.15
Market Cap	\$31.1M ¹
Avg. Daily Vol.	384,962
% Short	3.4%

Share Data

Outstanding	54.6M ¹
Cash/Share	\$0.56 ¹
Book/Share	\$0.63 ¹
Price/Book	1.0x ¹
Debt/Share	\$0.04 ¹

Most Recent Quarter

Revenue	\$531K
Net Income	(\$4.3M)
EPS	(\$0.18)
Cash	\$2.6M
Debt	\$2.0M

Financial Results and Projections

FYE Mar. 31	2009	2010	2011E	2012E	2013E
Revenue	\$0.3M	\$0.1M	\$0.0M	\$0.0M	\$0.0M
Net Income	(\$16.4M)	(\$17.7M)	(\$25.2M)	(\$31.5M)	(\$33.3M)
EPS	(\$0.98)	(\$0.80)	(\$0.46)	(\$0.50)	(\$0.46)



¹ Includes 30M Shares Sold for \$27.8M Net Cash Proceeds 2/2/11

Please See Last Two Pages For Important Disclosures And Analyst Certification

6.) **Obesity & Metabolic Syndrome:** On September 2, 2010 Bionovo announced the U.S. National Institutes of Health (NIH), National Center for Complementary and Alternative Medicine (NCCAM) approved and funded a grant to Bionovo and Dr. Dale Leitman from the University of California at Berkeley (UCB) to fund the first phase in a planned multi-phase study evaluating Bionovo's plant-derived tissue selective estrogen receptor modulators for preventing obesity and the metabolic syndrome. Dr. Leitman stated his results “*have demonstrated that Bionovo's drugs behave very selectively in that they reduce body mass and fat re-distribution without causing breast or uterine cell proliferation in mice.*”

We believe this is especially noteworthy as obesity drugs from 3 different companies VIVUS (Nasdaq:VVUS), Arena Pharmaceuticals (Nasdaq:ARNA) and Orexigen Therapeutics (Nasdaq:OREX) all recently failed to win FDA approval. VIVUS Qnexa (phentermine/topiramate), Arena's Lorcaserin (5-HT_{2C} receptor agonist) and Orexigen's Contrave (bupropion/naltrexone) all failed to prove benefits that outweigh the potential risks. **We believe that Bionovo's Phase IIIa and Phase IIIb clinical trials would provide a significant additional safety package should Bionovo eventually submit an obesity candidate to the FDA.**

7.) **Potential Blockbuster:** Menerba[®] could become the first botanical blockbuster drug which we believe represents an intriguing opportunity for patient investors. We are maintaining Bionovo, Inc. with a Strong Speculative Buy rating and 12-18 month Price Target of \$7.50 based on a 35x multiple on projected fiscal year 2015 EPS and discounted 45% for cumulative risk.

Investment Summary

The market for a safe and effective treatment for women transitioning through menopause who are experiencing hot flashes, night sweats and associated insomnia is currently estimated at \$10 billion or more. However, this market is currently underserved as hormone replacement therapy (HRT) carries FDA warnings for increased risk of breast cancer, strokes, heart attacks, and blood clots. The FDA's Safety Announcement on July 29, 2010 regarding adverse effects from Evamist[®] (estradiol spray) exposure in children and pets shows that the safety issues with HRT are still being discovered.¹

Alternatives to HRT, such as antidepressant and anti-seizure drugs, are not FDA-approved for menopause and can cause significant side-effects as well. For example, Depomed's (Nasdaq:DEPO) Phase III trials for Serada[®] (extended-release gabapentin) showed that approximately 20% of patients suffered dizziness (vs. 3% for placebo) and approximately 10% suffered drowsiness (vs. 3% placebo).²

We believe that Bionovo's approach using a botanical source, which research has shown to be a selective estrogen receptor modulator (SERM) could represent a significant breakthrough in the treatment for menopausal symptoms and address this large, underserved therapeutic market. Oral Menerba[®] selectively modulates estrogen receptor beta (ER β), which would avoid the safety issues in hormone replacement therapies that activate the ER α pathway thus increasing cancer risk. Menerba also appears to avoid the central nervous system (CNS) side-effects seen in the off-label use of antidepressant and anti-seizure drugs. As a result, Menerba[®] could become the first botanical blockbuster drug which we believe represents an intriguing opportunity for patient investors.

RESEARCH REFERENCES

¹ FDA Drug Safety Communication: “*Ongoing safety review of Evamist (estradiol transdermal spray) and unintended exposure of children and pets to topical estrogen*” July 29, 2010

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm>

² Depomed, Inc. “*Serada Phase 3 Results*” October 12, 2009

<http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Mjg0NDJ8Q2hpbGRJRDR0tMXxUeXBIPM=&t=1>

Company Description



Emeryville, California-based Bionovo, Inc. discovers and developments drugs focusing on women’s health needs and cancer treatments. Their lead drug candidate is Menerba[®] (formerly MF101), a new class of receptor sub-type selective estrogen receptor modulator (SERM), for the treatment of vasomotor symptoms of menopause, or “hot flashes.” Oral Menerba selectively modulates estrogen receptor beta (ERβ) with the intent to provide a safer and effective alternative to existing treatments which carry FDA Block Box Warnings due to significant risks. Bionovo is also developing Bezielle[®], an oral drug for advanced breast cancer which induces apoptosis (cell death) by induction of reactive oxygen species (ROS) which causes DNA damage, PARP hyperactivation and inhibition of glycolysis. Both Menerba and Bezielle drugs candidates are derived from botanical sources.

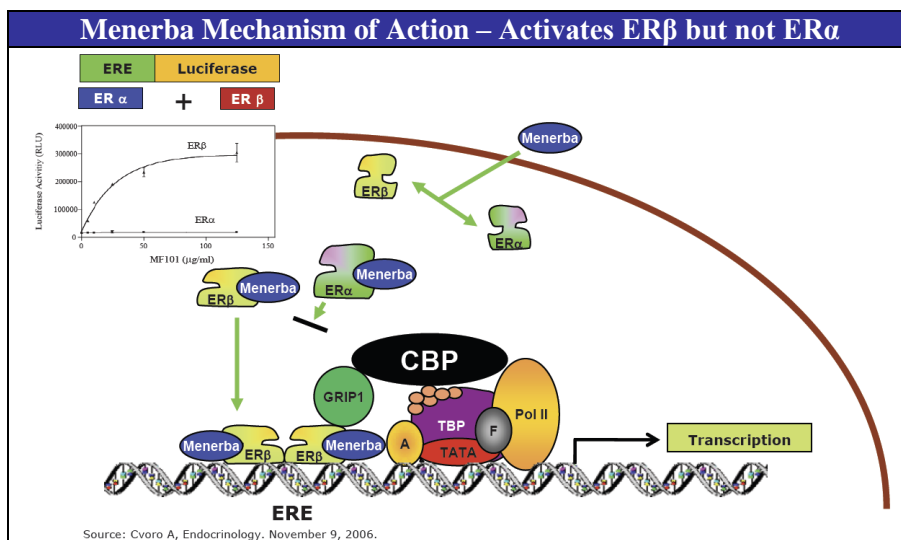
Calendar Quarter	MILESTONES & EVENTS
Q3 2010	✓ EMA Guidance & Trial Approval ✓ FDA CMC Approval
Q4 2010	✓ FDA Trial Approval
Q1 2011	✓ Manufacture High-Dose for Testing Preclinical High-Dose Safety Testing Initiate Phase I (High-Dose Safety)
Q2 2011	Data Phase I (High-Dose Safety) Manufacture Menerba for Phase III
Q3 2011	Initiate Menerba Phase IIIa – U.S.
Q4'11-Q2'12	5 Interim Data Safety Reviews
Q3 2012	Complete Menerba Phase IIIa – U.S.
Q4 2012	Data Menerba Phase IIIa – U.S.
Q1 2013	Initiate Menerba Phase IIIb – U.S.
Q1 2014	Complete Menerba Phase IIIb – U.S.
Q2 2014	Data Menerba Phase IIIb – U.S.
Q1 2015	FDA Menerba Approval & Launch

Source: Bionovo and LifeTech Capital Estimates

We have not included the European timeline for Menerba[®] at this time as it may be dependent on a partnership. In addition, we have not yet included Bezielle[®], Seala[®] or any other pipeline candidates in our financial model due to the current uncertainty regarding development timelines and resources.

Menerba[®] for Menopausal Hot Flashes

Bionovo’s Menerba[®] (formerly MF101) is derived from botanical extracts and is currently being developed to treat the menopausal vasomotor symptoms commonly referred to as “Hot Flashes”. Menerba consists of 22 herbs that have been used in traditional Chinese medicine and represents a new class of receptor sub-type Selective Estrogen Receptor Modulator (SERM). Specifically, while oral Menerba has been shown to bind equally to Estrogen Receptors alpha (ERα) and beta (ERβ), it only activates (agonist) the ERβ transcriptional pathways which studies have shown to control hot flashes. Menerba is also thought to be safer since it does not activate the ERα pathway (c-myc, cyclin D1 and MCF-7) which studies have implicated to increase the risk of breast and uterine cancer. Existing mixed agonist/antagonist SERMs (such as tamoxifen and raloxifene) carry the FDA Black Box Warnings “*Tamoxifen may cause cancer of the uterus (womb), strokes, and blood clots in the lungs*” and “*Taking raloxifene may increase the risk that you will develop a blood clot in your legs or lungs.*” Oral Menerba is a composition of 22 botanical species as shown below:



Source: Bionovo Inc.

Composition of Menerba® (formerly MF101)

Pin Yin ^a	Botanical name ^b	Family ^b	Pharmaceutical name ^c	Daily dose, g ^d	Percentage in formula ^e
Ban Zhi Lian	<i>Scutellaria barbata</i> D. Don	Lamiaceae	Herba Scutellaria Barbata	30	11.2
Shan Dou Gen	Sophorae Subprostratae or Tokinensis Gapnep	Leguminosae	Radix Sophora Subprostratae	15	5.6
Zhi Mu	<i>Anemarrhenae asphoeloides</i> Bunge	Liliaceae	Radix Anemarrhena	12	4.5
Hei Dou	<i>Glycine soja</i> Sieb. Et Zucc.	Leguminosae	Semen Glycine Sojae	20	7.5
Gan Cao	<i>Glycyrrhizae uralensis</i> Fisch.	Leguminosae	Radix Glycyrrhiza	8	3
Da Huang	<i>Rheum palmatum</i> L.	Polygonaceae	Rhizoma Rhei	8	3
Fu Xiao Mai	<i>Triticum sativum</i> L.	Gramineae	Fructus Triticis Levis	15	5.6
Huang Qi	<i>Astragalus membranaceus</i> Fisch. Bge. Var. mongolicus Bge.	Leguminosae	Radix Astragali	12	4.5
Sheng Di Huang	<i>Rehmannia glutinosa</i> Libosch.	Scrophulariaceae	Radix Rehmannia	12	4.5
Nu Zhen Zi	<i>Ligustrum lucidum</i> Ait.	Oleaceae	Fructus Ligustri Lucidi	15	5.6
Suan Zao Ren	<i>Ziziphus jujuba</i> Mill. Var spinosa Bunge Hu ex H.F. Chou	Rhamnaceae	Semen Zyziphi Spinozae	10	3.7
Lian Zi Xin	<i>Nelumbo nucifera</i> Gaertner	Nymphaeaceae	Plumula Nelumbinis	10	3.7
Fu Ling	<i>Poria cocos</i> Schw. Wolf	Polyporaceae	Poria Cocos	10	3.7
Ze Xie	<i>Alisma orientalis</i> Sam. Juzep.	Alismataceae	Rhizoma Alismatis	10	3.7
Mu Dan Pi	<i>Paeonia suffruticosa</i> Andr.	Ranunculaceae	Cortex Moutan Radicis	8	3
Shan Zhu Yu	<i>Cornus officinalis</i> Sieb. Et Zucc.	Comaceae	Fructus Corni	10	3.7
Huai Niu Xi	<i>Achyranthes bidentata</i> Bl.	Amaranthaceae	Radix Achyranthis	10	3.7
Mu Li	<i>Ostrea gigas</i> Thunberg	Osteridae	Concha Ostrea	12	4.5
Tian Men Dong	<i>Asparagus cochinchinensis</i> Lour. Merr.	Liliaceae	Radix Asparagi	12	4.5
Ge Gen	<i>Pueraria lobata</i> Willd. Ohwi	Leguminosae	Radix Pueraria	10	3.7
Bai Zhu	<i>Atractylodes macrocephala</i> Koidz	Compositae	Radix Atractylodis Macrocephala	10	3.7
Yin Yang Huo	<i>Epimedium brevicornum</i> Maxim.	Berberidaceae	Herba Epimedi	8	3
Total				267	100

For medicinal use, plant parts are selected for their particular pharmaceutical applications. The English translations of the plant parts are the following: *herba*, whole aerial part of the plant; *radix*, root; *semen*, seed; *rhizome*, tuber; *fructus*, fruit; *plumula*, flower bud; *cortex*, bark; *concha*, shell.

^a Pin Yin is the Romanization system accepted by the People's Republic of China.

^b Herb names are written in accordance with the international code for botanical nomenclature (Tokyo Code, 1994).

^c Herbs are sold under their pharmaceutical name, which indicates plant part and genus but not always the particular species and never the family.

^d Dose of dry plant before extraction to extract the 10-g dose of MF101. This is diluted by 50% to reach the 5-g dose.

^e Percentage of the dry plant material before extraction.

Source: Grady D., MD, et al., "MF101, a selective estrogen receptor A modulator for the treatment of menopausal hot flashes: a phase II clinical trial" *Menopause: The Journal of The North America Menopause Society*, Vol. 16, No. 3, pp. 000/000 2009 The North American Menopause Society

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Omar I. Vivar, Xiaoyue Zhao, Elise F. Saunier, Chandi Griffin, Oleg S. Mayba, Mary Tagliaferri, Isaac Cohen, Terence P. Speed and Dale C. Leitman "Estrogen Receptor β Binds to and Regulates Three Distinct Classes of Target Genes" July 16, 2010 The Journal of Biological Chemistry, 285, 22059-22066 <http://www.jbc.org/content/285/29/22059>

Paruthiyil S, Cvorova A, Zhao X, Wu Z, Sui Y, et al. 2009 "Drug and Cell Type-Specific Regulation of Genes with Different Classes of Estrogen Receptor β -Selective Agonists." PLoS ONE 4(7): e6271. doi:10.1371/journal.pone.0006271 <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0006271>

Recent Menerba® Research Papers

On October 21, 2010, the *Current Opinion in Pharmacology* reviewed of results from studies discussing new classes of estrogen receptor modulating drugs with distinct mechanism for pharmacological effect. The paper titled "Regulation of Specific Target Genes and Biological Responses by Estrogen Receptor Subtype Agonists" discusses the estrogen receptors alpha (ER α) and beta (ER β), which are triggered non-selectively by current hormone replacement therapies and can result in adverse effects. **Bionovo's Menerba is selective in that it activates only the ER β pathway.** It can be downloaded at: http://bionovo.com/static/doc/abstracts/10_Bionovo_Pharmacology.pdf

The importance of estrogen receptor targeting was highlighted once again in the October 20, 2010 issue of the *Journal of the American Medical Association (JAMA)* in a paper titled "Estrogen Plus Progestin and Breast Cancer Incidence and Mortality in Postmenopausal Women" which shows **that women who developed breast cancer after using hormone-replacement therapy (HRT) were diagnosed at a later stage than those not on HRT. The HRT women also had a slightly higher death rate.** It can be accessed at: <http://jama.ama-assn.org/cgi/content/short/304/15/1684>

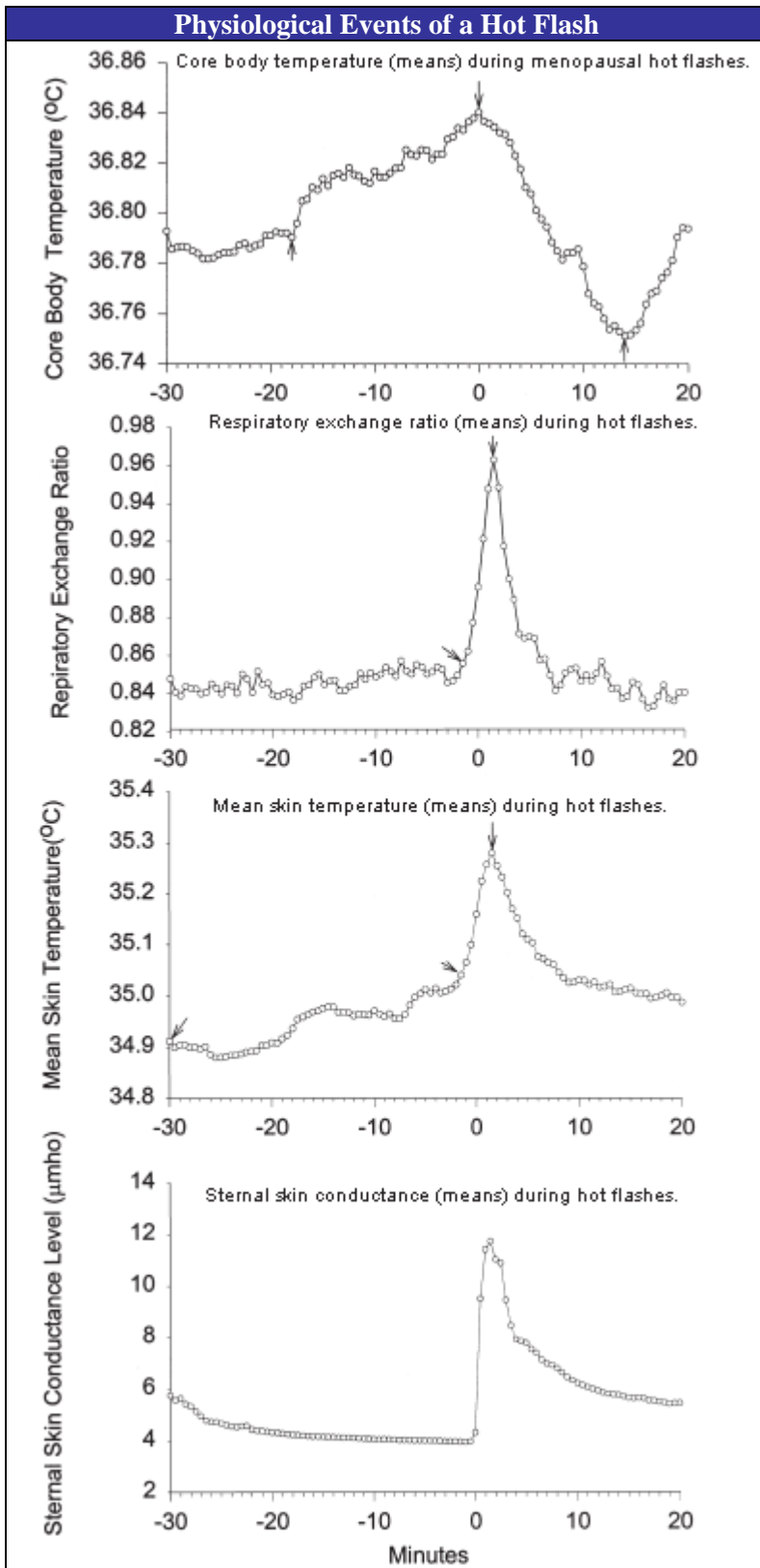
Menopause and Hot Flashes

According to the North American Menopause Society (NAMS), the onset of Menopause occurs at an average age of 51 with the final menstrual period and confirmed when a woman has missed her periods for 12 consecutive months. It is associated with reduced functioning of the ovaries due to aging, yielding lower estrogen and hormone levels. The most common symptom is hot flashes (or hot flush) thought to be the result of changes in the hypothalamus (the brain center regulating body temperature). It may erroneously sense a woman is too warm and begins to dilate blood vessels near the skin surface to dissipate heat. This produces a red flush in the face and neck and may also result in perspiration. An increased pulse rate and a sensation of rapid heart beating may also occur. Hot flashes are often followed by a cold chill with a few women experiencing only the chill.

Hot flashes are very common with the Massachusetts Women's Health Study¹ finding 75% of women had hot flashes between peri- and post-menopause and averaging of 3.8 years. A prevalence study² reported that 64% of peri-menopausal women experienced hot flashes from 1 to 5 years while another study³ reported the average duration of symptoms to be 4 years. Of the symptomatic women in latter study, 87% had daily hot flashes and 1/3 of those reported >10 per day. Hot flashes usually lasted from 1 to 5 minutes and described as sensations of intense heat, sweating, flushing, chills, and clamminess. Sweating was reported most frequently in the face, neck, and chest.

Two additional studies^{4,5} found high body mass index is directly related to hot flash frequency, possibly due to increased insulation from body fat, resulting in elevated body temperature which triggers hot flashes.⁶ Cigarette smoking also may increase the risk of hot flashes^{4,5} possibly through the effect on estrogen metabolism or through the thermogenic effects of nicotine.⁷

On August 2, 2010 Bionovo announced results from a study titled “*Estrogen Receptor B-Selective Agonists Stimulate Calcium Oscillations in Human and Mouse Embryonic Stem Cell-Derived Neurons*” in neurons treated with Menerba. The study described a novel model for thermoregulatory control with neurons that are differentiated from stem cells, and express native estrogen receptors. Menerba, an estrogen receptor beta selective modulator, was shown to regulate calcium influx, which is related to temperature regulation and believed to be a cause of hot flashes.⁸



Source: Freedman, R. "Pathophysiology and Treatment of Menopausal Hot Flashes: Physiological Events of the Hot Flash" Seminars Reproductive Medicine 2005;23(2):117-125 2005 Thieme Medical Publishers

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The North American Menopause Society (NAMS) http://www.menopause.org
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¹ Avis NE, Crawford SL, McKinlay SM. "Psychosocial, behavioral, and health factors related to menopause symptomatology." Womens Health 1997;3:103-120 http://www.ncbi.nlm.nih.gov/pubmed/9332153
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³ Kronenberg F. "Hot flashes: epidemiology and physiology." Ann N Y Acad Sci 1990;592:52-86 http://www.ncbi.nlm.nih.gov/pubmed/2197954
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⁵ Whiteman MK, Staropoli CA, Lengenber PW, McCarter RJ, Kjerulff KH, Flaws JH. "Smoking, body mass, and hot flashes in midlife women." Obstet Gynecol 2003;101:264-272 http://www.ncbi.nlm.nih.gov/pubmed/12576249
⁶ Freedman RR. "Editorial: hot flash trends and mechanisms". Menopause 2002;9:151-152 http://www.ncbi.nlm.nih.gov/pubmed/11973436
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⁸ Zhang L, Blackman BE, Schonemann MD, Zogovic-Kapsalis T, Pan X, et al. 2010 Estrogen Receptor β -Selective Agonists Stimulate Calcium Oscillations in Human and Mouse Embryonic Stem Cell-Derived Neurons. PLoS ONE 5(7): e11791. doi:10.1371/journal.pone.0011791 http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0011791

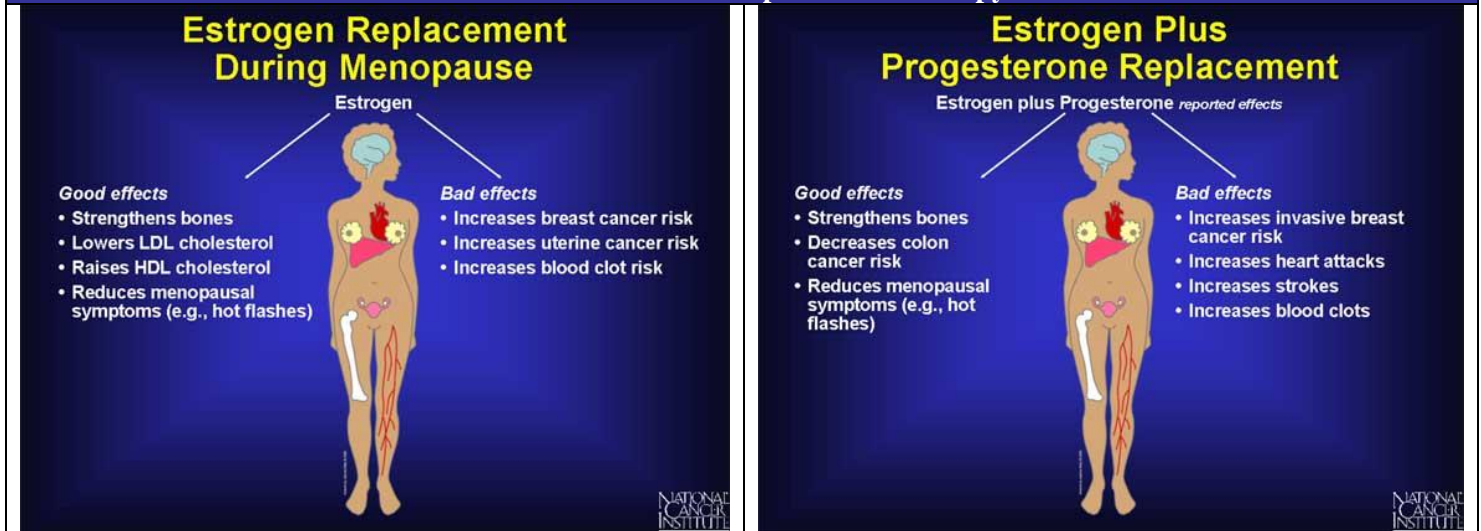
Current Treatments for Menopause and Hot Flashes

Currently, Hormone Replacement Therapy (HRT) can be used to treat menopausal symptoms. Originally, HRT treatment was to replace estrogen during menopause to strengthen bones and help control other menopausal symptoms. But as a consequence, women may also subject themselves to the harmful effects of estrogen such as an increased risk for invasive breast cancer, uterine cancer and blood clots. Studies then suggested that adding the hormone progesterone could offset the increased risk of uterine cancer linked to estrogen. HRT then standardized on using estrogen plus progesterone in treating women with menopausal symptoms.

However, a study of 16,000 menopausal women carried out by the Women's Health Initiative (WHI) was prematurely halted in 2002 when preliminary results indicated that the harm associated with this type of treatment outweighs the potential benefits. The major risks detected were an increased chance of developing invasive breast cancer, as well as an increased risk of strokes, heart attacks, and blood clots. While the data also revealed that hormone replacement with estrogen plus progesterone lowered the risk of osteoporosis and colon cancer, these benefits were not considered to be sufficient to outweigh the other risks.

The importance of estrogen receptor targeting was highlighted in the October 20, 2010 issue of the *Journal of the American Medical Association* (JAMA) in a paper titled "Estrogen Plus Progestin and Breast Cancer Incidence and Mortality in Postmenopausal Women" which shows that women who developed breast cancer after using hormone-replacement therapy (HRT) were diagnosed at a later stage than those not on HRT. The HRT women also had a slightly higher death rate. It can be accessed at: <http://jama.ama-assn.org/cgi/content/short/304/15/1684>

Effects of Hormone Replacement Therapy



Source: National Cancer Institute (NCI) - US National Institutes of Health (NIH)

Current hormonal agents include Pfizer’s (NYSE:PFE) Premarin® and Prempro® as well other brand name and generic versions of hormone replacement therapy agents. An alternative to HRT are antidepressant drugs such as GlaxoSmithKline’s (NYSE:GSK) Paxil® (paroxetine), Pfizer’s Effexor® (venlafaxine), Biovail’s (NYSE:BVF) Wellbutrin® (bupropion) and Eli Lilly’s (NYSE:LLY) Prozac® (fluoxetine). However, they are not FDA approved to treat menopausal symptoms and there can be significant side-effects from these antidepressants that may be the same or worse than the menopausal symptoms they are meant to treat. Other unapproved drugs that have been used for menopausal symptoms are the blood pressure drug clonidine and the anti-seizure drug gabapentin.

In addition, a dietary supplement called Femarelle® (DT56a) is currently being marketed for menopausal symptoms, which contains 322mg of soy extract and 108mg of laxseed, to be taken twice daily. However, it is not FDA-approved and is marketed as a dietary supplement rather than a therapeutic drug. The manufacturer has filed for a clinical trial for hot flashes but it has not yet begun. (see “A Double-Blind Study to Evaluate the Effect of Femarelle on Menopausal on Vasomotor Symptoms” <http://clinicaltrials.gov/ct2/show/NCT01063725>)

RESEARCH REFERENCES

Women’s Health Initiative – Estrogen Alone Study http://www.nhlbi.nih.gov/whi/estrogen_alone.htm

Women’s Health Initiative – Estrogen & Progesterone Study http://www.nhlbi.nih.gov/whi/estrogen_pro.htm

Clinical Trials for Menerba®

Update: Bionovo announced that the FDA will require a 40-patient Phase I safety trial of high-dose Menerba® 15g/day (7.5g BID) for 28 days (3x higher than that tested in Phase II). The Phase I will run concurrently with the 13-week animal toxicology studies. **Bionovo anticipates initiating the Phase I study in Q1 2011 and initiating enrollment for the U.S. Phase IIIa trial in Q2 2011.**

Planned Phase III Clinical Trials

Menerba® will be required to complete 2 Phase III trials for approval. The Phase IIIa trial will be structured identically for the U.S. and Europe while the Phase IIIb trial will have a different structure in Europe as it requires an estrogen comparator arm in addition to the placebo control arm.

Previously, on August 31, 2010, Bionovo announced that they received positive guidance and agreement from the FDA on the CMC (Chemistry, Manufacturing and Controls) plan for Menerba® for menopausal hot flashes. As a result of manufacturing adjustments, Bionovo will conduct a final 28-day bioequivalence study in rats and provide selected batch records for review. Investors should note that FDA agreement on the CMC plan for Menerba is a significant achievement

both for Bionovo and for botanical drug development. Because of the complex nature of a typical botanical drug and the lack of knowledge of its active constituents, the FDA may rely on a combination of tests and controls to ensure the identity, purity, quality, strength, potency, and consistency of botanical drugs. These tests and controls include (1) multiple tests for drug substance and drug product (e.g., spectroscopic and/or chromatographic fingerprints, chemical assay of characteristic markers, and biological assay), (2) raw material and process controls (e.g., strict quality controls for the botanical raw materials and adequate in-process controls), and (3) process validation (especially for the drug substance).

(PROPOSED) PHASE III HUMAN CLINICAL TRIAL PROTOCOL	
Title	A Phase 3, Double-blind, Placebo-Controlled, Randomized Clinical Trial, Assessing Safety and Efficacy of Menerba for Hot Flashes and Menopausal Symptoms in Postmenopausal Women
# of Patients	720 (female)
Trial Design	Interventional, Randomized, Double-Blind, Placebo-Controlled, Parallel Assignment, Safety/Efficacy Study
Ages	40 Years to 60 Years
Endpoints	Primary: <ul style="list-style-type: none"> Change in frequency and severity of moderate to severe hot flashes assessed at baseline, 12 weeks Evaluate the safety of Menerba assessed at baseline, 12 weeks
Arm 1:	Placebo Comparator: Placebo for 12 weeks
Arm 2:	Experimental: Menerba: 1 g/d, 2g/d, 5 g/d for 12 weeks
Inclusion	Postmenopausal Females 40 to 60 years in age Provide informed consent
Exclusion	History of breast and uterine cancer History of deep vein thrombosis Active liver or gallbladder disease. Use of exclusionary medicine (patients cannot take concomitant SNRIs or SSRIs)
Contact	Azin Olyaie, MS

Source: ClinicalTrials.gov NCT00906308

More information on the trial design is available at: <http://clinicaltrials.gov/ct2/show/NCT00906308>

Results of Phase II Clinical Trial

Bionovo completed a Phase II dose-ranging clinical trial for two doses of Menerba[®] versus placebo. The trial was conducted under the direction of Dr. Deborah Grady of the University of California, San Francisco. The trial was a randomized, double-blinded, placebo-controlled study enrolling 217 healthy postmenopausal women reporting severe hot flashes, and was conducted at 6 clinical sites in the U.S. After 12 weeks there was a statistically significant decrease in frequency of all hot flashes in the higher dose and when compared to placebo, women in the Menerba high dose group were 2.3 times more likely to have at least a 50% reduction in hot flashes after 12 weeks of treatment. Menerba also showed statistically significant improvement in reducing awakenings from sleep due to hot flashes at the high dose of Menerba.

Safety analyses showed no cases of endometrial hyperplasia or uterine cancer and there were no differences in incidents of vaginal bleeding between the placebo group and the two dose groups of Menerba. There was no increase in blood estradiol levels. The study appeared to support that Menerba will not lead to an increased risk for breast or uterine cancers.

% Change versus Baseline - 12 Week Data	Placebo	Menerba 5mg/Day	p-value	Menerba 10mg/Day	p-value
All Hot Flashes	-40.4%	-49.2%	0.10	-53.7%	0.04
Moderate to Severe Hot Flashes	-57.3%	-57.8%	0.34	-64.6%	0.30
Severity Score	-53.6%	-52.6%	0.19	-56.5%	0.11
Frequency of Hot Flashes	-36.7%	-37.1%	0.25	-48.4%	0.05
Frequency of Hot Flashes Reduced by \geq 50%	-30.9%	-39.1%	0.29	-47.1%	0.03
Hot Flashes per Week that Awoke Participants	-44.0%	-57.5%	0.10	-66.7%	0.05

Source: Grady D. MD, et al, "MF101, a selective estrogen receptor A modulator for the treatment of menopausal hot flashes: a phase II clinical trial" Menopause: The Journal of The North America Menopause Society Vol. 16, No. 3 and Bionovo Inc.

The data also showed that both Menerba doses trended to improvement over placebo in a number of data subgroups:

Menerba vs. Placebo % change from baseline to follow-up		Menerba 5mg/Day	p- value	Menerba 10mg/Day	p- value
Number of Patients (placebo=71)		71		75	
All Hot Flashes	Week 4	-10.0%	0.21	-4.9%	0.53
	Week 12	-9.7%	0.29	-12.9%	0.15
Moderate to Severe Hot Flashes	Week 4	-9.8%	0.41	0.0%	1.00
	Week 12	-3.6%	0.81	-4.2%	0.78
Mild Hot Flashes	Week 4	-16.0%	0.22	-19.2%	0.13
	Week 12	-26.9%	0.06	-32.9%	0.02
Daily Hot Flash Score	Week 4	-10.9%	0.25	-2.0%	0.84
	Week 12	-10.9%	0.35	-9.5%	0.42
Hot Flash Awakenings	Week 4	-10.0%	0.46	-6.8%	0.58
	Week 12	-17.6%	0.24	-21.1%	0.14

Source: Grady D. MD, et al, "MF101, a selective estrogen receptor A modulator for the treatment of menopausal hot flashes: a phase II clinical trial" Menopause: The Journal of The North America Menopause Society Vol. 16, No. 3

Menerba also appeared to be safe and well tolerated:

Vaginal Bleeding or Endometrial Abnormalities	Placebo	Menerba 5mg/Day	Menerba 10mg/Day	Endometrial Histology	Placebo	Menerba 5mg/Day	Menerba 10mg/Day
Number of Patients with Uterus	52	52	60	# of Patients	7	6	11
				Normal/benign	6	6	11
Vaginal Bleeding or Spotting	6	5	8	Inactive/atrophic	4	5	8
Endometrial Biopsy Completed	4	4	7	Proliferative	2	1	2
				Secretory	0	0	1
Thickened Endometrium	3	7	11	Hyperplasia/Cancer	0	0	0
Endometrial Biopsy Completed	3	4	10	Insufficient tissue	1	0	0
Loose stools associated with use of Menerba may be due to the presence of soluble fiber (12% Menerba vs. 3% placebo)							

Source: Grady D. MD, et al, "MF101, a selective estrogen receptor A modulator for the treatment of menopausal hot flashes: a phase II clinical trial" Menopause: The Journal of The North America Menopause Society Vol. 16, No. 3

Safety Summary:

- No difference in the number of uterine bleeding episodes between treatment and placebo
- No cases of endometrial hyperplasia
- "Transient loose stools" was most common side effect (12.0% vs. 3.0% for placebo)
- Benefit from lower BMI and lower blood pressure
- Tolerability: 91.0% of participants took > 75.0% of study medication at 12 weeks with very low drop out rate (2.0%)

PHASE II HUMAN CLINICAL TRIAL PROTOCOL

Title	A Phase II, Double-Blind, Placebo-Controlled, Randomized Clinical Trial Assessing Toxicity and Efficacy of MF101 for Hot Flashes and Menopausal Symptoms
# of Patients	180 (female)
Trial Design	Interventional, Treatment, Placebo-Control, Double-Blind, Parallel Assignment, Safety/Efficacy Study
Ages	40 Years to 60 Years
Endpoints	Primary: Frequency and severity of hot flashes
Inclusion	Women between the ages of 40 to 60
	Currently receiving medical care from a health care provider
	Self-report 5 hot flashes per day or 35 hot flashes per week.
	Postmenopausal as defined by 12 months of spontaneous amenorrhea or 6 months of spontaneous amenorrhea with serum FSH levels > 30mIU/ml or 6 weeks post-surgical bilateral oophorectomy with or without hysterectomy or hysterectomy with FSH levels > 30 mIU/ml
	Agree not to start new herbal or dietary supplements and not to change the dose of any currently used herbal or dietary supplements for the duration of the trial

	Successful completion of a Hot Flash Diary, a Daily Study Medication Diary and a Bleeding Diary, tolerates placebo, and 80% compliant at run-in
	Must have had a mammogram within the last 9 months
	Have access to a phone
	Provide informed consent
Exclusion	Inability to sign an informed consent or fill out questionnaires
	History of breast, uterine or ovarian cancer or melanoma
	Abnormal mammogram or breast examination within the last 9 months suggestive of cancer
	Abnormal Pap smear or pelvic examination within the last 9 months suggestive of cancer
	Double-wall endometrial thickness that exceeds 5 mm measured on transvaginal ultrasound
	Unexplained abnormal uterine bleeding within six months of enrollment
	Pregnancy or lactating
	Clinical evidence of active ischemic cardiovascular disease or a history of cardiovascular disease
	History of deep vein thrombosis or pulmonary embolism requiring anticoagulation
	Active liver or gallbladder disease
	Use of medications, herbal or dietary supplements known to possibly be effective for the treatment of hot flashes within three months of enrollment for oral or transdermal drugs, or within 6 months of enrollment for implanted or injected drugs
	Use of raloxifene or tamoxifen within three months of enrollment
	Use of another investigational agent within 3 months of enrollment
History of multiple or severe food or medicine allergies	
Any medical or psychiatric condition that, in the investigator's opinion, would preclude the participant from adhering to the protocol or completing the trial, including severe illness, plans to move, substance abuse, significant problems, or dementia	
Centers	University of Alabama at Birmingham, Birmingham, Alabama, United States, 35233
	University of California, San Francisco, San Francisco, California, United States, 94118
	University of Minnesota, Minneapolis, Minnesota, United States, 55415
	University of Tennessee Health Science Center, Memphis, Tennessee, United States, 38163
Investigator	Deborah Grady, MD, MPH, University of California, San Francisco


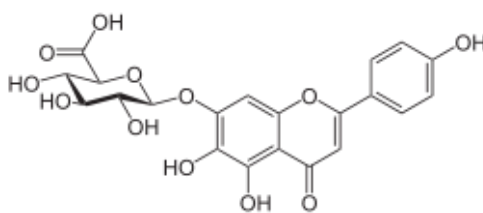
Source: ClinicalTrials.gov NCT00119665

More information on the trial design is available at: <http://clinicaltrials.gov/ct2/show/NCT00119665>

Bezielle® for Advanced Breast Cancer

Bionovo's Bezielle® (formerly BZL101) is also derived from botanical extracts, specifically an aqueous extract of *Scutellaria barbata*, also known as Barbat skullcap, Ban Zhi Lian, and Banjiryun, similar to Menerba®. *Scutellaria barbata* is a perennial herb found in Korea and southern China. The herb has been used in traditional Chinese medicine to treat ailments ranging from anxiety and depression to bacterial infections, hepatitis and cancer. Flavanoid components found within the herb including, Scutellarin (pictured left) are thought to be responsible for the reported antineoplastic properties of the plant.¹ Bezielle is currently being developed to treat advanced breast cancer (ABC). It



<i>Scutellaria barbata</i> and Flavanoid	
	
<i>Scutellaria barbata</i>	Scutellarin
Source: Memorial Sloan-Kettering Cancer Center	

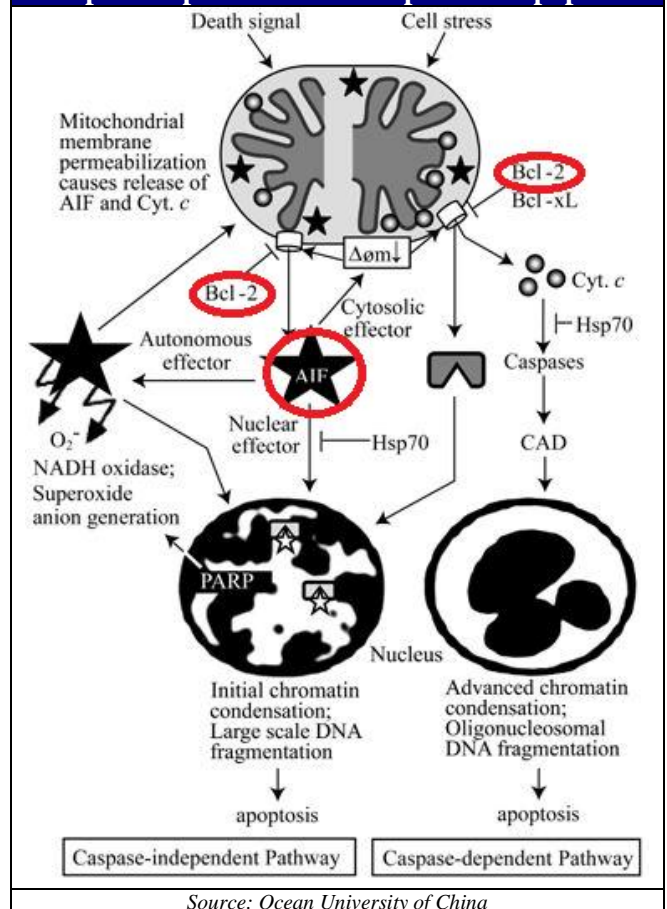
induces cell death selectively in tumor cells through oxidative stress by inhibiting glycolysis.

Mechanism of Action: Bezielle® exploits a unique physiological change found within neoplastic disease. Normal cells found in the human body depend primarily on the aerobic citric acid cycle (>85%) and very little on anaerobic glycolysis (<7%) for energy production. In contrast, cancerous cells depend largely on glycolysis (>85%) for energy or ATP needs of the cell. This phenomenon, named the "Warburg Effect" after the work of Nobel laureate Otto Heinrich Warburg, is thought to be partly due to hypoxia from the tumor microenvironment, as well as mitochondrial respiration injury from oncogenes attempting to shut down the normal apoptosis process. The Warburg effect has also been implicated in drug resistance in many different types of cancer.² This leads us to believe that Bezielle could be beneficial in adjuvant therapy where other drugs have encountered resistance. Bezielle inhibits the glycolysis pathway that tumor cells depend on for energy and by that mechanism of action effectively "targets" the diseased tissue while sparing healthy cells.

Glycolysis is inhibited in the diseased cells, and ATP production is shut down by Bezielle's ability to induce apoptosis or programmed cell death through caspase-dependent and caspase-independent pathways. Bezielle achieves this by attenuating the mitochondrial transmembrane potential (MTP) leading to the release of reactive oxygen species, causing the inhibition of glycolysis and killing the cell with induction of oxidative DNA damage.³ At the Mitochondrion level, Bezielle specifically facilitates translocation of the protein apoptosis-inducing factor (AIF) from the mitochondrial membrane into the nucleus in tumor cells, thereby causing tumor cell-specific chromatin condensation and DNA degradation followed by the induction of caspase-independent apoptosis. AIF is both a mitochondrial intermembrane flavoprotein with oxidoreductase activity and a caspase-independent death effector that, similar to cytochrome c, is released from mitochondria early in the apoptotic process. In vitro studies have also shown that *Scutellaria barbata* exerts anticancer effects via caspase-dependent apoptosis^{4,5,6}, and by down regulating Bcl-2 protein that is expressed by tumor cells.⁷

Therefore, we believe Bezielle could be useful for patients with either hormone receptor positive or negative tumors and Bionovo is targeting both premenopausal and postmenopausal patients and patients who are both HER2 positive and

Caspase Dependant and Independent Apoptosis



Source: Ocean University of China

negative. Because of the broad utility of Bezielle, it can reasonably be expected to compete with hormonal therapy, chemotherapy and/or biologic therapy. These would include AstraZeneca's (NYSE:AZN) Nolvadex[®] and Arimidex[®], Eli Lilly's (NYSE:LLY) Gemzar[®], Sanofi-Aventis's (NYSE:SNY) Taxotere[®] and Roche's (SWX:RO) Xeloda[®] and Herceptin[®] and GlaxoSmith Kline's (NYSE:GSK) Tykerb[®].

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Recent Bezielle[®] Research Papers

On December 9, 2010, Bionovo announced the publication of a study demonstrating that Estrogen Receptor Beta (ER β) causes cancer cell growth arrest by inactivating critical genes and enzymes responsible for cell growth. **These results provide evidence that drugs that stimulate the production of or activate ER β are potential new therapies to prevent breast cancer.** While Bionovo's candidate binds equally to Estrogen Receptors alpha (ER α) and beta (ER β), it only activates (agonist) the ER β transcriptional pathways and does not activate the ER α pathway. The paper published in the journal *Breast Cancer Research and Treatment* is titled "*Estrogen receptor beta causes a G2 cell cycle arrest by inhibiting CDK1 activity through the regulation of cyclin B1, GADD45A, and BTG2*" is available at <http://www.springerlink.com/content/n782717512802v46/fulltext.pdf>

Abstract

The role of estrogen receptor beta (ER β) in breast cancer is unclear. ER β is considered to have a protective role in breast cancer development based on findings demonstrating that ER β expression inhibits ER α -mediated proliferation of breast cancer cells. We previously demonstrated that ER β causes a ligand independent G2 cell cycle arrest in MCF-7 cells. To study the mechanisms of the ER β -mediated G2 cell cycle arrest, we investigated its effects on the regulatory pathways responsible for the G2/M phase transition. We found that ER β inhibits CDK1 activity, which is the critical determinant of the G2/M progression. CDK1 activity is modulated by both stimulatory and inhibitory factors. Cyclin B1 is the major activator of CDK1. ER β inhibited the cell cycle-dependent stimulation of cyclin B1 mRNA and protein. GADD45A and BTG2 are two major inhibitors of CDK1, which have been implicated in breast tumor formation. Based on these findings, we explored if the expression pattern of GADD45A and BTG2 is affected by ER β . We found that ER β stimulates GADD45A and BTG2 mRNA levels. The induction of these two genes is caused by ER β binding directly to these genes and recruiting c-jun and NCOA2. **Our findings demonstrated that unliganded ER β causes a G2 cell cycle arrest by inactivating CDK1 through the repression of cyclin B1 and stimulation of GADD45A and BTG2 expression.** These results provide evidence that drugs that stimulate the production of unliganded ER β may be effective new therapies to prevent breast cancer.

Clinical Trials for Bezielle®

Results of Phase Ia and Ib Clinical Trials in Advanced Breast Cancer

Bionovo has already completed Phase Ia and Phase Ib clinical trials for safety, dosing and indication of efficacy in 48 advanced breast cancer patients. The efficacy trends indicate Bezielle® may have a preferential effect on hormone-independent cancers. It should be noted that these patients had already failed a number of previous chemotherapy treatment regimens (averaging between 4 and 6) before being administered Bezielle. Despite the heavily pre-treated patient population, Bezielle trended toward a benefit as show:

EFFICACY	PHASE Ia		PHASE Ib	
# of Evaluable / Enrolled Patients	16 / 21		16 / 27	
# of Previous Cancer Treatments	3.9		5.9	
Complete Response	0	0%	0	0%
Partial Response	1	6%	0	0%
Minimal Response (between >0% and <30%)	5	31%	3	19%
Stable Disease	5	31%	5	31%
Progressive Disease	5	31%	8	50%

Source: Rugo H., et al "Tripathy "Phase I trial and antitumor effects of BZL101 for patients with advanced breast cancer" and Perez A. et al, A phase 1B dose escalation trial of Scutellaria barbata (BZL101) for patients with metastatic breast cancer and Bionovo Inc.

Both clinical trials also indicated that Bezielle had limited toxicities and a favorable tolerability profile. This is noteworthy whenever a heavily pre-treated patient population is taken into consideration:

PHASE Ia SAFETY	PHASE Ib SAFETY
Dose 10mg per day	Dose 40mg per day (at highest dose)
No deaths, serious adverse events, or hematological adverse events	No drug-related deaths, serious adverse events, or hematological adverse events
All adverse events related to Bezielle were grade 1 and grade 2	94% of adverse events related to Bezielle were grade 1 and grade 2
Majority of related adverse events were gastrointestinal side effects that were expected	Majority of related adverse events were gastrointestinal side effects that were expected
Most common related adverse events were diarrhea, nausea, stomach bloating, and Headaches	Most common related adverse events were diarrhea, nausea, vomiting, fatigue, and headaches
Mean percentage of prescribed doses taken while on study was 85%	Mean percentage of prescribed doses taken while on study was 90%
Median percentage of prescribed doses taken while on study was 92%	Median percentage of prescribed doses taken while on study was 90%

Source: Rugo H., et al "Tripathy "Phase I trial and antitumor effects of BZL101 for patients with advanced breast cancer" and Perez A. et al, A phase 1B dose escalation trial of Scutellaria barbata (BZL101) for patients with metastatic breast cancer and Bionovo Inc.

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Planned Phase II Clinical Trial in Advanced Breast Cancer

A Phase II clinical trial has been approved by the FDA and at several institutional review boards (IRB) at clinical sites in the United States. Bionovo has stated that they are awaiting funding before commencing the clinical trial. It is worth

noting that these patients with metastatic breast cancer will have failed no more than two prior chemotherapy regimens rather than the 4 to 6 average chemotherapy failures in the Phase I clinical trials.

PHASE II HUMAN CLINICAL TRIAL PROTOCOL	
Title	A Phase 2 Clinical Trial Assessing Safety and Efficacy of BZL101 for Metastatic Breast Cancer
# of Patients	80 (female)
Trial Design	Treatment, Open Label, Uncontrolled, Single Group Assignment, Safety/Efficacy Study
Ages	18 Years and Older
Endpoints	Primary: Tumor response rate defined by new RECIST criteria 1.1., and safety and toxicity as measured by NCI Common Terminology Criteria for Adverse Events (CTCAE), Version 4.0
Arm 1:	Experimental: Oral BZL101 20 grams/day (10 grams BID)
Inclusion	Women 18 years or older
	Histologically confirmed diagnosis of breast cancer based on pathology report of primary, regional or metastatic breast cancer
	Clinical evidence of metastatic (stage IV) involvement other than bone only metastasis based on the investigator's clinical and/or radiographic findings
	Availability of estrogen receptor and progesterone receptor status measured on biopsy tissue. (Status on the most recent biopsy where ER/PR status was documented will be used to determine hormone receptor status for stratification).
	At least one measurable disease site defined by RECIST criteria, with measurement made within 30 days of beginning study therapy
	No more than 2 prior cytotoxic regimens administered for metastatic breast cancer. (Participants may have received any number of exogenous hormone therapies for Stage IV disease and/or adjuvant therapy).
	Life expectancy of >12 weeks
	Eastern Cooperative Oncology Group (ECOG) performance status <2.
	Women of child bearing potential must agree to use two adequate methods of contraception or abstain from sexual intercourse during study treatment
	Adequate organ and marrow function measured within 14 days of study treatment: Absolute neutrophil count >1,500 cells/mm ³ , Platelets >100,000 cells/mm ³ , Hemoglobin >10 g/dL, Total bilirubin <1.5 mg/dL, AST(SGOT)/ALT(SGPT) <2.5 X institutional upper limit of normal or <5 X normal with documented liver metastasis, Alkaline Phosphatase <3 X institutional upper limit of normal or <5 X normal with documented liver or bone metastasis, Serum creatinine <1.5 mg/dL or Creatinine clearance >60 mL/min/1.73 m ² for participants with serum creatinine levels above institutional normal.
Center	M.D. Anderson Cancer Center, Houston, Texas, United States, 77030
Contact	Mary Tagliaferri, MD, Lac, Bionovo, Inc

Source: ClinicalTrials.gov NCT00907959

Seala®

Bionovo has another Women's Health product under development that is derived from traditional Chinese botanicals named Seala® (formerly VG101). Seala, is a topical Estrogen Receptor Beta (ERβ) modulator (SERM) for the treatment of postmenopausal vaginal and vulvar atrophy, or vaginal dryness. Vaginal atrophy (also known as atrophic vaginitis or urogenital atrophy) is an inflammation of the vagina due to the thinning and shrinking of the tissues in the reproductive and urinary tracts. The disorder is due to a decrease in the level of the reproductive hormone estrogen which happens naturally during peri-menopause, and even more so in postmenopausal women. Sufferers of vaginal atrophy complain of symptoms including decreased lubrication (ie vaginal dryness), soreness, itching, burning, painful intercourse, discharge, and increased risk of infection among others. As much as 55% of postmenopausal woman complain of vaginal atrophy and associated symptoms, and unlike other symptoms due to menopause, such as hot flashes, the affects of vaginal atrophy can be felt for decades after a woman has had regular menstrual cycles.



The traditional treatment for vaginal atrophy, as with menopausal hot flashes, had been dominated by hormone replacement therapy (HRT). As previously mentioned under current menopause treatments, the study conducted by the Women's Health Initiative (WHI) demonstrated systemic estrogen replacement increases the risks of cardiovascular

disease, venous thromboembolic events, breast cancer, uterine cancer and dementia. In addition to those risks, estrogen replacement appears to increase the risk of urinary incontinence, which is already widespread in the patient population.

Recently, more localized systems of administration have been developed, including creams, vaginal rings, and slow-release vaginal tablets. Unfortunately, systemic absorption of estrogen still occurs with the localized vaginal estrogen administration, especially at the beginning of treatment when the vaginal epithelium is thin and atrophic. Therefore, risks outlined in the WHI study may still be present in these new administration methods.

Seala, as with Menerba, is a SERM selective for the ER β subtype only. It is this selectivity (described earlier in Menerba[®] for Menopausal Hot Flashes section) that allow ER activation without the negative consequences that are associated with ER α subtype activation. The vaginal canal contains both the α and β subtypes of Estrogen Receptors and Bionovo's animal models have demonstrated Seala was subtype β selective and effective at treating vaginal atrophy without causing any untoward cancerous effects in the uterus. The company has filed an IND with the FDA and plans to start a phase I/II some time in the near future.

More information about the trial can be found at: <http://clinicaltrials.gov/ct2/show/NCT00453089>

While the potential future approval of Seala could represent a significant source of revenue for Bionovo, we have not yet included Seala in our financial model due to the current uncertainty regarding development timelines and resources.

Financial Model & Valuation

Hot Flashes (Menerba[®])

Hot flashes are the most common symptom of the climacteric and occur in most postmenopausal women. The Massachusetts Women's Health Study¹ found that 75% of women surveyed reported having hot flashes in the period between peri- and post-menopause, an average of 3.8 years. Feldman² reported that 64% of peri-menopausal women experienced hot flashes for 1 to 5 years and Kronenberg³ reported the average duration of symptoms to be 4 years.

Of the symptomatic women in the Kronenberg study, 87% reported daily hot flashes and one third of those reported more than 10 per day. Hot flashes usually lasted 1 to 5 minutes, with a small percentage persisting for more than 6 minutes. The experience of a hot flash was usually described as sensations of intense heat, sweating, flushing, chills, and clamminess. Sweating was reported most frequently in the face, neck, and chest.

With approximately 40 million women in the U.S. transitioning through menopause, and at least 70% experiencing vasomotor symptoms, including hot flashes, night sweats, and associated insomnia, we estimate the market at 28 million women (40M x 70%). We further estimate that approximately 30% of these women will experience at least 10 hot flashes per day which puts them into the range outlined in the Phase III clinical trial inclusion criteria. Thus, we are estimating the initial addressable market as 8.4 million women in the U.S. (28M x 30%) with an equal number in Europe.

Our initial pricing model of \$50 per month for Menerba[®] places it on the low end between hormone replacement therapy, currently \$30 per month, and Pristiq[®] (desvenlafaxine), an antidepressant from Pfizer (NYSE:PFE), currently \$150 per month. Therefore, a theoretical peak market size is \$5 billion per year in the U.S. and another \$5 billion in Europe. However, we are anticipating a conservative initial adoption rates of 5%-10% or \$250-\$500 million for the U.S. and another \$250-\$500 million for Europe with a royalty rate of 33% from an anticipated partner(s).

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Advanced Breast Cancer (Bezielle®)

The U.S. National Cancer Institute (NCI) estimates there were 194,280 new cases of Breast Cancer in the US during 2009 with an estimated 40,610 patient deaths. If we assume all of the expired patients had recurrent disease with additional patients showing a durable response to 2nd-line chemotherapy, we estimate the addressable U.S. market is approximately 50,000 patients annually for Bezielle in 2nd-line combination chemotherapy. Investors should note that due to the variety of breast cancer genotypes, staging and initial diagnosis times, combined with various treatment regimens, exact figures for this specific patient population can be difficult to calculate.

Our initial pricing model for Bezielle is five thousand dollar per entire course of therapy which is comparable to existing breast cancer therapies such as paclitaxel. This yields a theoretical market size of 250 million dollars annually in the U.S. and another 250 million dollars in Europe. However, we have not yet included Bezielle in our financial model due to the current uncertainty regarding development timelines and resources.

Botanical Drug Development and the FDA

What is a Botanical drug?

According to the FDA’s CDER Botanical Review Team (BRT), a botanical drug product is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, that:

- consists of vegetable materials, which may include plant materials, algae, macroscopic fungi, or combinations thereof.
- may be available as (but not limited to) a solution (e.g., tea), powder, tablet, capsule, elixir, topical, or injection.
- often have unique features, for example, complex mixtures, lack of a distinct active ingredient, and substantial prior human use. Fermentation products and highly purified or chemically modified¹

How does the FDA treat Botanical drugs?

A botanical drug's special features require consideration and adjustment during the FDA review process. In June 2004, the FDA’s Center for Drug Evaluation and Research (CDER) issued a Guidance for Industry-Botanical Drug Products to take into consideration these features and to facilitate development of new therapies from botanical sources. The Botanical Guidance applies to only botanical products intended to be developed and used as drugs.¹

How does the FDA approve the Manufacturing Process?

Because of the complex nature of a typical botanical drug and the lack of knowledge of its active constituents, the FDA may rely on a combination of tests and controls to ensure the identity, purity, quality, strength, potency, and consistency of botanical drugs. These tests and controls include (1) multiple tests for drug substance and drug product (e.g., spectroscopic and/or chromatographic fingerprints, chemical assay of characteristic markers, and biological assay), (2) raw material and process controls (e.g., strict quality controls for the botanical raw materials and adequate in-process controls), and (3) process validation (especially for the drug substance).¹

Are there any FDA approved Botanical drugs?

On October 31, 2006, The FDA approved the New Drug Application (NDA) for VEREGEN® (kunecatechins) ointment 15%.² VEREGEN® is the first botanical drug approved for prescription use in the United States and is made from the extract of green tea leaves for topical use of warts on the outside of the genitals and around the outside of the anus.³ Genital warts (Condylomata acuminata, venereal warts, anal warts and anogenital warts) is a highly contagious sexually transmitted disease caused by some sub-types of human papillomavirus (HPV).⁴ VEREGEN® was developed by Medigene AG (Frankfurt:MDG), and is marketed in the United States by the PharmaDerm, a division of Nycomed US, Inc. (Private).



Source: PharmaDerm div. of Medigene AG

There are also some botanical drugs, including *cascara*, *psyllium*, and *senna*, (as laxatives) that are included in the over-the-counter (OTC) drug review. For a botanical drug substance to be included in an OTC monograph, there must be published data establishing a general recognition of safety and effectiveness, including the results of adequate and well-controlled clinical studies.¹

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⁴ Gearhart MD, Peter A. "Human Papillomavirus: EMedicine Infectious Diseases." EMedicine - Medical Reference. Web MD, 08 Mar. 2010. Web. 02 Aug. 2010. <http://emedicine.medscape.com/article/219110-overview>

Intellectual Property

Bionovo has 74 patent applications pending in the United States Patent and Trademark Office, as well as in the Patent Cooperation Treaty (PCT), the European Patent Office, Japan, and other markets. Selected U.S. patents and patent applications are shown below:

SELECTED BIONOVO U.S. INTELLECTUAL PROPERTY FILINGS			
NUMBER	DESCRIPTION	FILED	ISSUED
7,815,949	Estrogenic Extracts Of Morus Alba And Uses Thereof	December 9, 2005	October 19, 2010
7,700,136	Scutellaria Barbata Extract For The Treatment Of Cancer	Nov. 14, 2005	April 20, 2010
7,482,029	Composition For Treatment Of Menopause	Apr. 1, 2005	January 27, 2009
20100173026	Estrogenic Extracts Of Astragalus Membranaceus Fisch. Bge. Var. Mongolicus Bge. Of The Leguminosae Family And Uses Thereof	January 13, 2010	Pending
20100143511	Scutellaria Barbata Extract For The Treatment Of Cancer	January 21, 2010	Pending
20100069481	Methods And Compositions For The Treatment Of Cancer	September 3, 2009	Pending
20100069480	Methods And Compositions For The Treatment Of Cancer	September 3, 2009	Pending
20100009017	Anticancer Methods Using Extracts Of Anemarrhena Asphodeloides Bunge	April 10, 2009	Pending
20090312437	Anthraquinones And Analogs From Rhuem Palmatum For Treatment Of Estrogen Receptor Beta-Mediated Conditions	June 5, 2009	Pending
20090312274	Nyasol And Analogs Thereof For The Treatment Of Estrogen Receptor Beta-Mediated Diseases	June 12, 2009	Pending
20090311349	Method Of Quantification Of Multiple Bioactives From Botanical Compositions	June 5, 2009	Pending
20090304825	Estrogenic Extracts For Use In Treating Vaginal And Vulvar Atrophy	May 5, 2009	Pending
20090297638	ESTROGENIC EXTRACTS OF Anemarrhena Asphodeloides Bge. From The Liliaceae Family And USES THEREOF	April 10, 2009	Pending
20090297637	Estrogenic Extracts Of Anemarrhena Asphodeloides Bge. From The Liliaceae Family And Uses Thereof	April 10, 2009	Pending
20090258942	Calycosin And Analogs Thereof For The Treatment Of Estrogen Receptor Beta-Mediated Diseases	April 14, 2009	Pending
20090258096	Anticancer Methods Employing Extracts Of Gleditsia Sinensis Lam	April 10, 2009	Pending
20090130684	Methods Of Detecting And Treatment Of Cancers Using Scutellaria Barbata Extract	November 19, 2008	Pending
20090130237	Process Of Making Purified Extract Of Scutellaria Barbata D. Don	November 19, 2008	Pending
20090130118	Scutellaria Barbata Extract And Combinations For The Treatment Of Cancer	May 21, 2009	Pending
20090130101	Anti-Cancer Therapy With An Extract Of Scutellaria Barbata	November 19, 2008	Pending
20090068299	Estrogenic Extracts Of Pueraria Lobata Willd. Ohwi Of The	September 5, 2008	Pending

	Leguminosae Family And Uses Thereof		
20090068298	Estrogenic Extracts Of Astragalus Membranaceus Fisch. Bge. Var. Mongolicus Bge. Of The Leguminosae Family And Uses Thereof	September 5, 2008	Pending
20090068297	Estrogenic Extracts Of Scutellaria Barbata D. Don Of The Labiatae Family And Uses Thereof	September 5, 2008	Pending
20090068294	Estrogenic Extracts Of Rheum Palmatum L Of The Polygonaceae Family And Uses Thereof	September 5, 2008	Pending
20090068293	Estrogenic Extracts Of Asparagus Conchinchinensis (Lour.) Merr Of The Liliaceae Family And Uses Thereof	September 5, 2008	Pending
20090053339	Composition For Treatment Of Menopause	October 28, 2008	Pending
20090042818	Liquiritigenin And Derivatives As Selective Estrogen Receptor Beta Agonists	June 19, 2008	Pending
20090041867	Estrogenic Extracts Of Ligustrum Lucidum Ait. Of The Oleaceae Family And Uses Thereof	August 8, 2008	Pending
20080319051	Liquiritigenin And Derivatives As Selective Estrogen Receptor Beta Agonists	June 22, 2007	Pending
20070110832	Scutellaria Barbata Extract For The Treatment Of Cancer	November 13, 2006	Pending
20060222721	Composition For Treatment Of Menopause	March 29, 2006	Pending
20060134243	Method Of Using Extracts Of Epimedium Species	December 9, 2005	Pending

Source: U.S. Patent and Trademark Office

Recent Financing Activity

On February 2, 2011, Bionovo sold 30,031,200 units at a price per unit of \$1.00 for aggregate gross offering proceeds of \$30,031,200. Each unit consists of one share of common stock and a warrant to purchase one half of one share of common stock at an exercise price of \$1.30 per share. The warrants may be exercised at any time after the date of the closing and will expire after five years.

On October 6, 2010, Bionovo, Inc. raised \$3 million in gross proceeds by selling 2,727,270 shares of common stock at \$1.10 per share and issuing 2,045,451 warrants to purchase shares of common stock. The warrants are exercisable six months after issuance at \$1.64 per share and will expire five years from the date of issuance.

On July 6, 2010, Bionovo, Inc., entered into a Common Stock Purchase Agreement with a single institution, which is committed to purchase up to an aggregate of \$15 million shares of common stock over a 2 year term. The purchase price of the stock will be equal to the lesser of (i) the lowest sale price of the common stock on the purchase date and (ii) the arithmetic average of the three lowest closing sale prices for common stock during the twelve consecutive trading days ending on the trading day immediately preceding each purchase date. Under the Agreement, the sale price cannot be less than \$0.396 per share without shareholder approval.

On October 7, 2009, Bionovo completed a registered public offering and issued 30,933,140 shares of its common stock and 29,324,570 warrants at a price of \$6.20 per unit including 10 shares of common stock and 10 warrants to purchase common stock at \$0.85 per share and \$6.00 per unit of 10 shares of common stock exclusive of warrants.

Outstanding Warrants as of December 31, 2010	Number of Shares Exercisable	Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Issued January 2007 / Expires January 2012	719,000	10.62	1.05
Issued October 2007 / Expires October 2012	1,491,000	12.50	1.84
Issued October 2009 / Expires October 2014	6,174,000	4.28	3.77
Issued October 2010 / Expires October 2015	2,045,000	1.64	4.77
Total	10,429,000		
Weighted average exercise price		\$ 5.37	
Weighted average duration in years			3.50 years

Source: Bionovo Inc. 10-K

In addition, as of December 31, 2010, there were 1.1 million exercisable stock options with a weighted average price of \$6.74. As of March 10, 2011, there were 54,561,312 shares of common stock outstanding.

Management

Isaac Cohen, O.M.D., L.Ac., 47, is a co-founder of Bionovo Pharmaceuticals, Inc. (“Bionovo Pharmaceuticals”), and has served as its Chairman, President, Chief Executive Officer, and Chief Scientific Officer and as a director since February 2002. He became Bionovo, Inc.’s Chairman, Chief Executive Officer and Chief Scientific Officer and a Director in April 2005. Mr. Cohen has been a Guest Scientist at the University of California, San Francisco (UCSF) Cancer Research Center and UCSF Center for Reproductive Endocrinology since 1996. Mr. Cohen was in private practice at The American Acupuncture Center, located in Berkeley, California from 1989-2005.

Mary Tagliaferri, M.D., L.Ac., 44, is a co-founder of Bionovo Pharmaceuticals, and has served as its Chief Regulatory Officer, Chief Medical Officer, Secretary and Treasurer and as a director since February 2002. She became Vice President, Chief Medical Officer, Chief Regulatory Officer, Secretary and Treasurer of Bionovo, Inc. in April 2005, and a director effective in May 2005. She became President of Bionovo, Inc. in addition to continuing her functions as the Company’s Chief Medical Officer, Secretary, Treasurer and Director in May 2007. Dr. Tagliaferri was conducting translational research at the University of California, San Francisco from 1996 to 2002.

Thomas C. Chesterman, M.B.A., 50, has served as our Senior Vice President, Chief Financial Officer and Assistant Secretary since July 2007. From January 2002 to June 2007, Mr. Chesterman was Sr. Vice President and Chief Financial Officer at Aradigm, Corporation, a drug development company. From March 1996 to December 2001, Mr. Chesterman was Vice President and Chief Financial Officer at Bio-Rad Laboratories, Inc., a life-science research products and clinical diagnostics company. From 1993 to 1996, Mr. Chesterman was Vice President of Strategy and Chief Financial Officer of Europolitan AB, a telecommunications company.

BOARD OF DIRECTORS

John D. Baxter, M.D., 69, has been a Director since April 14, 2008. Dr. Baxter is currently Senior Member and Co-Director of the Center for Diabetes Research at The Methodist Hospital Research Institute, and Head of Endocrinology at the University of Houston. He was associated with the University of California, San Francisco (or “UCSF”) from 1970-2008 where he was a Professor of Medicine from 1979-2008, Chief of the Endocrinology, Parnassus Campus from 1980 to 1997, and Director of UCSF’s Metabolic Research Unit from 1981 to 1999. Dr. Baxter was President of The Endocrine Society from June 2002 to June 2003. He was a founder and served as a director of California Biotechnology, Inc., a drug development company (now Scios, Inc., a division of Johnson & Johnson) from 1982 until 1992 and was a Founder and Director of Karo Bio A.B., a Swedish biotechnology company and SciClone Pharmaceuticals, a drug development company. Dr. Baxter has also been elected to the National Academy of Sciences and the Institute of Medicine of the National Academy of Sciences, and he received the Outstanding Investigator Award from the Howard Hughes Medical Institute. Dr. Baxter is an independent and unaffiliated director, and serves on our Audit Committee, and on our Compensation and Nominations Committee.

George Butler, Ph.D., 62, has been a Director since March 11, 2008. Currently, Dr. Butler serves as the Chairman and President of SingEval (Singapore) Pte. Ltd., a drug development company based in Singapore and the US. Dr. Butler was formerly the vice president, Customer Relationships, Global Development of AstraZeneca, plc, a global pharmaceutical company. Prior to this, he was vice president, head of regulatory affairs. Prior to his time at AstraZeneca, Dr. Butler was vice president and head of regulatory affairs with Novartis AG. Dr. Butler has over 30 years of healthcare research and business experience, primarily in a development environment in multiple biopharmaceutical companies and has also been active for many years in advancing Asian-Western development/regulatory single programs. Dr. Butler is an independent and unaffiliated director, and serves on our Compensation and Nominations Committee.

Louis Drapeau, CPA, MBA, 66, has been a Director since March 14, 2008. Currently, Mr. Drapeau serves as the Chief Executive Officer of InSite Vision since November 2008 and as its Chief Financial Officer since October 1, 2007. Prior to InSite Vision, he served as Chief Financial Officer, Senior Vice President, Finance, at Nektar Therapeutics, a biopharmaceutical company headquartered in San Carlos, California from January 2006 to August 2007. Prior to Nektar,

Mr. Drapeau served as Acting Chief Executive Officer from August 2004 to May 2005 and as Senior Vice President and Chief Financial Officer from August 2002 to August 2005 for BioMarin Pharmaceutical Inc, a pharmaceutical company. Previously, Mr. Drapeau spent more than 30 years at Arthur Andersen. Mr. Drapeau also serves on the boards of Intermune, Inc., a pharmaceutical company and Bio-Rad Laboratories, a life science and clinical diagnosis company. Mr. Drapeau is an independent and unaffiliated director, and serves as the chair of our Audit Committee. Mr. Drapeau meets the qualifications as a “Financial Expert”, according to the definition in Item 407 (d)(5)(ii) on Regulation S-K.

Isaac Cohen, O.M.D., L.Ac., 47, is a co-founder of Bionovo Pharmaceuticals, Inc. (“Bionovo Pharmaceuticals”), and has served as its Chairman, President, Chief Executive Officer, and Chief Scientific Officer and as a director since February 2002. He became Bionovo, Inc.’s Chairman, Chief Executive Officer and Chief Scientific Officer and a Director in April 2005. Mr. Cohen has been a Guest Scientist at the University of California, San Francisco (UCSF) Cancer Research Center and UCSF Center for Reproductive Endocrinology since 1996. Mr. Cohen was in private practice at The American Acupuncture Center, located in Berkeley, California from 1989-2005.

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SCIENTIFIC ADVISORY BOARD

- John D. Baxter, M.D., The Methodist Hospital Research Institute, Endocrinology.
- Len Bjeldanes, Ph.D., University of California, Berkeley, Molecular Toxicology/Bioactive Compound Isolation and Identification
- Paul Pui-Hay But, Ph.D., Food and Drug Authentication Laboratory Ltd., Hong Kong, Botanical Authentication and Chinese Medicine Quality Control
- Michael J. Campbell, Ph.D., University of California, San Francisco, Cell Biology/Immunology
- Uwe Christians M.D., Ph.D., University of Colorado, Pharmacology
- Isaac Cohen, O.M.D., L.Ac., Bionovo, Inc., Herbology, Pharmacology, Cell Biology and Pharmaceutical development
- Gary L. Firestone, Ph.D., University of California, Berkeley, Molecular and Cell Biology
- Richard Gless, Ph.D., Arete Therapeutics, Chemical Research Management
- Jan Ake Gustafsson, M.D., Ph.D., Houston University, Nuclear Receptors and Cell Signaling
- Craig Henderson, M.D., University of California, San Francisco, Breast Cancer
- Willa A. Hsueh, M.D., The Methodist Hospital Research Institute, Nuclear Receptor Regulation
- Bert W. O’Malley, M.D., Baylor College of Medicine, Molecular and Cell Biology, Nuclear Receptor Regulation
- Moshe Rosenberg, D.Sc., University of California, Davis, Microencapsulation Properties of Proteins, Lipids and Carbohydrates
- Terry Speed, Ph.D., Walter and Eliza Hall Institute of Medical Research, Melbourne, Australia, Bioinformatics
- Zung Vu Tran, Ph.D. University of Colorado, Biostatistics and Bioinformatics
- Debasish Tripathy, M.D. University of Texas, Southwestern Medical Center, Breast Cancer
- Richard Weiner, Ph.D. University of California, San Francisco, Neuroendocrinology, Cancer
- Ethan Weiss, M.D. University of California, San Francisco, Cardiology

MEDICAL ADVISORY BOARD

- Mary Cushman, M.D., University of Vermont, Hematology, Epidemiology
- Marco Gambacciani, M.D., Santa Chiara University Hospital, Menopause
- Steven Goldstein, M.D., New York University, Menopause, Uterine Safety
- Deborah Grady, M.D., University of California, San Francisco, Menopause
- James Pickar, M.D. Columbia University, Menopause
- Mary Tagliaferri, M.D., L.Ac., Bionovo, Inc., Menopause, Breast Cancer

- Debasish Tripathy, M.D., University of Southern California, Breast Cancer
- Wulf H. Utian, M.D., Rapid Medical Research, Inc., Gynecological Endocrinology
- Ethan Weiss, M.D., University of California, San Francisco, Cardiology
- Janet Wittes, Ph.D., Statistics Collaborative, Inc., Clinical Biostatistics

Risks

Some of the operational and financial risks to Bionovo, Inc. are:

- **FDA and Regulatory risks:** All of Bionovo, Inc. products are reliant on approvals by the U.S. FDA and other national regulatory bodies. There can be no guarantee of timely or definite FDA or other national regulatory body approvals for any of their products. In addition, the published Botanical Guidance document from the FDA is relatively new and there are limited precedent botanical drug candidates which have been submitted to the FDA for final approval.
- **Need to Raise Additional Funds:** Although it is possible that Bionovo, Inc. may raise sufficient operating funds for the development, approval and commercialization of their drug candidates through warrant conversions and potential partnerships, we believe that the company will be required to raise additional funds through the issuance of stock which would be dilutive to existing shareholders and could potentially affect the share price. We have included our estimate of future share issuance in our financial model but there can be no guarantee that our estimates are accurate.
- **NASDAQ Listing:** On March 14, 2011, Bionovo, Inc. received a letter from NASDAQ stating they were not in compliance with listing rules requiring a minimum bid price of \$1.00 per share. NASDAQ granted Bionovo a period of 180 calendar days, or until September 12, 2011, to regain compliance. If before September 12, 2011, the bid price closes at \$1.00 per share or more for a minimum of 10 consecutive business days compliance will have been regained. However, there can be no assurance that Bionovo shares will meet compliance for a continued listing in the future. If delisted, investors could have significantly less liquidity and more difficulty purchasing and selling shares of Bionovo stock.
- **Patent Litigation:** Third-party claims of infringement of intellectual property could require Bionovo, Inc. to spend time and money on defending their intellectual property rights up to and including adverse judgments against Bionovo.
- **Sector Rotation:** Bionovo, Inc. is a small biotechnology development company often kept in a portfolio with similar companies. In such cases, a significant event for one company may have a material impact on the valuation of all similar companies regardless of their unique qualities.

Bionovo, Inc.
Consolidated Income Statement
(in \$000s, except EPS)

FYE December 31st

	2007	2008	1Q09	2Q09	3Q09	4Q09	2009	1Q10	2Q10	3Q10	4Q10	2010	1Q11E	2Q11E	3Q11E	4Q11E	2011E	2012E	2013E	2014E	2015E	
Revenue																						
Member Royalties	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	165,000
Other Revenues	582	233	0	7	155	126	288	0	14	68	531	613	0	10	70	120	200	200	200	200	200	200
Total Revenues	582	233	0	7	155	126	288	0	14	68	531	613	0	10	70	120	200	200	200	200	200	165,200
Operating Expenses																						
Research & Development	9,938	11,416	3,601	2,954	2,938	3,006	12,499	3,806	3,328	3,673	3,835	14,642	4,410	4,851	5,336	5,870	20,468	23,538	25,892	27,187	28,546	28,546
Sales, General & Administrative	4,284	6,097	1,009	1,175	926	943	4,053	852	788	987	899	3,526	1,034	1,086	1,194	1,314	4,627	5,090	5,599	6,718	8,062	8,062
Marketing Contribution	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2,000	7,000
Total Operating Expenses	14,222	17,513	4,610	4,129	3,864	3,949	16,552	4,658	4,116	4,660	4,734	18,168	5,444	5,937	6,530	7,184	25,095	28,628	31,491	35,905	43,608	43,608
Income from Operations	(13,640)	(17,280)	(4,610)	(4,122)	(3,709)	(3,823)	(16,264)	(4,658)	(4,102)	(4,592)	(4,203)	(17,555)	(5,444)	(5,927)	(6,460)	(7,064)	(24,895)	(28,428)	(31,291)	(35,705)	(43,705)	121,592
Change Fair Value Warrants	0	0	0	0	0	0	0	0	0	0	(94)	(94)	225	125	(300)	(500)	(450)	(3,000)	(2,000)	(2,000)	(2,000)	(4,000)
Interest Income	850	730	54	16	5	9	84	8	6	2	2	18	100	70	40	10	220	34	30	28	25	25
Interest Expense	(87)	(129)	(33)	(22)	(22)	(18)	(95)	(14)	(10)	(9)	(28)	(61)	(10)	(10)	(10)	(10)	(40)	(64)	(47)	(39)	(42)	(42)
Other Expense	(21)	(17)	(79)	(6)	0	(3)	(88)	3	(14)	(28)	0	(39)	(5)	(5)	(5)	(5)	(20)	0	0	0	0	0
Total Other Income/Expense	742	584	(58)	(12)	(17)	(12)	(99)	(3)	(18)	(35)	(120)	(176)	310	180	(275)	(505)	(290)	(3,030)	(2,017)	(2,011)	(4,017)	(4,017)
Income Before Tax	(12,898)	(16,696)	(4,668)	(4,134)	(3,726)	(3,835)	(16,363)	(4,661)	(4,120)	(4,627)	(4,323)	(17,731)	(5,134)	(5,747)	(6,735)	(7,569)	(25,185)	(31,458)	(33,308)	(37,716)	117,575	117,575
Provision for Income Taxes	(3)	(4)	0	0	0	(1)	(1)	(3)	(3)	(3)	8	(1)	0	0	0	0	0	(3)	(3)	(3)	(3)	(3)
Net Income (Loss)	(12,901)	(16,700)	(4,668)	(4,134)	(3,726)	(3,836)	(16,364)	(4,664)	(4,123)	(4,630)	(4,315)	(17,732)	(5,134)	(5,747)	(6,735)	(7,569)	(25,185)	(31,461)	(33,311)	(37,719)	117,572	117,572
EPS - Diluted	<u>(\$0.98)</u>	<u>(\$1.09)</u>	<u>(\$0.31)</u>	<u>(\$0.27)</u>	<u>(\$0.24)</u>	<u>(\$0.18)</u>	<u>(\$0.98)</u>	<u>(\$0.22)</u>	<u>(\$0.19)</u>	<u>(\$0.21)</u>	<u>(\$0.18)</u>	<u>(\$0.80)</u>	<u>(\$0.10)</u>	<u>(\$0.10)</u>	<u>(\$0.12)</u>	<u>(\$0.13)</u>	<u>(\$0.46)</u>	<u>(\$0.50)</u>	<u>(\$0.46)</u>	<u>(\$0.45)</u>	<u>\$1.38</u>	<u>\$1.38</u>
Shares Outstanding - Diluted [2]	13,153	15,271	15,273	15,273	15,287	21,066	16,725	21,508	21,524	21,785	24,377	22,299	49,561	55,107	56,209	57,333	54,552	62,735	72,145	82,967	85,456	85,456

Balance Sheets
(in \$000s)

<u>Assets:</u>	12/31/08	12/31/09	12/31/10	2/2/11
Cash and Marketable Securities	\$3,270	\$2,799	\$2,638	+\$28M
Short-Term Investments	10,292	13,135	0	
Accounts Receivable	126	251	49	
Prepaid Expenses	334	214	973	
Other Current	471	161	396	
Total Current Assets	\$14,493	\$16,560	\$4,056	
Property & Equip, net	6,938	6,197	6,647	
Patents Pending, net	575	822	1,259	
Other Assets	498	570	1,020	
TOTAL ASSETS	<u>\$22,504</u>	<u>\$24,149</u>	<u>\$12,982</u>	
<u>Liabilities:</u>				
Accounts Payable	\$521	\$311	\$655	
Accrued Comp. and Benefits	456	367	901	
Lease Obligation ST	682	476	1,055	
Debt ST	0	59	40	
Warrant Liability	0	0	1,843	
Other Current Liabilities	668	823	970	
Total Current Liabilities	\$2,327	\$2,036	\$5,464	
Lease Obligation LT	545	96	836	
Debt LT	0	121	81	
Stockholders' Equity	19,632	21,896	6,601	
TOTAL LIAB. & EQ	<u>\$22,504</u>	<u>\$24,149</u>	<u>\$12,982</u>	

NOTES

- As of December 31, 2010 Bionovo had net operating loss carryforwards of approximately \$68.1 million
- Historical EPS adjusted for 5 for 1 Reverse Split on 8/31/10

DISCLOSURES



Ratings and Price Target Changes over Past 3 Years

Initiated August 9, 2010 – Strong Speculative Buy - Price Target \$7.50

Analyst Certification: We, Stephen M. Dunn and William D. Dawson, the authors of this research report certify that a.) All of the views expressed in this report accurately reflect our personal views about any and all of the subject securities or issuers discussed b.) No part of our compensation is directly or indirectly related to the specific recommendations or views expressed in this research report and c.) We may be eligible to receive other compensation based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

DISCLOSURES

Does the Analyst or any member of the Analyst's household have a financial interest in any securities of the Company?	NO
Does the Analyst or any member of the Analyst's household or Firm serve as an officer, director or advisory board member of the Company?	NO
Has the Analyst or any member of the Analyst's household received compensation directly or indirectly from the Company in the previous 12 months?	NO
Does the Firm or affiliates beneficially own ≥1% of the Company's common stock?	NO
Has the Firm or affiliates received investment banking services compensation in previous 12 months?	YES
Has the Firm or affiliates received non-investment banking securities-related services compensation in previous 12 months?	NO
Does the Firm or affiliates expect to receive or intend to seek investment banking compensation in next 3 months?	YES
Has the Firm or affiliates received non-securities services compensation in previous 12 months?	NO
Does the Firm or affiliates make a market in the Company's securities?	NO

The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. The Firm, its officers, directors, analysts or employees may effect transactions in and have long or short positions in the securities (or options or warrants with respect thereto) mentioned herein. The Firm may effect transactions as principal or agent in the securities mentioned herein.

Ratings Definitions: 1) **Strong Buy:** the stock is expected to appreciate and produce a total return of at least 40% over the next 12-18 months; 2) **Buy:** the stock is expected to appreciate and produce a total return of at least 20% over the next 12-18 months; 3) **Strong Speculative Buy:** the stock is expected to appreciate and produce a total return of at least 40% over the next 12-18 months but **the volatility and investment risk is substantially higher** than our "Strong Buy" recommendation; 4) **Speculative Buy:** the stock is expected to appreciate and produce a total return of at least 20% over the next 12-18 months but **the volatility and investment risk is substantially higher** than our "Buy" recommendation; 5) **Neutral:** the stock is fairly valued for the next 12-18 months and should be avoided or sold if held; 6) **Avoid/Sell:** the stock is expected to decline at least 20% over the next 12-18 months and should be avoided or sold if held; 7) **Under Review:** the previous rating and/or price target is suspended due to a significant event which now requires additional analysis and the previous rating and/or price target cannot be relied upon; 8) **Not Rated:** the stock has too much business or financial uncertainty to form an investment conclusion or is currently in the process of being acquired and 9) **Restricted:** coverage cannot be initiated or has been temporarily suspended to comply with applicable regulations and/or firm policies in certain circumstances such as investment banking or an advisory capacity involving the company.

LifeTech Capital Research	Research Coverage	Investment Banking	FINRA RULE 2711	Research Coverage	Investment Banking
Ratings Distribution	% of Total	% of Total	Ratings Distribution	% of Total	% of Total
Strong Buy	20%	50%	Buy	100%	70%
Strong Speculative Buy	80%	75%	Hold/Neutral	0%	0%
Buy	0%	0%	Sell	0%	0%
Speculative Buy	0%	0%	Total	100%	70%
Neutral	0%	0%			
Avoid/Sell	0%	0%			
Under Review	0%	0%			
Not Rated	0%	0%			
Restricted	0%	0%			
Total	100%	70%			

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