



# INSTITUTIONAL RESEARCH

## Healthcare & Biotechnology

### INITIATION REPORT

Member FINRA/SIPC

Toll Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 925 Federal Highway, 6<sup>th</sup> Floor ♦ Boca Raton, FL 33432

November 3, 2009

## Bionovo, Inc. (Nasdaq/BNVI)

Robert M. Wasserman

Director of Research

561-208-2905

rwasserman@dawsonjames.com

### BUY Funded for Menerba Phase III

*Bionovo is developing innovative therapeutics from botanical extracts*

### Investment Highlights

1) Bionovo's **Menerba** (Menopause-related hot flashes) Phase II trial design and results have received rave reviews from key opinion leaders in the Women's Health medical sphere – everywhere from the founder of the Menopause Society to an FDA director. Treatment of prevalent menopausal symptoms, including hot flashes and vaginal dryness, has stagnated in recent years, and Bionovo is poised to complete its Phase III trial application for Menerba this year and begin this pivotal trial in 2010, with a Phase I/II trial for **Seala** (vaginal dryness) starting the following year or even earlier if new funding comes in.

2) **The potential market for cancer therapeutics** is even larger than the multi-billion dollar women's health area – and Bionovo's **Bezielle** programs for advanced breast cancer and pancreatic cancer employ a novel targeted approach and botanical agent-based composition to battle these difficult-to-treat cancers. Bezielle has also received high marks from the medical community for its approach and clinical trial design, and Bionovo is ready to launch Phase II trials for advanced breast cancer and Phase I/II for pancreatic cancer once new funding is obtained, either through partnerships or federal grants.

3) A recent round of equity financing by Bionovo will allow the Company to fund the next stage of Menerba research and possibly fuel the further development of its cancer therapeutic pipeline, including early Phase trials of **two additional Chinese herbal medicine-derived breast cancer treatments**. Additional working capital will also help Company management seek new sources of funding for existing R&D programs currently on hold, such as Bezielle and Seala, or even leverage existing relationships with a large number of leading research institutions and researchers across the US and the Company's extensive experience with novel botanical agents to develop products in even more unmet medical areas.

**Current Price \$0.39**

**Price Target \$2.00**

Estimates	F2008A	F2009E	F2010E
Revenues(\$000s)	\$233	\$227	\$1,000
EPS	(\$0.22)	(\$0.20)	(\$0.15)

Stock Data	
52-Week Range	\$0.17-\$1.15
Shares Outstanding (mil.)	108.7
Market Capitalization (mil.)	\$42.4
Enterprise Value (mil.)	\$38.0
Debt to Capital (6/09)	8.2%
Book Value/Share (6/09)	\$0.10
Price/Book	3.8 x
Average Trading Volume (3-Month)	716,000
Insider Ownership	20.2%
Institutional Ownership	13.0%
Short interest	284,000
Dividend / Yield	\$0.00/0.0%



Price target and ratings changes over the past 3 yrs:  
Initiated - November 3, 2009 - Buy -Price Target \$2.00

Please find Important Disclosures beginning on Page 13.

## Conclusion

Bionovo has developed a novel technology platform using extracts from Chinese traditional medicine botanical agents, a readily available and well studied source of materials, to target several areas of difficult to treat, unmet medical needs. The Company has published clinical results in several trials showing strong efficacy and unusually positive safety, thus attracting a strong following in the medical/scientific community. Up next for the Company will be further clinical studies on the existing Menerba portfolio program, and possibly accelerating progress on other programs with the potential signing of new partnerships or receipt of government research funding, which has begun to flow again this fall. Bionovo's shares trade at a steep discount to other stocks in the Women's Health/Oncology area, perhaps due to the recent round of equity financing or the recent clinical failure of a rival treatment for menopausal hot flashes, albeit one with a very different mechanism of action. Thus, we are initiating coverage on BNVI with a BUY rating and an 18-24 month price target of \$2.00, still below highs of just several years ago.

## History/Capitalization

Bionovo, Inc. ("Bionovo") was incorporated in February 2002 in California as Bionovo Biopharmaceuticals and came public in April 2005 through a reverse merger. At that time the Company changed its name to the current Bionovo Inc. The Company's development program grew out of earlier research conducted at the University of California San Francisco funded in part by a State of California program. Bionovo has also funded its clinical program to a lesser extent through research grants from US federal agencies, including the NIH. The Company completed one private placement in 2005 and two secondary equity offerings in 2007 to fund its research and development efforts since publicly trading, in addition to a very recent secondary offering completed in 2009. Bionovo has its corporate headquarters in Emeryville, California with additional laboratory facilities in Aurora, California.

## Technology/Scientific Platform

Bionovo employs a dual ancient/modern strategy to discover and develop therapeutic products from traditional medicinal botanical agents. First, the Company utilizes the extensive clinical knowledge and experience with natural compounds of the combined internal researchers and collaborative agreements with noted university programs at University of California, San Francisco, University of California at Berkeley, the University of California at Davis, University of Southern California, University of Texas MD Anderson Cancer Center, Case Western Reserve, the University of Colorado, Houston University, Baylor University and Methodist Hospital Research Institute in Houston.

Next, Bionovo researchers select the most likely candidate compounds and test them for efficacy and toxicity with state of the art screening models – such as estrogen receptor regulation (Women's Health) or induction of cancer cell death (Oncology). While research on botanical-based anti-neoplastic agents has been ongoing in China since the 1950's, with a number of Chinese medicinal herbs traditionally being used to prevent and treat cancer, Bionovo's evaluation of extracts from 71 Chinese medicinal herbs on five breast cancer cell lines narrowed down the possible extracts to 26% (19/71). Similarly, over 300 plants synthesize compounds that interact with estrogen receptors, and Bionovo tested 71 traditional Chinese medicine herbs for their ability to regulate transcriptional activity in the presence of estrogen receptors (ER $\alpha$  or ER $\beta$ ) and narrowed this group down to 33 agents (46%). Prior clinical knowledge (in some cases centuries old) of toxicities of the traditional herbs also accelerated preclinical testing, especially when compared with new chemical entities.

Finally, the Company has developed methods for manufacturing batch consistency measures using state of the art analytical technology, eventually reducing risk and decreasing production times if new drugs should be approved and manufactured on a commercial, large scale basis.

## Primary Market/Competition

Bionovo has focused initially on medical applications with urgent needs and very large potential markets, specifically menopausal symptoms (Women's Health) and Oncology. Below is an analysis of the current size of these two therapeutic markets, current standards of treatment, and existing and potential competition:

### Women's Health (Menopausal Symptoms)

According to the North American Menopause Society (NAMS), there were approximately 46 million post-menopausal women in the US as of the most recent census survey in 2000, with approximately 2 million more women reaching menopause each year. Furthermore, the Society states that hot flashes are the most common menopause-related discomfort, affecting 32 million women in the U.S. annually. The most robust estimate of the potential market for an effective treatment for these symptoms may come from statistics compiled in 2001 for sales of Wyeth's (now Pfizer) Premarin (conjugated estrogen) family of products, which topped \$10 billion in sales on over 2 billion prescriptions that year. Peak sales of Premarin occurred just before the damaging results of the World Health Initiative (WHI) report (funded by Wyeth oddly enough) were released showing unexpected high incidences of breast cancer in long-term users of hormone replacement therapy, such as Wyeth's Premarin, which at that time dominated the market. Since the study was halted and results were released, sales of hormone replacement products have declined steadily, although new products such as transdermal patches and shorter duration of action therapies have revived this market to some extent. The chart below outlines current treatments for post-menopausal symptoms such as hot flashes, including several newer-generation anti-depressants which may be prescribed off-label to relieve hot flash frequency:

<i>Drug(s)</i>	<i>Marketer</i>	<i>Type</i>	<i>Active Ingredient</i>
<b>Premarin/Prempro</b>	Pfizer (Wyeth)	Oral	Conjugated estrogens/progesterone
<b>Vivelle-DOT</b>	Hisamitsu (Noven)	Transdermal	Synthetic estradiol
<b>Cenestin</b>	Teva (Barr)	Oral	Synthetic conjugated estrogens
<b>Provera</b>	Pfizer (Wyeth)	Oral	Medroxyprogesterone acetate tablets
<b>Anti-depressants (off-label)</b>	Pfizer, Lilly, GSK	Oral	Venlafaxine, fluoxetine, paroxetine

In addition to a number of large, already-marketed oral medications or transdermal patches, several large and smaller pharmaceutical companies are actively developing new treatments for menopausal symptoms such as hot flashes. Many of these new treatments are new formulations of well-established anti-depressants, such as selective Serotonin reuptake inhibitors (SSRIs) or Serotonin-Norepinephrine reuptake inhibitors (SNRIs). As is the case in the marketing area for menopausal symptoms treatments, but to a greater extent perhaps, recent and future merger activity could alter the competitive landscape for potential new treatments. Particularly of note is the recently completed purchase of Wyeth by Pfizer, both of which had active R&D programs in this area. The chart below outlines current product development programs for the treatment of menopausal-related hot flashes, including name, sponsor, stage, and key ingredient:

<i>Drug</i>	<i>Sponsor</i>	<i>Phase</i>	<i>Category/Active Ingredient</i>
<b>Aprala</b>	Pfizer (Wyeth)	III	Combination Bazedoxefine/ Conjugated estrogen
<b>Angeliq</b>	Bayer	III	Combination drospirenone/estradiol
<b>Pristiq sustained release</b>	Pfizer (Wyeth)	III	Desvenlafaxine succinate
<b>ORG 50081</b>	Merck (Organon)	III	Esmirtzapine
<b>Serada</b>	Depomed	III	Gabapentin extended-release
<b>Climara PRO</b>	Bayer	III	Estradiol transdermal delivery system
<b>Mesafem</b>	Hisamitsu (Noven)	II	Low-dose paroxetine
<b>Estratest</b>	Solvay	II	Esterified estrogens & Methyltestosterone
<b>GSK 232802</b>	GlaxoSmithKline	II	3G-selective estrogen receptor modulator
<b>PD-0299685</b>	Pfizer	II	alpha-2 delta receptor

## Oncology

According to the American Cancer Society (2005), cancer is a leading cause of death in the US, with advanced breast cancer one of the largest types of cancer. It is further estimated that 200,000 new cases (American Cancer Society 2009) of advanced breast cancer are diagnosed in the US each year, and that the approximate size of the market for therapeutics to treat this disease in the US is \$4-\$5 billion. There are a number of different types of therapeutics for breast cancer, ranging from hormonal treatments such as Femara, Tamoxifen, Evista and Arimidex, most often given for early stage breast cancer in post-menopausal women, Chemotherapy agents including Abraxane, Gemzar, Taxol and Taxotere, and more recently developed biologic agents, such as Herceptin, Avastin and Tykerb. Recent research and development on breast cancer treatment has focused on combinations of existing drugs or new delivery systems/formulations of already-approved drugs rather than new chemical entities or biologics, both because of adverse side effect profiles of existing therapeutics and increasingly more complex clinical trial regimens required by the FDA.

## Products under Development

### *Menerba*

Menerba (formerly MF-101) is a novel, oral selective estrogen receptor beta (ER $\beta$ ) modulator (SERM), or agonist, which targets menopausal-related vasomotor symptoms, more commonly known as hot flashes. Unlike many SERMs, Menerba is derived from botanical extracts rather than a “designer drug”, such as tamoxifen or raloxifene, which are created synthetically. Menerba’s mix of botanical agents was carefully screened to be selective in transcriptional regulation to one of the two known estrogen receptor subtypes, and specifically does not activate the ER $\alpha$  pathway, which has been implicated in both breast and uterine cancer formation. In addition, black box warnings have been given to many of the existing FDA-treatments for hot flashes, in addition to cancer, such as cardiovascular disease and dementia. Thus, Menerba has the potential to be a first-line treatment for menopausal hot flashes, with increased safety and tolerability.

Bionovo completed a Phase II trial for Menerba in 2007, with 217 patients at six clinical sites in the US, in a randomized, double-blinded, three-armed study in postmenopausal women between the ages of 40-60 who experienced 7 hot flashes a day or 50 per week. Dr. Deborah Grady of the University of California, San Francisco was the principal investigator of the trial. The three arms of the study treated over 70 patients each with 5.0 grams/day of Menerba, 10.0 grams/day of Menerba and placebo, with primary endpoints of a change in the frequency and severity of hot flashes at baseline and after 4 and 12 weeks of treatment. The results

demonstrated statistically significant reductions in number of hot flashes and nighttime awakenings (“night sweats”) and a lower severity score, especially for the higher, 10.0 gram/day dosage level (p-values ranging from 0.04 to 0.11). The study also yielded fewer side effects, including no difference in the number of uterine bleeding episodes, no cases of endometrial hyperplasia, and a very low drop-out rate (2%). Other current popular treatments such as hormone therapy and off-label use of Pristiq (Pfizer/Wyeth) show a higher number of side effects, compared only to loose stools for the Menerba study group. Bionovo published the results of the Phase II Menerba trial in the US in March 2009 and in Europe in September 2009.

Late last year, the Company outlined plans to begin Phase III clinical trials with Menerba. After finishing three discussions with the FDA regarding Chemistry, Manufacturing and Control (CMC) issues, Bionovo and its regulatory consultant are confident that they can successfully address the agency’s recommendations for further development of Menerba related to drug consistency, and can begin Phase III trials sometime early next year. The Company has already designed a Phase III dose-ranging trial, to be conducted at 20 clinical sites in the US with Principal Investigator Dr. Wulf Utian, Founder of the North American Menopause Society (NAMS). The 720-patient, 3-month study will compare four patient groups (180 each) with the lowest efficacious dose, twice the lowest dose, 5x the lowest dose and placebo. Primary endpoints will include a safety assessment at 4 weeks and a reduction in frequency and severity of hot flashes at baseline, 4 and 12 weeks.

Initiation of this Phase III study has been delayed this year due to a lack of funding (recently completed), CMC discussions, and also certain general concerns of the FDA related to the recent Depomed (Nasdaq/DEPO/Not Rated) Breeze 1 and 2 Phase III trials for Serada (Gabapentin extended release), which did not show a great enough decrease in hot flash frequency to meet many of the trials endpoints, especially after 12 weeks.

Longer-term, Bionovo management believes that FDA approval of Menerba will require successful completion of a second Phase III trial, enrolling more patients and including a 1-year follow-up period for further safety assessment. This second Phase III trial can be initiated after an NDA is filed using the initial Phase III study, can employ a similar design, use the same clinical sites or perhaps some new ones outside of the US, and most likely will be conducted by a marketing partner.

### ***Bezielle***

Bezielle, formerly BZL101, is a botanically-derived oral medication drug. Unlike typical cancer therapeutics or drug candidates that try to control cancer through genomic and proteomic cancer pathways, Bezielle is designed to take advantage of the unique metabolism of cancer cells. Bezielle inhibits glycolysis, which generates much of the cancer cell’s energy, leading to DNA damage and death of the cancer cells with lasting harm to normal cells. Bezielle’s most promising application may be for hormone-independent cancers, a subset with few treatment options. Bezielle may also show promise in use as an adjuvant therapy with more established chemotherapy drugs.

In August 2009, Bionovo announced positive results from a Phase 1B clinical trial of Bezielle in the treatment of advanced breast cancer. The Phase 1B study was conducted at eight clinical sites in the US with Dr. Charles Shapiro of Ohio State University serving as Principal Investigator. In the trial, twenty seven women with metastatic breast cancer were enrolled, with the primary objective to determine the maximum tolerated dose as well as to determine the safety and efficacy of the therapy. The patients had received nearly six prior cancer treatments, on average. In the trial, sixteen of the twenty-seven participants were evaluable according to the Response Evaluation Criteria in Solid Tumors (RECIST) scale. Of these sixteen, five (31%) were stable for greater than 90 days while two (13%) were stable for more than 180 days. Three patients (19%) had objective tumor regression, after evaluation by an independent radiologist. Four patients discontinued the trial with stable disease, including one who had objective tumor regression for 449 days of Bezielle treatment and 600 days altogether, a second who continues to be stable for 832 days, and a third who was stable for 591 days before evidence of regression. Safety results were very positive, with no drug-related deaths or serious adverse effects, and 94% of all adverse related classified as grade 1 or 2. Overall compliance was good, with 90% of prescribed

doses taken. The maximum tolerated dose was never established as dose escalation reached four times (40g/day) the Phase 1A dose.

The earlier Phase 1A study enrolled 21 patients with metastatic breast cancer, again showed no deaths or serious adverse effects, with five patients (31%) exhibiting stable disease, including three for over 180 days.

Bionovo has received FDA approval for its protocol for a Phase II Bezielle clinical study and has identified eight clinical sites – including two of the sites serving as primary clinic for the two principal investigators – Dr. Banu Arun of the MD Anderson Cancer Research Center in Houston and Dr. Alejandra Perez of Memorial Cancer Institute in Hollywood, Florida. The Phase II study will treat 80 patients in two 40-patient cohort groups – each with + or – estrogen receptors, and who have received no more than two prior cytotoxic cancer therapy treatments. The Company is currently awaiting additional funding, possibly a government grant and/or partnership, before initiating a Phase II trial for Bezielle.

Bionovo also is developing a program for the use of Bezielle in the treatment of pancreatic cancer, one of the largest causes of cancer deaths in the US (4<sup>th</sup> largest) but with few treatment options and a very small long-term survival rate. The Company hopes to file an IND with the FDA for a Phase I/II dose escalation clinical trial next year. The trial will include men and women with advanced stage pancreatic cancer who have failed at least one prior treatment regimen, first three participants for each dose in an escalating fashion to determine maximum tolerated dosage levels, and then 20 patients on this dose until progression. The primary endpoints of the study are expected to be tumor response based on RECIST criteria, adverse events based in common terminology criteria, and duration of response and survival, with the up to 12 months of patient study.

### ***Seala***

Seala, formerly VG101, is a novel topical Estrogen Receptor Beta (ER $\beta$ ) modulator for the treatment of postmenopausal vulvar and vaginal atrophy, or vaginal dryness. Seala is also derived from Chinese traditional medicine botanical agents and is delivered in a non-steroidal vaginal gel suppository. Vaginal atrophy is a frequent complaint of postmenopausal women, affecting as much as 55%, and unlike hot flashes, these symptoms can persist for many years after menopause. The most frequent treatment for vaginal dryness currently remains traditional hormone replacement therapy, including oral medications and transdermal patches, in addition to newer localized therapies such as creams, vaginal rings, and slow-release vaginal tablets. Similar to oral application, however, these newer methods of estrogen administration still present potential adverse side effect problems as evidenced in the WHI study. In pre-clinical studies, Seala has proven to be effective in treating vaginal atrophy without causing cancerous effects in the uterus.

Bionovo has submitted an IND to the FDA and expects to begin a Phase I/II study for Seala by next year or the year after. The study will be conducted at two clinical sites, the University of California, San Francisco and the University of Alabama, Birmingham by Dr. Utian. The 40-patient, 5-arm study will treat groups of 8-patients each taking 25, 50, 100 and 250 milligrams of Seala, and a placebo, with primary endpoints at baseline and 12 weeks being a reduction in self-reported symptoms of vaginal atrophy, a change in the percent of superficial vaginal epithelial cells, a change in the pH of vaginal secretions, and a change in the physical signs of vaginal atrophy upon a physician exam. Eligibility for the 12-18 month trial will include postmenopausal women between the ages of 45-65 who have exhibited at least one moderate-to-severe symptom of vaginal atrophy, high vaginal pH (>5.0), and less than 5% superficial vaginal epithelial cells.

### ***BN 107 and 108***

Bionovo is also developing two additional drugs targeting advanced stage breast cancer derived from Chinese traditional medicine-related botanical agents. The first is BN107, a novel agent which induces death only in estrogen receptor negative breast cancer cells, exerting its growth inhibition properties in these cells through the

mitochondrial apoptotic machinery. The second drug, BN108, has a unique, targeted mechanism of action which induces cancer cell death by rapid inactivation of both AKT and mTOR pathways. BN108's active compound is timosaponin AIII, and the potential drug's active mechanism was described in a publication earlier this year in the open-access journal Public Library of Science One (PLoS ONE). Bionovo intends to submit IND applications to the FDA for a 20-patient, multi-center, Phase I/II dose escalation trials for both BN107 and BN108 in the near future.

#### ***Other R&D Programs (Obesity and menopausal metabolic syndrome)***

Bionovo also recently presented the results of a preclinical (mice) study of two plant-derived, selective estrogen receptor alpha modulators on obesity. Menopausal transition period oftentimes results in a 10-15 pound weight gain and a redistribution of fat to the abdomen, increasing the risk of developing metabolic syndrome. The study employed mice who were ovariectomized (mimicking menopause) and then placed on a high fat diet. The subject mice that were treated with the Bionovo compound lost weight, while untreated mice continued to gain weight. In addition, while mice treated with estrogens to reduce body fat mass in these situations show significantly enlarged mammary glands and uterus, the same tissues in subject mice receiving the Bionovo compounds closely resembled those of the untreated mice.

#### **Recent Results**

In mid-August, Bionovo reported financial results for their second quarter ending June 30<sup>th</sup>, 2009, including a loss of \$4.1 million from operations on revenues of \$7,000. Operating expenses included \$2.95 million in research and development costs, up 15.7% from the prior year period, and general and administrative costs of \$1.175 million, down significantly from \$1.8 million spent in Q2/2008. Operating expenses in Q2/2009 included purchases of lab supplies and raw materials to support establishment of manufacturing processes for Menerba as the Company seeks to finalize protocols for a Phase III clinical trial, while other overhead expenses declined year-over-year due to cost control measures undertaken early in 2009, primarily related to compensation freezes, headcount reductions, and deferral of preclinical R&D efforts. Loss per share for the quarter came in at (\$0.05) on 76.4 million shares outstanding, as compared with a loss of (\$0.06) per share in the prior year period on a similar numbers of shares.

Cash burn during the quarter was \$3.7 million.

#### **Balance Sheet and Operating Cash Flow**

Bionovo maintained \$4.4 million in cash and equivalents and \$1.0 million in short-term investments, offset by slightly under \$1.0 million in lease obligations and notes payable. Subsequent to the quarter-end, Bionovo raised over \$18 million net from a recent public equity offering. We estimate that the Company will continue the quarterly cash burn between \$3.5-\$4.0 million experienced in Q2 in the upcoming quarters, at least until Phase III clinical trials for Menerba are initiated sometime next year, unless outside government grants or partnership funding is obtained in the meantime. At current levels of cash burn, barring additional funding or stepped-up R&D spending, we estimate that Bionovo has approximately 18 months of operating cash burn on hand.

#### **Outlook/Growth Drivers**

Bionovo now has plenty of cash to continue its ongoing R&D programs following the recent equity placement. At the most recent earnings conference call (Q2/09 in August), Company management stated that they "continue to work towards satisfying the FDA's requests for clarification of the manufacturing and analytical strategy to be used in ensuring the consistency of its drug products", the most immediate of which is Menerba,

which is awaiting a nod by the FDA before Phase III clinical trials get underway. The start of the Menerba Phase III trial, most likely early next year, will be the most significant event for Bionovo, although Company management continues to seek other funding sources or partnerships for its other pipeline programs (and Menerba as well) and any progress or news on these fronts could also be classified as major events and would add value to the Company's portfolio and future prospects. Also worth watching, if less under the control of the Company, will be industry developments in the near future, ranging from FDA action on potential competitive programs in the menopausal symptoms and/or advanced breast cancer therapeutic areas, to the effects of consolidation of several high profile mergers, notably Pfizer/Wyeth, on marketing and R&D in the Women's Health space. As noted above, Bionovo has approximately 18 months or 6 quarters worth of cash at hand following the recent equity raise, and can continue at current operating levels through 2011, or possibly longer with the signing of new partnerships or receipt of new grant funding for R&D.

## Management

**Isaac Cohen** is a co-founder of Bionovo and has served as Chairman, Chief Executive Officer, Chief Scientific Officer and as a director since February 2002. Mr. Cohen has also served as a Guest Scientist at the University of California, San Francisco 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.** is a co-founder of Bionovo, and has served as Chief Medical Officer, Chief Regulatory Officer, Secretary and Treasurer since 2002, as well as President since 2007. She is also a Director of the Company. Prior to founding Bionovo, Dr. Tagliaferri conducted translational research with the University of California, San Francisco and continues to do so today. Dr. Tagliaferri received her undergraduate degree from Cornell University and her medical degree from the University of California, San Francisco. She also holds a Master's degree in traditional Chinese medicine from the American College of Traditional Chinese Medicine.

**Tom Chesterman** joined Bionovo in July 2007 as Senior Vice President, Chief Financial Officer and Assistant Secretary. Prior to joining the Company, Mr. Chesterman was Chief Financial Officer at Aradigm and also at Bio-Rad Laboratories. Mr. Chesterman holds a bachelors degree from Harvard University and an M.B.A. in Finance and Accounting from the University of California at Davis.

In addition to management team members Mr. Cohen and Dr. Tagliaferri, Bionovo's board includes **Dr. John D. Baxter**, currently Head of endocrinology at The Methodist Hospital in Houston, Texas; **George Butler, PhD.**, Chairman of SingEval Pte. Ltd and formerly with AstraZeneca and Novartis; **Louis Drapeau**, currently the CEO of InSite Vision and formerly the CFO of Nektar Therapeutics and BioMarin Pharmaceuticals; **David Naveh, Ph.D.**, formerly Chief Technological Officer of Bayer Biologicals Products, Worldwide; and **Michael Vanderhoof**, Chairman of Cambria Asset Management.

## Intellectual Property

Bionovo has filed 66 patent applications with the US Patent & Trademark Office (PTO) to date, with additional concurrent filings completed in international jurisdictions, including the European Community, Japan and other emerging markets. One of the key patents filed by the Company, US7482029 for Menerba titled "Composition for Treatment of Menopause" which covers the ingredient mixture for the product, was issued with an effective date of March 29, 2006. Altogether, 38 patents on Menerba have been filed to date, including other applications covering composition of matter, structure/function, and methods of treatment. Six patent applications have been

filed on Bezielle, including those related to composition of matter, combination of chemical components, and methods of therapeutic use. Bionovo has filed seven applications related to Seala, and 15 additional patents have been filed related to other drugs and technologies in the pipeline.

### **Stock Valuation/Comparables**

We have compiled a two-tiered stock comparison group for Bionovo in Table 1, separated in oncology therapeutics (especially hormone-related cancers) and Women's Health medical areas, again focusing on estrogen-related therapies. Stocks in the oncology group include Abraxis Bioscience (Nasdaq/ABII/Not Rated); Ariad (Nasdaq/ARIA/NR); Onyx (Nasdaq/ONXX/NR); OSI Pharmaceuticals (Nasdaq/OSIP/NR); and Poniard Pharmaceuticals (Nasdaq/PARD/NR), while stocks in our Women's Health group include BioSante (Nasdaq/BPAX/NR); Columbia Labs (Nasdaq/CBRX/NR) and Noven Pharmaceuticals, which was bought-out earlier this year at \$16.50 per share by Hisamitsu of Japan at an approximate valuation of \$400 million. Measuring each group by progress points (5 points for an approved product, 4 points for a product in Phase III clinicals, 3 points for Phase II, etc.) per enterprise value, we estimate that the average EV/Progress Point for the oncology group at \$36.7 million is considerably higher than the valuation for the Women's Health group at \$10.8 million, perhaps taking into account the higher market potential for cancer therapeutic drugs as well as the heightened investor awareness of cancer R&D programs. Even taking into account the further pipeline progress of Bionovo's Menerba (Women's Health, entering Phase III) over Bezielle (entering Phase II) the Company's valuation per R&D program is very low, less than \$3 million per progress point. Even using a weighted average valuation skewed toward the lower end of the overall average, at \$25 million per progress point, we estimate that Bionovo is worth upwards of \$220 million on an enterprise value/point basis, or \$2.00 per share. Thus, we are recommending that investors purchase these shares with an 18-24 month price target of \$2.00.

### **Catalysts/Investor Timeline**

- 1) Results for Q3/2009 – 11/5/09 after market closes
- 2) Approval of CMC and Phase III protocol for Menerba – Q4/2009
- 3) Initiation of Phase III Menerba trial – Q1 or Q2/2010
- 4) Results for grant application for Bezielle for pancreatic cancer – 2010
- 5) Launch Bezielle Phase III for advanced breast cancer – 2011 (unless outside funding received)
- 6) Launch Seala Phase I/II – 2011 (unless outside funding received)
- 7) Publish Phase III data/Sign partnership agreement for Menerba – 2011
- 8) Release interim and final data results from Phase I/II Bezielle study for advanced breast cancer – 2012
- 9) Launch Phase I/II trial and release interim data for Seala – 2012
- 10) File IND for BN107 and/or BN108 for advanced breast cancer - 2012

## Risk Factors

### We believe an investment in Bionovo involves the following risks:

- **FDA and regulatory risks** – Bionovo is subject to regulatory review for its ongoing research and development activities, principally the US Food and Drug Administration but also potentially with other regulatory agencies as well, including in Europe and Asia. In addition, the manufacture and handling of the Company's novel botanical agent-derived pharmaceuticals are subject to additional oversight and regulation and in fact are somewhat ground-breaking in terms of FDA approval.
- **Reliance on joint venture partners and/or additional capital** — Currently, Bionovo has enough cash on hand to fund ongoing research and marketing development programs into calendar 2011, approximately. Alternatively, the Company could obtain partnership agreements or government funding to offset planned R&D spending or to accelerate development of an existing or new R&D program in the pipeline. While other companies in the oncology and women's health areas have obtained such partnerships or grants in the past, there can be no assurance that Bionovo will do so in the present environment. However, many of the Company's current management team and directors have successfully negotiated such deals in the past and this may aid efforts for Bionovo to do so in the future.
- **Need to defend patents and other intellectual property** – Bionovo currently has filed 66 patents on its technology and product pipeline, including one key patent for Menerba in the US declared effective in 2006. However, the Company may need to defend its patents in the US and overseas in the future, particularly if one or more products receive approval and are successfully marketed.

**Bionovo, Inc.**  
**Consolidated Statements of Income**  
 (in \$000s, except EPS)

Robert M. Wasserman

FYE December	2006	2007	1Q08 March	2Q08 June	3Q08 Sept	4Q08 Dec	2008	1Q09 March	2Q09 June	3Q09E Sept	4Q09E Dec	2009E	2010E	2011E
Revenues	\$15	\$582	\$0	\$0	\$0	\$233	\$233	\$0	\$7	\$10	\$210	\$227	\$1,000	\$2,000
Expenses														
Research and development	4,021	9,938	2,387	2,553	3,941	2,534	11,416	3,601	2,954	3,000	3,050	12,605	12,500	13,500
General and administrative	1,799	4,284	1,822	1,808	1,222	1,245	6,097	1,009	1,175	1,200	1,250	4,634	5,000	5,500
One-time and other	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total operating expenses	5,820	14,221	4,209	4,361	5,164	3,779	17,513	4,610	4,129	4,200	4,300	17,239	17,500	19,000
Loss from operations	(5,805)	(13,640)	(4,209)	(4,361)	(5,164)	(3,546)	(17,280)	(4,610)	(4,122)	(4,190)	(4,090)	(17,012)	(16,500)	(17,000)
Interest income	262	850	306	190	143	92	731	54	16	50	200	320	700	600
Interest expense	(47)	(87)	(27)	(36)	(36)	(31)	(129)	(33)	(22)	(20)	(20)	(95)	(80)	(80)
Other expense, net	(23)	(25)	(19)	0	(1)	(0)	(21)	(79)	(6)	(10)	(10)	(105)	(100)	(100)
Net income (loss)	(5,615)	(12,901)	(3,949)	(4,207)	(5,058)	(3,486)	(16,700)	(4,668)	(4,134)	(4,170)	(3,920)	(16,892)	(15,980)	(16,580)
Basic and diluted income (loss) per share	(\$0.11)	(\$0.20)	(\$0.05)	(\$0.06)	(\$0.07)	(\$0.05)	(\$0.22)	(\$0.06)	(\$0.05)	(\$0.05)	(\$0.04)	(\$0.20)	(\$0.15)	(\$0.15)
Basic and diluted shares outstanding	49,923	65,763	76,343	76,344	76,363	76,363	76,353	76,363	76,363	76,400	108,700	84,457	109,000	110,000
Key ratios:														
Cash Flow/share	(\$0.10)	(\$0.17)	(\$0.04)	(\$0.05)	(\$0.06)	(\$0.04)	(\$0.19)	(\$0.06)	(\$0.05)	(\$0.05)	(\$0.03)	(\$0.18)	(\$0.12)	(\$0.12)
EBITDA/share	(\$0.09)	(\$0.16)	(\$0.04)	(\$0.05)	(\$0.06)	(\$0.04)	(\$0.18)	(\$0.06)	(\$0.05)	(\$0.05)	(\$0.03)	(\$0.18)	(\$0.12)	(\$0.12)

**Investor Catalyst Timeline**

Balance Sheets (\$000s)	12/31/08	6/30/09	Investor Catalyst Timeline					
			2Q09 June	3Q09E Sept	4Q09E Dec	2010E	2011E	2012E
<i>Assets:</i>								
Cash and equivalents	\$3,270	\$4,397						
Short-term investments	10,292	1,006						
Prepaid expenses & other	126	44						
Receivables	805	472						
Total current	14,493	5,919						
Property & equip., net	6,938	6,601						
Other assets and patent pending, net	1,073	1,334						
<b>TOTAL ASSETS</b>	<b>\$22,504</b>	<b>\$13,854</b>						
<i>Liabilities:</i>								
Accounts payable	\$521	\$408						
Accrued liabilities & other	1,124	1,220						
Current portion of notes & obligations	682	645						
Total current	2,327	2,273						
Notes payable & other	545	352						
Stockholders' equity	19,632	11,229						
<b>TOTAL LIAB &amp; EQ</b>	<b>\$22,504</b>	<b>\$13,854</b>						
			<b>Menerba - Menopausal Hot Flashes</b>					
			Launch Phase III			Q1/Q2		
			Partnership agreement				X	
			Release Phase III data				X	
			<b>Bezielle - Advanced Breast Cancer</b>					
			Launch Phase II				X	
			Release of interim data				X	
			Release complete Phase II data				X	
			<b>Seala - Vaginal Atrophy</b>					
			Launch Phase I/II				X	
			Release Phase I/II data				X	
			<b>Bezielle - Pancreatic Cancer</b>					
			Results for grant application				X	
			<b>BN 107 - Advanced Breast Cancer</b>					
			File IND				X	
			<b>BN 108 - Advanced Breast Cancer</b>					
			File IND				X	

Source: Dawson James Securities, Inc. estimates; Company documents

**Table 1. Comparable Company Analysis - Women's Health/Cancer Therapeutics**

Company	Symbol	Price	Shares (millions)	Market Cap (\$Millions)	Net cash (\$Millions)	Enterprise Value	Progress Points*	EV/Point (\$Millions)
<b><u>Oncology</u></b>								
Abraxis Bioscience	ABII	\$31.78	40.1	\$ 1,274.4	\$ 258.3	\$1,016.1	25	\$40.6
Ariad	ARIA	\$1.82	108.8	198.0	27.3	\$170.7	20	\$8.5
Onyx	ONXX	\$26.45	57.1	1,510.3	428.6	\$1,081.7	23	\$47.0
OSI Pharmaceuticals	OSIP	\$32.85	58.0	1,905.3	177.8	\$1,727.5	23	\$75.1
Poniard	PARD	\$6.68	34.7	231.8	27.8	\$204.0	14	\$14.6
<b><u>Women's Health</u></b>								
Biosante	BPAX	\$1.54	33.4	\$ 51.4	\$6.0	\$45.4	14	\$3.2
Columbia Labs	CBRX	\$0.93	54.7	50.9	(\$36.5)	\$87.4	14	\$6.2
Noven**	NOVN	\$16.50	24.8	409.2	\$63.1	\$346.1	15	<u>\$23.1</u>
*(5 pts each for approved product, 4 pts for Phase III, 3 pts for Phase II, 2pts for Phase I and 1 point for 1								\$10.9
** Buy-out price 2009								
Average								\$27.3
Bionovo	BNVI	\$0.39	108.7	\$ 42.4	21.4	\$21.0	8	\$2.6

Source: Capital IQ; Dawson James Securities

## Important Disclosures:

### Price Chart:



### Price target and ratings changes over the past 3 years:

Initiated – November 3, 2009 – Target \$2.00

**Analyst Certification:** The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) All Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James 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.

Dawson James has received investment banking compensation from the company mentioned in this report and may actively seek compensation for investment banking services in the future. Dawson James does not make a market in this security. Neither the research analyst whose name appears on this report nor any member of his household is an officer, director or advisory board member of the company. Dawson James did not receive any other compensation from the company in the previous 12 months. 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.

**Ratings definitions:** 1) **Speculative Buy:** the stock is expected to appreciate and produce a total return of at least 30% over the next 12-18 months but **the volatility and investment risk is substantially higher** than our "Strong Buy" recommendation; 2) **Strong Buy:** the stock is expected to appreciate and produce a total return of at least 30% over the next 12-18 months; 3) **Buy:** the stock is expected to appreciate and produce a total return of at least 20% over the next 12-18 months; 4) **Neutral:** the stock is fairly valued for the next 12-18 months; 5) **Sell:** the stock is expected to decline at least 20% over the next 12-18 months and should be sold; 6) **Sell Short:** the stock is expected to decline at least 30% over next 12-18 months and should be sold short, however **the volatility and investment risk is substantially higher** than our "Sell" recommendation; 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; and 8) **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.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Speculative Buy	5	31%	5	100%
Strong Buy	0	0%	0	0%
Buy	8	50%	2	25%
Neutral	3	19%	2	67%
Sell	0	0%	0	0%
Sell Short	0	0%	0	0%
Under Review	0	0%	0	0%
Restricted	0	0%	0	0%
Total	16	100%	9	56%

---

**Information about valuation methods and risks can be found in the “STOCK VALUATION” and “RISKS” sections of this report.**

DAWSON JAMES SECURITIES, INC., Member SIPC, FINRA, (the "Firm") does not make a market in these securities. The Firm may perform or seek to perform investment banking services for these companies in the future. Analysts receive no direct compensation in connection with the firm's investment banking business. All Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James 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. 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. Although the statements of fact in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice. The Firm may effect transactions as principal or agent in the securities mentioned herein. The securities discussed or recommended in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only, and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.