

## Morning Note – February 7, 2012

- **Research Published on Bionovo's Cancer Drug Candidate Bezielle®**
- **Bionovo's Botanical SERM Could Address Postmenopausal Obesity**
- **Bionovo's Botanical Menerba® Begins U.S. Phase IIIa Clinical Trial**
- **Menerba® Could Be First Botanical Blockbuster Drug**

Please See Last 2 Pages For Important Disclosures And Analyst Certification

| Company | Ticker        | Price  | Mkt. Cap. | Daily Volume                              | Rating                       | Target | Analysts   |
|---------|---------------|--------|-----------|---|------------------------------|--------|--|
| Bionovo | BNVI<br>(OTC) | \$0.12 | \$6.2M    | 3-month<br>640,486<br>10-day<br>2,284,950 | Strong<br>Speculative<br>Buy | \$5.00 | Stephen M. Dunn<br>Sr. Managing Director Research<br>sdunn@LifeTechCapital.com<br>(954) 240-9968 |

### Summary

Investors should note that Bionovo has been delisted from NASDAQ as of today but the company expects to trade on the OTC Bulletin Board promptly following the delisting. (see *Nasdaq Delisting Strategy*)

Bionovo announced the publication of two studies that characterize the anticancer properties of their drug candidate Bezielle®. Bezielle® (formerly BZL101) is 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 are thought to be responsible for the reported antineoplastic properties of the plant.<sup>1</sup> Bezielle is currently being developed to treat advanced Breast Cancer.

The two research papers were published in the *Journal of the Public Library of Science One* as shown below:

***Bezielle Selectively Targets Mitochondria of Cancer Cells to Inhibit Glycolysis and OXPHOS***

Source: <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0030300>

#### Abstract

Bezielle (BZL101) is a candidate oral drug that has shown promising efficacy and excellent safety in the early phase clinical trials for advanced breast cancer. Bezielle is an aqueous extract from the herb *Scutellaria barbata*. We have reported previously that Bezielle was selectively cytotoxic to cancer cells while sparing non-transformed cells. In tumor, but not in non-transformed cells, Bezielle induced generation of ROS and severe DNA damage followed by hyperactivation of PARP, depletion of the cellular ATP and NAD, and inhibition of glycolysis. We show here that tumor cells' mitochondria are the primary source of reactive oxygen species induced by Bezielle. Treatment with Bezielle induces progressively higher levels of mitochondrial superoxide as well as peroxide-type ROS. Inhibition of mitochondrial respiration prevents generation of both types of ROS and protects cells from Bezielle-induced death. In addition to glycolysis, Bezielle inhibits oxidative phosphorylation in tumor cells and depletes mitochondrial reserve capacity depriving cells of the ability to produce ATP. Tumor cells lacking functional mitochondria maintain glycolytic activity in presence of Bezielle thus supporting the hypothesis that mitochondria are the primary target of Bezielle. The metabolic

effects of Bezielle towards normal cells are not significant, in agreement with the low levels of oxidative damage that Bezielle inflicts on them. Bezielle is therefore a drug that selectively targets cancer cell mitochondria, and is distinguished from other such drugs by its ability to induce not only inhibition of OXPHOS but also of glycolysis. This study provides a better understanding of the mechanism of Bezielle's cytotoxicity, and the basis of its selectivity towards cancer cells.

### ***Identification and Analysis of the Active Phytochemicals from the Anti-Cancer Botanical Extract Bezielle***

Source: <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0030107>

#### Abstract

Bezielle is a botanical extract that has selective anti-tumor activity, and has shown a promising efficacy in the early phases of clinical testing. Bezielle inhibits mitochondrial respiration and induces reactive oxygen species (ROS) in mitochondria of tumor cells but not in non-transformed cells. The generation of high ROS in tumor cells leads to heavy DNA damage and hyper-activation of PARP, followed by the inhibition of glycolysis. Bezielle therefore belongs to a group of drugs that target tumor cell mitochondria, but its cytotoxicity involves inhibition of both cellular energy producing pathways. We found that the cytotoxic activity of the Bezielle extract in vitro co-purified with a defined fraction containing multiple flavonoids. We have isolated several of these Bezielle flavonoids, and examined their possible roles in the selective anti-tumor cytotoxicity of Bezielle. Our results support the hypothesis that a major Scutellaria flavonoid, scutellarein, possesses many if not all of the biologically relevant properties of the total extract. Like Bezielle, scutellarein induced increasing levels of ROS of mitochondrial origin, progressive DNA damage, protein oxidation, depletion of reduced glutathione and ATP, and suppression of both OXPHOS and glycolysis. Like Bezielle, scutellarein was selectively cytotoxic towards cancer cells. Carthamidin, a flavonone found in Bezielle, also induced DNA damage and oxidative cell death. Two well known plant flavonoids, apigenin and luteolin, had limited and not selective cytotoxicity that did not depend on their pro-oxidant activities. We also provide evidence that the cytotoxicity of scutellarein was increased when other Bezielle flavonoids, not necessarily highly cytotoxic or selective on their own, were present. This indicates that the activity of total Bezielle extract might depend on a combination of several different compounds present within it.

## **NASDAQ Delisting Strategy**

Investors should note that Bionovo has been delisted from NASDAQ as of today but the company expects to trade on the OTC Bulletin Board promptly following the delisting.

On January 27, 2012, Bionovo announced that their Board of Directors decided to seek a voluntary delisting from the NASDAQ Capital Market. Form 25 will be filed with the SEC on February 7, 2012 to commence the NASDAQ delisting process and is expected that the delisting will take effect as of the close of trading on February 17, 2012. Investors should note that, at that time, Bionovo will no longer trade on NASDAQ under the symbol "BNVI" but expects to trade on the OTC Bulletin Board promptly following the delisting.

**We believe this allows Bionovo to more easily raise funds in this challenging environment for their Phase IIIa clinical trial for Menerba<sup>®</sup>** and the supporting expenses which are expected to be approximately \$50M, which we have included in our model. Specific benefits of the OTCBB are:

- A reverse split is not required as there is no minimum bid requirement
- No financial restrictions on capital raising
- There are no listing requirements that need to be met
- Lower continued compliance costs

We continue to believe that the top-line efficacy and safety results of the Phase IIIa trial, if favorable, would unlock additional shareholder value and attract significant financial support from a partner for the Phase IIIb trial.

## Other Recent News

### New Board Member

On January 5, 2012, Robert E. Farrell, J.D. was named to Bionovo's Board of Directors. Mr. Farrell will also serve as an independent director and member of the Audit and Compensation committees. From 1996-2009, Mr. Farrell held the positions of EVP and CFO of Titan Pharmaceuticals and was appointed President and CEO of Titan in December 2008, a position that he held through 2009. From 1991-1996, Mr. Farrell served as Corporate Group VP and CFO of Fresenius USA. Mr. Farrell holds an undergraduate degree from the University of Notre Dame and received his J.D. degree from the University of California.

### New Chief Financial Officer

On January 4, 2012, David Boyle was named SVP and Chief Financial Officer. He was previously SVP and Chief Financial Officer of AVI BioPharma. Prior to AVI, he was VP, Finance and Chief Financial Officer of XOMA. In addition to his past positions as VP of Finance at Polycom and Director of Business Development at Intel, Mr. Boyle has held senior positions in biotechnology and specialty pharmaceutical companies. He was previously at Salix Pharmaceuticals, Ltd. in the U.S. and at Ares Serono Group both in the U.S. and Switzerland.

### \$5M Preferred Stock Agreement

On January 3, 2012, Bionovo announced that it entered into a \$5M securities purchase agreement with an institutional investor where Bionovo has the right over 2 years to sell up to \$5M redeemable Series A 10% Preferred Stock. In addition, Bionovo will issue warrants to purchase shares of common stock valued at 35% of the Preferred Stock amount. The exercise price of the warrants will equal the closing bid price of Bionovo's common stock on the preceding day.

When Preferred Stock is sold, the investor is also obligated to exercise an additional investment right to purchase a number of shares of common stock valued at 100% of the amount of Preferred Stock purchased at a per share price equal to the exercise price of the warrants received in the sale of Preferred Stock. Both the warrants and additional investment right are exercised when Bionovo elects to sell a tranche of Preferred Stock to the investor.

Upon exercise, the investor must pay for the shares underlying the additional investment right and the warrants, at its option, either in cash or by delivering a full-recourse secured promissory note. Any such promissory note will bear interest at 2.0% per year calculated on a simple interest basis and be secured by certain securities owned by the investor with a fair market value equal to the principal amount of the promissory note. Bionovo may redeem the Preferred Stock at any time and, at the option of either Bionovo or investor, all outstanding promissory notes may be offset, exchanged and cancelled for all outstanding shares of Preferred Stock then held by the investor.

## Recent Research

On December 8, 2012, Bionovo announced the publication of a study on the effects of two botanically-derived, tissue selective estrogen receptor modulators (SERM) for the treatment of postmenopausal obesity. The paper titled "Estrogenic Plant Extracts Reverse Weight Gain and Fat Accumulation without Causing Mammary Gland or Uterine Proliferation" was published in the *Journal of the Public Library of Science One* and can be accessed free of charge at:

<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0028333>

The study describes a new class of botanically-derived, tissue selective estrogen receptor modulators in adipose tissue, which cause weight loss in mice without the unwanted proliferative effects in breast and uterine tissue that are associated with cancer. Currently, estrogen used for menopausal hormone therapy can result in weight-loss and improvement for Type 2 diabetes, but at the cost of increased risk of breast and uterine cancer. **This study shows preclinical evidence that Bionovo's unique botanical drug approach might reduce obesity and diabetes without increasing cancer risk.**

**Abstract:** "Long-term estrogen deficiency increases the risk of obesity, diabetes and metabolic syndrome in postmenopausal women. Menopausal hormone therapy containing estrogens might prevent these conditions, but its prolonged use increases the risk of breast cancer, as well as endometrial cancer if used without progestins. Animal studies indicate that beneficial effects of estrogens in adipose tissue and adverse effects on mammary gland and uterus are

mediated by estrogen receptor alpha (ER $\alpha$ ). One strategy to improve the safety of estrogens to prevent/treat obesity, diabetes and metabolic syndrome is to develop estrogens that act as agonists in adipose tissue, but not in mammary gland and uterus. We considered plant extracts, which have been the source of many pharmaceuticals, as a source of tissue selective estrogens. Extracts from two plants, *Glycyrrhiza uralensis* (RG) and *Pueraria montana var. lobata* (RP) bound to ER $\alpha$ , activated ER $\alpha$  responsive reporters, and reversed weight gain and fat accumulation comparable to estradiol in ovariectomized obese mice maintained on a high fat diet. **Unlike estradiol, RG and RP did not induce proliferative effects on mammary gland and uterus. Gene expression profiling demonstrated that RG and RP induced estradiol-like regulation of genes in abdominal fat, but not in mammary gland and uterus. The compounds in extracts from RG and RP might constitute a new class of tissue selective estrogens to reverse weight gain, fat accumulation and metabolic syndrome in postmenopausal women.**"

## 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<sup>®</sup> (estradiol spray) exposure in children and pets shows that the safety issues with HRT are still being discovered.<sup>1</sup>

Alternatives to HRT, such as antidepressant and anti-seizure drugs, are not FDA-approved for menopause and can cause significant side-effects as well. As an example, Bionovo competitor Depomed (Nasdaq:DEPO) announced mixed results of their BREEZE 3 Phase III results of Serada<sup>®</sup> (extended-release gabapentin) for menopausal hot flashes on October 14, 2011 as shown:

| Depomed BREEZE3 Results  |         |          |          |
|--------------------------|---------|----------|----------|
| Statistical Significance | 4 Weeks | 12 Weeks | 24 Weeks |
| Frequency                | YES     | NO       | NO       |
| Severity                 | YES     | YES      | NO       |

Source: Depomed

**Safety:** The incidence of dizziness 12.7% for Serada versus 3.4% for placebo. Somnolence (sleepiness) was 6.0% for Serada versus 2.7% for placebo. Withdrawals due to adverse events were 17% for Serada versus 12% for placebo.

**Trial Design:** 600 females, randomized double-blind placebo-controlled study. 1800mg Serada (600mg morning 1200mg Evening)

**We believe the results of this trial (and previous BREEZE trials) shows that anti-seizure / postherpetic neuralgia drugs, such as Depomed's gabapentin, are not the solution to menopausal hot flashes, especially when side effects such as dizziness and sleepiness are taken into account.**

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<sup>®</sup> selectively modulates estrogen receptor beta (ER $\beta$ ), which would avoid the safety issues in hormone replacement therapies that activate the ER $\alpha$  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<sup>®</sup> could become the first botanical blockbuster drug which we believe represents an intriguing opportunity for patient investors.

## RESEARCH REFERENCES

<sup>1</sup> 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>

<sup>2</sup> Depomed, Inc. "Serada Phase 3 Results" October 12, 2009

<http://phx.corporate-ir.net/External.File?item=UGFvZW50SUQ9Mjg4NDJ8Q2hpbGRJRjRD0tMXxUeXBIPtM=&t=1>

## Company Description



Emeryville, California-based Bionovo, Inc. discovers and develops drugs focusing on women's health needs and cancer treatments. Their lead drug candidate is Menerba<sup>®</sup> (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 (ER $\beta$ ) 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<sup>®</sup>, 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.

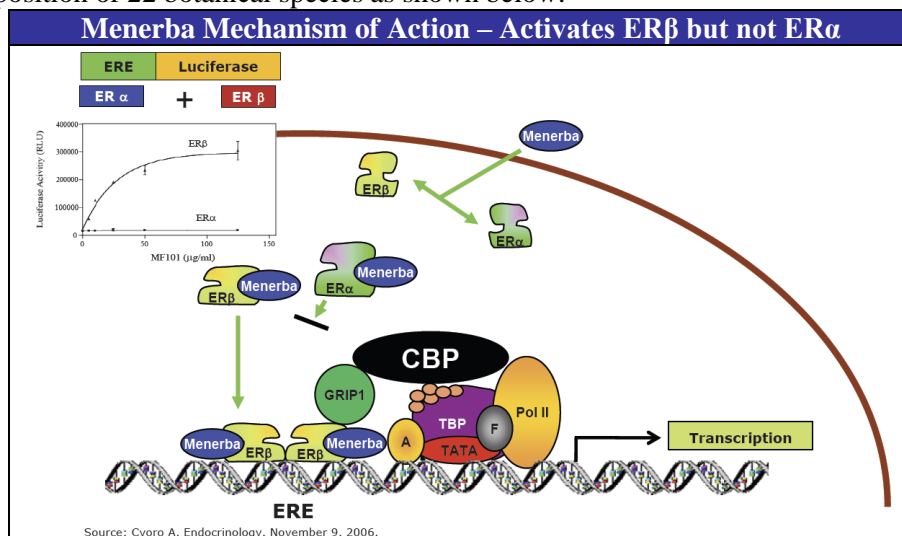
| Calendar Quarter | MILESTONES & EVENTS  |
|------------------|--|
| Q3 2010          | ✓ EMA Guidance & Trial Approval<br>✓ FDA CMC Approval                        |
| Q4 2010          | ✓ FDA Trial Approval   |
| Q1 2011          | ✓ Manufacture High-Dose for Testing<br>✓ Initiate Phase I (High-Dose Safety) |
| Q2 2011          | ✓ Complete Phase I (High-Dose Safety)<br>✓ Manufacture Menerba for Phase III |
| Q3 2011          | ✓ Complete Toxicology Testing<br>✓ Data Phase I (High-Dose Safety)           |
| Q4 2011          | ✓ Initiate Menerba Phase IIIa – U.S.   |
| Q4'11-Q4'12      | 5 Interim Data Safety Reviews  |
| Q1 2013          | Data Menerba Phase IIIa – U.S.<br>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<sup>®</sup> at this time as it may be dependent on a partnership. In addition, we have not yet included Bezielle<sup>®</sup>, Seala<sup>®</sup> or any other pipeline candidates in our financial model due to the current uncertainty regarding development timelines and resources.

## Menerba<sup>®</sup> for Menopausal Hot Flashes

Bionovo's Menerba<sup>®</sup> (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 (ER $\alpha$ ) and beta (ER $\beta$ ), it only activates (agonist) the ER $\beta$  transcriptional pathways which studies have shown to control hot flashes. Menerba is also thought to be safer since it does not activate the ER $\alpha$  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: Cvoro A, Endocrinology, November 9, 2006.

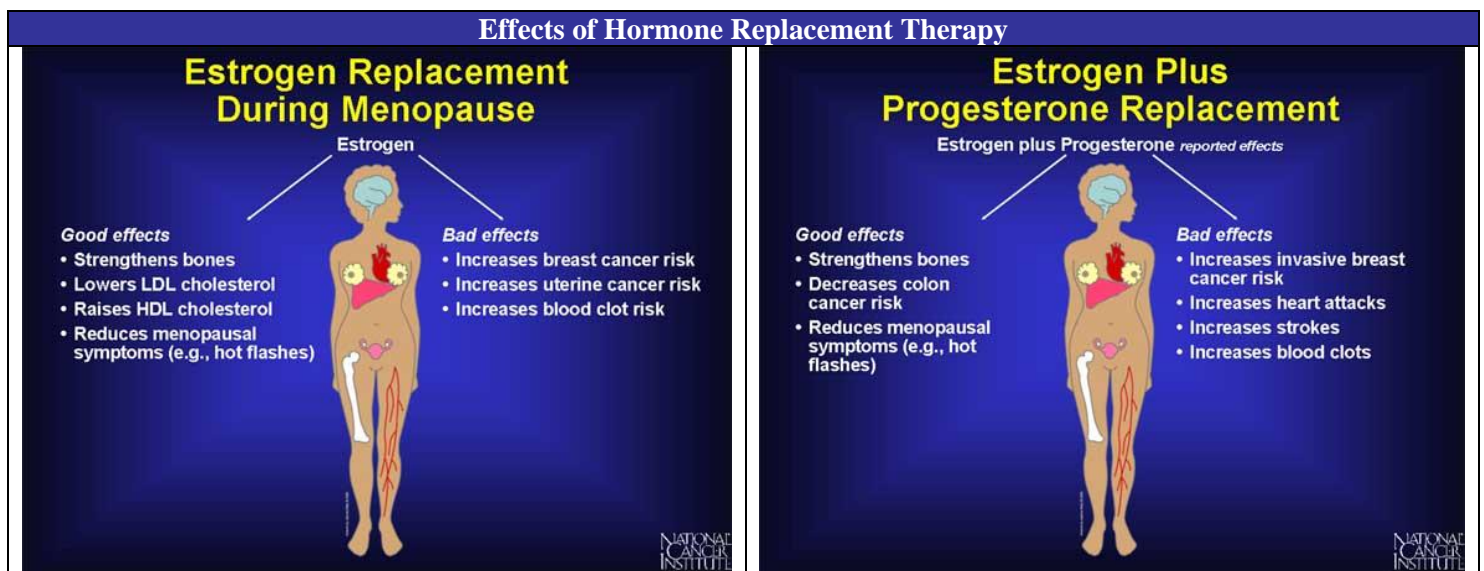
Source: Bionovo Inc.

## 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>

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.

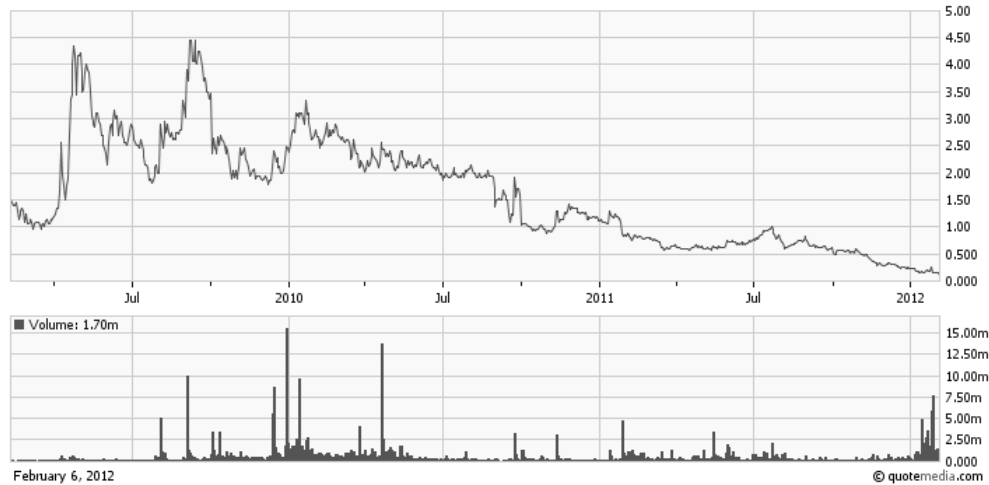
In addition, a dietary supplement called Femarelle® (DT56a) is currently being marketed for menopausal symptoms, which contains 322mg of soy extract and 108mg of laxeed, to be taken twice daily. However, it is not FDA-approved and is marketed as a dietary supplement rather than a therapeutic drug. The 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 Vasomotor Symptoms*” <http://clinicaltrials.gov/ct2/show/NCT01063725> )

**RESEARCH REFERENCES**

Women's Health Initiative – Estrogen Alone Study [http://www.nhlbi.nih.gov/whi/estro\\_alone.htm](http://www.nhlbi.nih.gov/whi/estro_alone.htm)

Women's Health Initiative – Estrogen & Progesterone Study [http://www.nhlbi.nih.gov/whi/estro\\_pro.htm](http://www.nhlbi.nih.gov/whi/estro_pro.htm)

**DISCLOSURES**



Ratings and Price Target Changes over Past 3 Years  
 Initiated August 9, 2010 – Strong Speculative Buy - Price Target \$7.50  
 Updated August 3, 2010 – Strong Speculative Buy - Price Target \$5.00

**Analyst Certification:** I, Stephen M. Dunn, the author of this research report certifies that a.) All of the views expressed in this report accurately reflect my personal views about any and all of the subject securities or issuers discussed b.) No part of my 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.

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|---|-----|
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| 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  |
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| Has the Firm or affiliates received investment banking services compensation in previous 12 months?   | NO  |
| 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 |
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|---------------------------|-------------------|--------------------|----------------------|-------------------|--------------------|
| Ratings Distribution      | % of Total        | % of Total         | Ratings Distribution | % of Total        | % of Total         |
| Strong Buy                | 14%               | 0%                 | Buy                  | 100%              | 29%                |
| Strong Speculative Buy    | 86%               | 33%                | Hold/Neutral         | 0%                | 0%                 |
| Buy                       | 0%                | 0%                 | Sell                 | 0%                | 0%                 |
| Speculative Buy           | 0%                | 0%                 | Total                | 100%              | 29%                |
| Neutral                   | 0%                | 0%                 |                      |                   |                    |
| Avoid/Sell                | 0%                | 0%                 |                      |                   |                    |
| Under Review              | 0%                | 0%                 |                      |                   |                    |
| Not Rated                 | 0%                | 0%                 |                      |                   |                    |
| Restricted                | 0%                | 0%                 |                      |                   |                    |
| Total                     | 100%              | 29%                |                      |                   |                    |

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