



Ausio Pharmaceuticals, LLC

Medicines for an Aging Population™

Fact Sheet
August 2011



About Ausio Pharmaceuticals

Ausio Pharmaceuticals, LLC is a biopharmaceutical company focused on the development of safe and effective medicines for the aging population. The lead product is AUS-131 (also referred to as S-equal) that is being developed as an oral formulation for the most common medical conditions affecting the elderly: Vasomotor Symptoms (VMS, hot flashes) associated with menopause and Benign Prostatic Hyperplasia (BPH or enlarged prostate). Phase 1 clinical trials have been completed, and Phase 2a studies are underway.

In addition, topical cream and gel formulations have been developed and have progressed to clinical trials, where a 3-month clinical study demonstrated a significant reduction in blemishes, indicating support for potential future use against acne.

Product Profile

AUS-131 is a potent, first-in-class, non-hormonal, non-steroidal, selective estrogen receptor β (ER β) agonist. The receptor binding activity for ER β is 0.73 nM vs. 6.41 nM for ER α . The safety issues associated with estrogen on the breast and uterus are thought to be due to ER α . A selective ER β agonist may provide a safer medicine for the patient.

Preclinical efficacy studies have been conducted with AUS-131 for VMS, BPH and osteoporosis. The animal studies were carried out in industry-standard models that are predictive of human efficacy. In the VMS hot flash model, AUS-131 reduced skin temperature to the same level as ethynyl estradiol. In an osteoporosis model, AUS-131 had equivalent effects as estradiol benzoate on bone formation and peak load on lumbar vertebrae. In the BPH model, a reduction in prostate weight with AUS-131 was similar to that of a potent anti-androgen.

The preclinical studies demonstrated a large safety margin in both rodents and non-human primates. The compound and method for synthesis are covered by world-wide patent applications, with patents issued in the US, China and Australia.

Clinical Development

Clinical trials on AUS-131 began in August 2008 after a successful Pre-IND meeting with FDA and filing of the US IND. A full ICH/FDA compliant set of preclinical safety studies were carried out. Two Phase I clinical trials (single dose and 14-day repeat dose) have been completed. Both studies demonstrated that the drug was well tolerated at multiples of the expected efficacious dose. The 14-day repeat dose study also showed that steady state was achieved by 3 days of BID dosing of the immediate release capsules. International multi-center Phase 2a efficacy trials in patients with VMS and BPH have begun at sites in Australia and the US.

Partnering Strategy

Ausio is seeking a partner for AUS-131 for certain indications in the US and is open to partnering arrangements for ex-US markets, including Japan, Korea, China and Europe.

**AUS-131 is a First-in-Class
Estrogen Receptor β
Selective Agonist in Phase 2
Clinical Development for
Large Markets with Major
Unmet Medical Needs**

Issued Patents

- US 7,396,855, US 7,960,432
Compositions and products containing S-equal, and methods for their making (expiry December 2024)
- US 7,528,267, US 7,960,573
Method for enantioselective hydrogenation of chromenes (expiry January 2027)
- AUS 2003259220
Compositions and products containing enantiomeric equal, and methods for their making (expiry July, 2023)
- CN ZL 03822155.1
Compositions and products containing S-equal, and methods for their making

Market Opportunity

Vasomotor Symptoms (VMS) In the US, there are 40 million post-menopausal women. The major products for VMS are estrogens with current US sales of \$1.8 billion. The results of the Women's Health Initiative study showing an increased risk of breast cancer, cardiovascular events, stroke and venous thrombosis with long-term estrogen-progestin therapy dramatically decreased the use of estrogen therapy and increased the market opportunity for new VMS therapy with an estrogen receptor β (ER β) selective agonist, such as AUS-131.

Benign Prostatic Hyperplasia (BPH) The incidence of BPH increases with age and is > 50% in men over the age of 65. It is estimated that in 2010, 17 million men will be in this age group. The total US market for drugs for BPH is approximately \$2.5 billion. The marketed drugs fall into two classes: 5 α -reductase inhibitors and adrenergic receptor α blockers. The highest volume products are the α blockers, which relieve the symptoms of BPH but do not reduce prostate size.

Osteoporosis Osteoporosis and low bone mass is a major public health threat for both women and men aged 50 and older. The National Osteoporosis Foundation estimates that in the U.S. 61 million people will be affected by osteoporosis in 2020. The global sales of drugs for the prevention and treatment of osteoporosis exceeds \$10 billion. The market is dominated by Hormone Replacement Therapy (HRT), bisphosphonates and Selective Estrogen Modulators (SERMs). The substantial share held by HRT prior to the publication of the Women's Health Initiative study indicates an opportunity for an estrogen receptor β (ER β) selective agonist, such as AUS-131.

Acne The forecast sales for the world-wide acne market is estimated at \$2.7 billion by 2011. The major topical products for acne are benzoyl peroxide, antibiotics, and combinations of the two. Often the peroxide therapy results in burning and dry skin. A safe and effective topical anti-androgen therapy is likely to expand the market and capture a large share.

Company Presentations

- ◆ October 16-19, 2010. 9th International Symposium of the Role of Soy. Washington D.C.
- ◆ October 6-9, 2010. 21st Annual Meeting of The North American Menopause Society. Chicago, Illinois.
- ◆ September 11-15, 2009. The American Society for Bone and Mineral Research. Denver, Colorado.
- ◆ June 22, 2009. Endocrinology Society Annual Meeting. Washington D.C.
- ◆ November 10, 2008. 8th International Meeting on the Role of Soy in Health and Disease. Tokyo, Japan.



Contact Information

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Management Team

Richard Jackson, PhD **President & CEO**

He has 40 years in academic medicine and the pharmaceutical business. He held executive positions as Head of Research at Marion Merrell Dow, Wyeth, and Atrix Laboratories before founding Ausio.

Rick Schwen, PhD, DABT, RAC **Vice President, Regulatory Affairs**

He has 23 years experience in drug discovery, toxicology and regulatory affairs at Procter & Gamble. He was VP of Global Safety and Regulatory Affairs at Kendle International and VP of Regulatory and Clinical Quality Assurance at Parexel International before joining Ausio.

Jeff Greiwe, PhD **Associate Director of Clinical Development**

He has 13 years experience in academic and pharmaceutical research. He held positions at Washington University School of Medicine, Xanodyne Pharmaceuticals, and LBR Regulatory

Board of Managers

Kevin Jackson (Chairman)
Chief Executive Officer, Sanitarium Health and Wellbeing

Jeff Courtney
Group Director International, Sanitarium Health and Wellbeing

Richard Jackson
President & CEO, Ausio Pharmaceuticals, LLC

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