BiologicsMD™

Company Overview

BiologicsMD was founded in 2010 to develop highly-targeted, novel human therapeutics for the treatment of hair loss diseases and conditions, as well as severe bone disorders. The company's portfolio of hair cycle stimulators (HCS) are 'first-in-class' treatments that hold the promise to restore hair and prevent hair loss in conditions of alopecia by providing powerful stimulatory effects directly to the target receptors at the hair follicle – and to do so with sustained therapeutic exposure in either a single dose or very infrequent dosing regimens. The company is working on formulation and delivery vehicles that can accommodate parenteral, local, and topical administration.

Technology Solutions … for Better Medicines

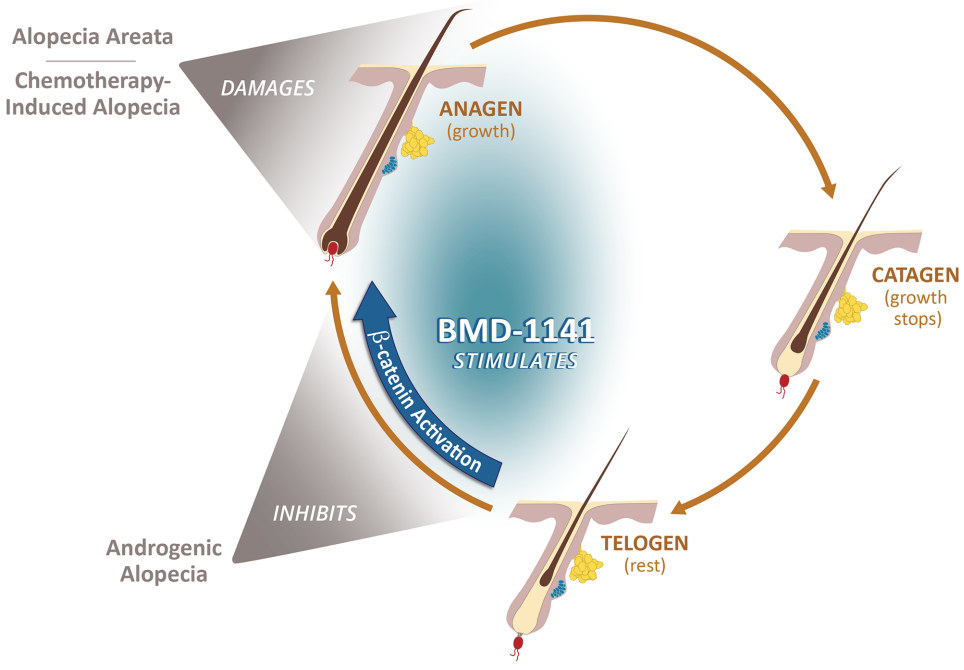
The company's core, patented technology relies on targeting physiologically active agents to Type I collagen, found in skin and bone, via fusion to a proprietary collagen-binding domain. BiologicsMD has developed a series of recombinant fusion proteins that specifically target the parathyroid hormone (PTH) receptor pathway with sustained activity at a low total dose (bioactive for a period of months from a single application).

The company has multiple assets in 3 therapeutic areas (alopecia, bone repair and spinal fusion, and prevention of bone metastases in cancer). Alopecia is the lead program with 3 discrete products in development:

Alopecia Pipeline – Hair Cycle Stimulation

First-in-class Hair Class Stimulators (BMD-1141, BMD-1341 and BMD-2341) are based upon biologic hormones that are known stimulators of the hair follicle growth cycle and include a targeting domain which focuses the proteins to the target site with negligible off-target effects and a persistence of hair growth effect.

BMD-1141 – is a subcutaneous injection of the recombinant agonist PTH-CBD which is a fusion of PTH(1-33) to a collagen binding domain (CBD) from ColH collagenase. This lead program is being developed to restore hair-growth and prevent recurrence of hair-loss in patients with alopecia areata. BMD-1141 demonstrated significant prevention of hair-loss through beta-catenin stimulation of hair follicles in the highly predictive animal model of alopecia areata (C3H/HeJ engrafted mice). The product manufacturing process has been developed and GLP toxicology is in progress, with the project moving towards IND filing in 2017.



Board of Directors:
Ramsay Ball
Calvin Goforth, PhD
Lynn Kirkpatrick, PhD
J. David Owens

Mission:
The mission of BiologicsMD is to develop highly targeted biologic therapies for disorders of hair-loss and therapeutic-device combinations for the treatment of severe bone disease. The company plans to achieve rapid value creation by building a high-quality pipeline leveraging their core targeting technology. The business model calls for a strategic acquisition or licensure to a major pharmaceutical firm following early clinical trials.

Intellectual Property:
PCT patent applications for the company's technology were filed in 2008 to cover PTH-CBD agonists and antagonists for stimulating bone growth, reversing bone loss, and treating hair-loss. Claims include compositions and methods of treatment. National applications are being sought in the United States, Europe, Japan and Canada. A US patent entitled "Fusion Proteins of Collagen-Binding Domain and Parathyroid Hormone" was issued May, 2013 (8,450,273). Divisional applications remain pending. BiologicsMD will seek to gain a twelve-year extension of exclusive rights via biologics data exclusivity under patent term restoration following FDA approval. The Japanese Patent Office issued Patent No. 5520811 in 2014.

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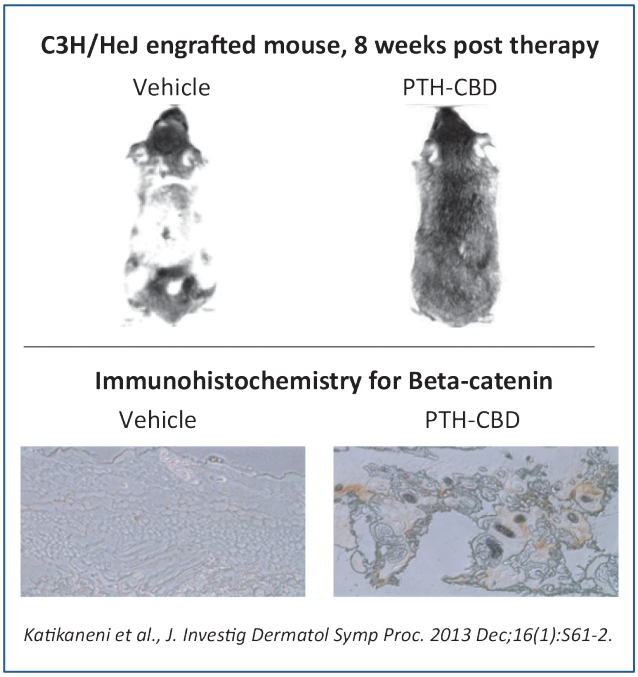
BMD-1341 – is a topical formulation of BMD-1141 and is being developed to treat androgenic alopecia – or male-pattern baldness. The product is currently in formulation development.

BMD-2341 – is a topical formulation of the agonist PTH-PKD-CBD, and is being developed to facilitate hair regrowth and prevent hair-loss in chemotherapy-induced alopecia. PTH-PKD-CBD binds more tightly to collagen, and when applied topically, remains resident in the dermal layer, stimulating the anagen (growth) phase of the hair cycle. Efficacy has been demonstrated in animal models of chemotherapy-induced alopecia. The program is in the formulation development stage.



Katikaneni et al., J. Investig Dermatol Symp Proc. 2013 Dec;16(1):S61-2.

Spinal Fusion

BMD-1231 – is a bone graft substitute that includes (i) recombinant PTH-CBD and (ii) a β-tricalcium phosphate and collagen putty used for spinal fusion procedures in lieu of autologous bone grafts. The osteogenic and bone-remodeling effects of the PTH-CBD protein have been demonstrated to last 4-6 months from a single dose in rodent models. It is anticipated that this program will be grant funded by a pending NIH SBIR Direct to Phase 2 grant for preclinical efficacy testing in the Boden model of posterolateral spinal fusion.

Bone Metastases

BMD-3151 – is a subcutaneous injection of the PTHrP antagonist, PTH(7-33)-CBD, and is being studied for the prevention and treatment of breast cancer metastasis to the bone. The program is in early preclinical development with preclinical animal efficacy data suggesting that the compound will prevent breast cancer bone metastases. Funding is being provided though Department of Defense grants in an academic collaboration.

Key Personnel

The BiologicsMD management team is well balanced, with significant scientific and development expertise, complemented by contracted regulatory experts and outsourced expertise for manufacturing and toxicology. Key team members include:

J. David Owens, President & CEO, brings 30 years of pharmaceutical and biotechnology management and commercialization experience. Mr. Owens was formerly the Chief Business Officer for Novira Therapeutics, Inc., a privately held antiviral drug discovery company, were he co-led a syndicated angel investment in 2011 and then a Series A financing in 2012. Prior to Novira, Mr. Owens held executive positions as Senior Vice President, and Business Unit Head of the Surgical Products Division at King Pharmaceuticals (now part of Pfizer) and prior to that as Vice President of Global Marketing & Medical Affairs at Aventis Pharma (now part of Sanofi). Earlier in his career, Mr. Owens held commercial operations roles at Genentech, Merck and Abbott Labs. Mr. Owens is a graduate of the University of Wisconsin, School of Pharmacy and a former Registered Pharmacist.

Robyn Goforth, PhD, Chief Scientific Officer, has over 15 years of experience in functional protein design and production. She has published over a dozen scientific papers in the fields of biochemistry and bioengineering. Dr. Goforth has also been principal investigator and co-principal investigator on over $10MM in National Institute of Health, Department of Energy, and Small Business Innovation Research grants. She was named in June 2011 one of the top 40 business leaders Under 40 by the Arkansas Business Journal. She also serves as an appointed member of the State Science Advisory Committee.

Rob Gensure, MD, PhD, Chief Medical Officer, is one of the inventors of the technology and is Chief of Pediatric Endocrinology at Tufts University School of Medicine in Boston. He is board certified in pediatric endocrinology and pediatrics. Dr. Gensure graduated from Tulane University School of Medicine and completed his residency at Massachusetts General Hospital.