

Calithera files to raise up to \$80 million in IPO

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Tumor metabolism and immunology specialist Calithera Biosciences Inc. on Tuesday revealed plans to raise up to \$80 million in a yet-to-price initial public offering (IPO). The company will debut on Nasdaq under the symbol CALA and said it would use proceeds from the offering to advance CB-839, its phase I glutaminase inhibitor for triple-negative breast cancer and multiple myeloma as well as a preclinical arginase inhibitor.

South San Francisco-based Calithera is evaluating CB-839, its wholly owned lead program, in a trio of single-agent phase I trials enrolling patients with solid tumors, leukemias, lymphomas and multiple myeloma. Initiated in February 2013, the dose-escalation trials are intended to establish tolerability and safety of the drug. Each of the single-agent trials is also offering an expansion stage to seek preliminary evidence of efficacy. (See *BioWorld Today*, Oct. 30, 2013.)

In addition to evaluating CB-839 as a single agent, Calithera plans to run two phase Ib combination trials, one pairing CB-839 with paclitaxel in patients with triple-negative breast cancer and a second combining it with Pomalyst (pomalidomide, Celgene Corp.) and dexamethasone in patients with multiple myeloma.

Early stage findings have been encouraging for the company. It reported preclinical data for CB-839 in December 2013 showing the drug reduced cancer cell viability and induced apoptosis in the majority of triple-negative breast cancer cell lines tested. CB-839 also demonstrated significant antitumor activity in two triple-negative breast cancer xenograft models, both as a single agent and in combination with paclitaxel, the company said.

Calithera next plans to initiate at least one phase II trial of CB-839 in late 2015 or early 2016, pending FDA feedback on the results of the phase I trials and protocols for one or more planned phase II trials. Altogether, the company expects to spend as much as \$35 million moving CB-839 through completion of phase II.

The company's preclinical tumor immunology program is focused on developing selective inhibitors of arginase, an enzyme that depletes arginine, a nutrient that's critical for the activation, growth and survival of the body's cancer-fighting immune cells. Calithera said it believes that arginase inhibition can promote antitumor immune activity by restoring arginine levels, thereby restoring activation of patients' cancer-fighting immune cells. The company is optimizing candidate molecules with the aim of submitting an investigational new drug application (IND) to the FDA near the end of 2015, it said. It plans to spend as much as \$15 million to move that program through a phase I trial.

Research and drug discovery activities intended to advance a third program to IND are also planned, with as much as \$10 million devoted to the endeavor.

Calithera's 36-employee work force is led by co-founder Susan Molineaux, who also founded and served as CEO of Proteolix Inc., where she and several members of Calithera's management team led the group that discovered and advanced Kyprolis (carfilzomib) through phase II before selling Proteolix to Onyx Pharmaceuticals Inc. for \$851 million in 2009. Onyx later was snapped by Amgen Inc. (See *BioWorld Today*, Oct. 19, 2009, and Aug. 27, 2013.)

Calithera first filed confidentially as an emerging growth company in July under the Jumpstart Our Business Startups Act. Since its founding in March 2010, the company has raised net proceeds of about \$79.4 million from the sale of preferred stock, including net proceeds of \$16 million from the issuance and sale of 91.3 million shares of series D preferred stock in July 2014. It recorded a net loss of \$12.3 million in 2013 and another net loss of \$9.6 in the first half of 2014. As of June 30, the company had cash and equivalents of \$27.8 million, which it expected would be sufficient to support planned preclinical studies and clinical trials for its product candidates through at least the end of 2015.

Prior to the offering, Delphi Ventures holds 19.5 percent of Calithera's outstanding shares, while Morgenthaler Venture Partners, Advanced Technology Ventures and Adage Capital Management each owned about 18 percent of shares. The company also has backing from Longwood Fund, which owns 5.8 percent of shares.

Citigroup Global Markets Inc. and Leerink Partners LLC are the joint bookrunners on the deal, joined by underwriters Wells Fargo Securities LLC and JMP Securities LLC.

In other financings news:

Ibio Inc., of Newark, Del., reported plans to raise nearly \$500,000 through the sale to Aspire Capital Fund LLC of about 1.1 million shares of common stock priced at 44 cents each. Aspire committed to buy up to \$9.5 million in additional shares of common stock over a 24-month period once the SEC declares a registration statement for the transaction effective. No warrants are associated with the agreement. Ibio said the deal would help ensure adequate funding for development of its idiopathic pulmonary fibrosis therapy, an endostatin modulator, to a point at which efficacy could be demonstrated and will help to enable expansion of its Brazil product partnerships.

Immunovaccine Inc., of Halifax, Nova Scotia, had trading of shares (TSX:V:IMV) temporarily halted Tuesday as the company moved to undertake an overnight marketed offering of about \$5 million common shares. Net proceeds of the offering will be used primarily to advance its R&D and clinical cancer and infectious vaccine candidates. Mackie Research Capital Corp. will be the lead underwriter and sole bookrunner on behalf of a syndicate of underwriters including Maxim Group LLC and Cormark Securities Inc. Immunovaccine granted to the underwriters a 30-day overallotment option entitling them to acquire up to an additional 15 percent of common shares distributed in the offering at the same issue price as the offering. The company, which gained attention Monday after announcing positive data from an early trial of an Ebola vaccine incorporating its Depovax adjuvanting technology, expects to close the offering during the week of Sept. 1. (See *BioWorld Today*, Aug. 26, 2014.)