Taxus Cardium Pharmaceuticals Group Inc.
Form 8-K
September 13, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of

the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): September 12, 2016

Taxus Cardium Pharmaceuticals Group, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	001-33635	27-0075787
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
11750 Sorrento Valley Rd., Suite 130, San Diego, California		92121
(Address of Principal Executive Offices)		(Zip Code)

Registrant's Telephone Number, Including Area Code: (858) 436-1000

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 8.01 FDA Approves Generx for Phase 3 Clinical Trial

On February 9, 2016, the U.S. FDA Center for Biologics Evaluation and Research (CBER) cleared the Angionetics' Generx® [Ad5FGF-4] angiogenic gene therapy cardiac biologic product candidate for Phase 3 clinical study as a new, single dose, treatment for patients with myocardial ischemia and refractory angina due to advanced coronary artery disease (the AFFIRM study). The Ad5FGF-4 product candidate is being developed by Angionetics as a new and innovative biologic tool for use by the interventional cardiology community. For more information about the Generx clinical development program, visit www.angionetics.com

The Generx product candidate provides a new therapeutic approach, termed "medical revascularization", pioneered by researchers at Angionetics and its predecessor companies, Collateral Therapeutics, Cardium Therapeutics, and Schering AG (now Bayer Healthcare). After over two decades of basic, pre-clinical and clinical research in the field of gene therapy by universities, research institutes, as well as pharmaceutical and biotechnology companies worldwide, Angionetics' Generx represents one of only a few cardiovascular DNA-based therapeutic product candidates to successfully advance into late-stage, U.S. Phase 3 clinical study.

Analogous to the rapidly advancing field of immunotherapy for cancer, researchers at Angionetics seek to harness the human body's natural healing capacity in patients with certain forms of ischemic heart disease. The Generx product candidate is designed to leverage cardiac plasticity by stimulating and augmenting the heart's innate capacity to grow functional collateral vessels to improve cardiac perfusion, increase exercise capacity and to reduce angina attacks and the use of anti-anginal medications.

The Generx product candidate is biologically engineered using an E1-region deleted, adenovector serotype 5 to deliver the 621 base pair human FGF-4 DNA sequence (including the secretory signal sequence), under the control of a modified CMV promoter. The Ad5FGF-4 biologic product candidate is administered into the heart using a standard balloon catheter, intended to transfect cardiac cells which researchers believe release the FGF-4 protein, which in turn activates other growth factors and angiogenic pathways to modulate the enlargement of pre-existing collateral arterioles (arteriogenesis), and the formation of new capillary vessels (angiogenesis) in select ischemic regions downstream from large coronary arteries.

The Generx biologic product candidate is initially being developed for an estimated 1.0 million U.S. patient population (and an estimated 7.0 million patients worldwide) who have advanced coronary artery disease and refractory angina due to myocardial ischemia. These patients are no longer responsive to maximally tolerated anti-angina medication, have no immediate angiographic risk, and thus, based on contemporary clinical research findings, are not candidates for mechanical revascularization procedures, and would be unlikely to benefit from early prophylactic percutaneous coronary intervention (PCI) involving the use of stents, and coronary artery bypass graft surgery (CABG).

The Company issued a press release announcing the FDA approval of the Phase 3 clinical trial for Generx on September 12, 2016. A copy of the press release is attached as Exhibit 99.1 hereto

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Description of Exhibit

No.

99.1 Press release issued on September 12, 2016

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Cardium Therapeutics, Inc.

By: /s/ Christopher J. Reinhard
Christopher J. Reinhard
Chief Executive Officer

Date: September 12, 2016

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