GALECTIN THERAPEUTICS INC
Form 8-K
February 07, 2013

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): February 1, 2013

GALECTIN THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Nevada	001-31791	04-3562325
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4960 PEACHTREE INDUSTRIAL BOULEVARD
NORCROSS, GA 30071
(Address of principal executive office) (zip code)

Registrant's telephone number, including area code: (678) 620-3186

N/A
(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))

SECTION 1 – REGISTRANT'S BUSINESS AND OPERATIONS

Item 1.01 Entry into a Material Definitive Agreement.

On February 1, 2013, Galectin Therapeutics Inc. (the "Company) entered into an Amended and Restated Master Services Agreement (the "Agreement") with CTI Clinical Trial Services, Inc. and CTI Clinical Consulting Services, Inc. (individually and collectively, "CTI"), whereby CTI will assist the Company in the design, development and conduct of one or more clinical research studies from time to time. All work performed by CTI for the Company will be conducted pursuant to the terms of work orders that describe the specific obligations undertaken by CTI with respect to any particular clinical research study sponsored or conducted by the Company. Unless otherwise terminated sooner in accordance with the terms of the Agreement, the Agreement will be effective until January 31, 2018.

On February 1, 2013, the Company entered into a work order (the "Work Order") with CTI in accordance with the terms of the Agreement. The Work Order provides that CTI will provide services with respect to the Company's Phase I Clinical Trial to evaluate the safety of the Company's drug GR-MD-02 in subjects with Non-Alcoholic Steatohepatitis ("NASH") with advanced hepatic fibrosis. CTI will provide the following services, amongst others, with respect to the Work Order:

- reviewing and providing notices regarding IND safety reports,
- selecting investigators and monitors for the study,
- informing investigators of new observations,
- monitoring the progress of the study and reviewing ongoing investigations,
- keeping certain records,
- inspecting the Company's records and reports, and
- disposing of any unused supply of the investigational drug.

The Work Order provides for CTI's anticipated involvement in the study from February 1, 2013 until March 31, 2014. The estimated budget for the Work Order is $2,155,440, which is subject to change as necessary, with upfront startup costs of approximately $384,000 and the remaining majority of the payments made either on a monthly basis throughout the term of the project as the work is performed or with specific costs billed as incurred.

The Agreement or any work order may be terminated for any reason by any party upon ninety (90) days prior written notice to the other party. In addition, the Agreement may be terminated by either party immediately if the other party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, files or has filed against it (and does not obtain a dismissal within ninety (90) days) a petition of bankruptcy, or has a receiver appointed for it or a substantial part of its assets, among other reasons. Further, the Agreement or any relevant work order may be terminated immediately by written notice from the Company, in the following circumstances:

(1) The FDA withdraws authorization and approval to conduct a study; or

(2) The Company reasonably determines that for medical, clinical or patient safety reasons, a study should terminate immediately.

In addition, either party may terminate the Agreement or any work order for material breach upon thirty (30) days' written notice specifying the nature of the breach, if such breach has not been substantially cured within the thirty (30) day period.

SIGNATURES

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

Galectin Therapeutics Inc.

Date: February 7, 2013

By: /s/ Peter G. Traber
Peter G. Traber, M.D.
President, Chief Executive Officer &
Chief Medical Officer