Galmed Pharmaceuticals Ltd.
Form 6-K
May 03, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16

Under the Securities Exchange Act of 1934

For the Month of May 2016

001-36345

(Commission File Number)

GALMED PHARMACEUTICALS LTD.

(Exact name of Registrant as specified in its charter)

16 Tiomkin St.

Tel Aviv 6578317, Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F x Form 40-F ¨

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

On May 3, 2016, Galmed Pharmaceuticals Ltd. (the “Company”) issued a press release announcing it has signed an investigator initiated clinical trial agreement (the "Agreement") with the Icahn School of Medicine at Mount Sinai ("Mount Sinai") to conduct a Phase IIA Study entitled: "A Placebo-controlled Single-blinded Study of Aramchol™ with Supplemental Vitamin D in Patients with Vitamin D Deficiency and Nonalcoholic Fatty Liver Disease (NAFLD) and Fibrosis” (the “Study”). The Study will be conducted under the leadership of principal investigator, Andrea Branch, PhD, Professor of Medicine in Mount Sinai, United States and in additional center in Israel. The Study will enroll 80 patients with NAFLD and fibrosis, and is anticipated to be completed in the first half of 2018. The Study design includes four dose alternatives: (a) Aramchol™ 400 mgs, (b) Vitamin D, (c) Aramchol™ 400 mgs and Vitamin D in combination, and (d) Placebo, administrated for 24 weeks, followed by a 4-week follow-up period. The Study’s primary endpoint is the change in liver stiffness (baseline to end of treatment), measured by Magnetic Resonance Elastography (MRE). Secondary endpoints include changes in the intrahepatic fat content (measured by MRI and FibroScan/CAP), and other metabolic parameters. The Company has filed a patent application for the composition of matter patent on the new combination therapy.

Pursuant to the terms of the Agreement, the Company shall provide its proprietary drug product candidate Aramchol™ and shall provide funds to conduct the Study over the duration of the Study. Under the Agreement, Mount Sinai grants the Company a worldwide, perpetual, irrevocable, fully paid up, royalty-free, non-exclusive, non-sublicensable (except to affiliates) license to use any Invention (as defined in the Agreement) for its internal research and development purposes. In addition, Mount Sinai further grants the Company a worldwide, perpetual, irrevocable, fully paid up, royalty-free, non-exclusive, non-sublicensable (except to affiliates) license to make, use, sell, offer for sale and import any Inventions that are new formulations or improvements or derivatives of Aramchol™, provided that such license shall be subject to Minimum Licensing Terms (as set out in the Agreement). Further, Mount Sinai grants the Company an exclusive option to negotiate an exclusive license to practice Mount Sinai’s rights in Inventions, subject to certain terms as set out in the Agreement.

All data and results from the Study (the “Study Data”) shall be the property of Mount Sinai; however, the Company shall be entitled to make use of such Study Data for any legal purpose after the earlier of the publication of the Study Data by Mount Sinai or twelve months after disclosure of the Study Data by Mount Sinai; provided, however, that in the event any Study Data materially contributes to any regulatory approval of any products of the Company combined with Supplemental Vitamin D3, the Company agrees to negotiate a reasonable compensation appropriate for Mount Sinai's contribution.

Either party may terminate the Agreement (i) upon the other party’s breach if such party fails to cure such breach within thirty days after receiving written notice thereof, or (ii) if the authorization and approval to perform the Study in the United States is withdrawn by the FDA or, if the emergence of any adverse reaction or side effect with the drug administered or the device employed in the Study is of such magnitude or incidence in the opinion of either the Company or Mount Sinai to support termination. The Company may terminate the Agreement for convenience upon thirty days’ prior written notice. Further, either party may terminate the Agreement upon customary events such as insolvency or bankruptcy. Upon any termination, (i) Mount Sinai will stop screening and enrolling subjects and will reasonably cooperate with the Company to continue monitoring Study Subjects (as defined in the Agreement) and shall reasonably cooperate with the Company to provide for an orderly winding down of the services provided under

the Agreement, and (ii) all CRFs (as defined in the Agreement) outstanding must be completed and returned to the Company together with completed product inventory and records.

The Company shall indemnify Mount Sinai from and against all liabilities Mount Sinai may suffer to the extent directly arising from (i) the Company's negligence or misconduct in the manufacture of any study drugs or devices provided by Company to Mount Sinai for use in the Study; (ii) the exercise of the license rights granted to the Company, subject to customary exclusions.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

This Form 6-K is incorporated by reference into the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on August 11, 2015 (Registration No. 333-206292) and its Registration Statement on Form F-3 filed with the Securities and Exchange Commission on March 31, 2015 (Registration No. 333-203133).

Exhibit Index

Exhibit No.	**Description**
99.1	Press Release, dated May 3, 2016

SIGNATURES

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

Galmed Pharmaceuticals Ltd.

Date: May 3, 2016 By: /s/ Allen Baharaff
Allen Baharaff

President and Chief Executive Officer