

Galmed Pharmaceuticals Ltd.
Form 6-K
July 28, 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 July 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.

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Form 20-F 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 July 28, 2016, Galmed Pharmaceuticals Ltd. (the "Company") issued a press release announcing it had entered into a license agreement (the "Agreement") with Samil Pharma. Co., Ltd. ("Samil"), for the commercialization of Aramchol™ (with the option to manufacture) in the Republic of Korea (the "Territory").

Under the terms of the Agreement, the Company grants Samil an exclusive licence (the "License") for fatty liver indications including nonalcoholic Steatohepatitis, or NASH (the "Field of Use") in the Territory to the Licensed Information and the Patents (as defined in the Agreement) for the import, marketing, use, sale, offer for sale, commercialisation and distribution (and, if the option is exercised, manufacture) of the Products (as defined in the Agreement).

The License shall remain in force with respect to each Product (if not previously terminated in accordance with the provisions of the Agreement) until the later of: (i) the date of expiry in the Territory of the last of any Patent covering such Product or any formulation, dosing or administration form thereof; and (ii) the date of expiry of a period of 20 years commencing on the date of first commercial sale by Samil or a Sublicensee (as defined in the Agreement) of such Product in the Territory.

Upon the signing of the Agreement, Samil will pay the Company an up-front fee of approximately \$2.0 million (of which, US\$300,000 has already been paid by Samil). Samil has also agreed to pay additional clinical and regulatory-based milestone payments, which may aggregate to additional \$6.0 million, as well as tiered, double-digit royalties payable on sales (lower if sales of a generic equivalent commences in the Territory).

Pursuant to the terms of the Agreement, following the first achievement of US\$25 million of Net Sales (as defined in the Agreement) in any calendar year following the first commercial sale of the Product in the Territory, Samil shall have the option to request that the Licensed Information include methods for the formulation of Aramchol™ from its active pharmaceutical ingredient, or API, to allow of the manufacture of Aramchol™ by Samil; provided, however, that the Company shall have the option, to widen the definition of Licensed Information as aforesaid at any time (the "Option").

Additionally, following Successful Completion of the Company's ARREST Study or Agreed Continuation following non-achievement of Successful Completion of the ARREST Study (both terms as defined in the Agreement), Samil shall, for a period of 90 days following the date of written notification to it by the Company of such Successful Completion or following the date of Agreed Continuation following non-achievement of Successful Completion, have an option to require that the Territory be extended to include Vietnam ("the Extension Option"). In the event that Samil shall exercise the Extension Option, the parties shall conduct negotiations in good faith for up to 30 days thereafter in order to agree on milestone payments which would replace those set out in the Agreement. In the event that agreement is not reached in such regard within such period, the Extension Option shall terminate.

The Company shall be entitled, at its option: (i) to modify the Licence with respect to any Product so that it is non-exclusive only; or (ii) to terminate the Licence hereunder, with respect to any Product if: (a) a first purchasing order from Samil for at least one Product shall not have been placed by 6 months following the grant of the Korean Ministry of Food and Drug Safety new drug approval; or (b) commercial sale of such Product having commenced and either (i) there shall be a period of 1 year during which no sales of any Product shall take place, or (ii) within 1 year of such commencement, aggregate sales of Products shall not have reached a reasonable level, as determined by the joint development committee, in each case, except as a result of force majeure or other factors beyond the control of Samil. Further, the Company shall be entitled to terminate the Agreement if Samil challenges the validity of any of the Patents. If any such challenge is unsuccessful, Samil shall (in addition to the Company's right to terminate) pay to the Licensor liquidated damages in the amounts of US \$8,000,000. Either party may terminate the Agreement (i) upon the other party's material breach if such party fails to cure such breach within 30 days, or, in the case of failure by Samil to pay any amount due from Samil to the Company pursuant to or in connection with the Agreement 14 days after receiving written notice thereof, or (ii) upon customary events such as the granting of a winding-up order if such order or act is not cancelled within 60 days.

In the event that the Company shall not achieve Successful Completion of the ARREST Study, the Company shall as soon as practicable notify Samil of the non-achievement of such Successful Completion, and within 60 days thereof, notify Samil in writing either: (i) that it has decided not to develop the Licensed Information further for the Field of Use ("Cessation Notice"), or (ii) that it intends to continue with such development notwithstanding the non-achievement of such Successful Completion ("Licensor Continuation Notice"). In the event that the Company shall not achieve Successful Completion of the Phase III Study, the Company, shall notify Samil accordingly ("Notice of Non-Success"). Samil shall thereafter have the option, by notice in writing served on the Company within 45 days of Samil's receipt of either a Cessation Notice, a Licensor Continuation Notice or a Notice of Non-Success, as applicable, to indicate its intention either: (i) to terminate the License, or (ii) to continue research and development of the Licensed Information in the Field of Use in the Territory. Any such continuation by Samil shall be subject to the entry by Samil into a written agreement with the Company as to the terms and conditions which would govern such continued research and development, which would be carried out according to Samil's own development plan and at its sole expense.

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).

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Exhibit Index

Exhibit No. Description

99.1 Press Release, dated July 28, 2016

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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.

By: /s/ Allen Baharaff

Date: July 28, 2016 Allen Baharaff

President and Chief Executive Officer

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