

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

DIVISION OF CORPORATION FINANCE

January 28, 2014

<u>Via E-mail</u> Allen Baharaff Chief Executive Officer Galmed Pharmaceuticals Ltd. 8 Shaul Hamelech Blvd. Amot Hamishpat Bldg. Tel Aviv, Israel 64733

Re: Galmed Pharmaceuticals Ltd. Draft Registration Statement on Form F-1 Submitted December 31, 2013 CIK No. 0001595353

Dear Mr. Baharaff:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

<u>General</u>

- 1. Please file all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 2. Prior to its use please provide us proofs of all graphic, visual or photographic information you will provide in the printed prospectus. Please note that we may have comments regarding this material.
- 3. Please supplementally provide us with any written materials that you or anyone authorized to do so on your behalf provides in reliance on Section 5(d) of the Securities Act to potential investors that are qualified institutional buyers or institutional accredited investors. Similarly, please supplementally provide us with

any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

Explanatory Note, page ii

4. Please note that it is not appropriate to state or imply that you do not have liability for the statements in your registration statement. Your statements in this section that the accuracy and completeness of information is not guaranteed and that you have not independently verified information from third-party sources could imply that you are not taking liability for the statistical and other industry and market data included in your registration statement. In order to eliminate any inference that you are not liable for all of the information in your registration statement, please delete these statements or include a statement specifically accepting liability for these statements.

<u>Risk Factors, page 11</u> We manage our business through a small number of employees . . ., page 31

5. Please expand your discussion to identify your key consultants.

We may not be able to enforce our intellectual property rights throughout the world. ..., page 37

6. Given your interest in licensing and marketing aramchol in China (see, e.g., pp. 88 and 91), please disclose that China is one of those foreign countries that do not protect intellectual property rights to the same extent as the United States.

Our U.S. shareholders may suffer adverse tax consequences if we were to be characterized as a passive foreign investment company, or PFIC, page 43

7. Briefly define a PFIC in this risk factor. Then disclose that you do not currently intend to provide the information that would enable investors to take a qualified electing fund ("QEF") election, which election would mitigate to some extent the adverse tax consequences of PFIC status.

As a "foreign private issuer," we are permitted, and intend, to follow certain home country corporate governance practices. . ., page 45

8. Please disclose that, as a foreign private issuer, you will also not be subject to Regulation FD (see 17 CFR 243.101(b)).

Exchange rate fluctuations between the U.S. dollar, Euro and the New Israeli Shekel currencies may negatively affect our earnings, page 47

9. Please supplementally advise us, with a view to disclosure, whether the inflation rate in the EU or Israel has exceeded the rate of devaluation of the Euro or the NIS during 2011, 2012, or 2013.

Use of Proceeds, page 52

10. Please amend your disclosure to include the estimated amount of proceeds you plan to allocate for each of the uses identified on page 52. If the company has specific purposes in mind for the use of proceeds, you must disclose the estimated net amount of the proceeds broken down into each principal intended use. This is required even if management will have broad discretion in allocating the proceeds and the amount and timing of your actual expenditures may vary significantly from your current intentions depending on numerous factors. Please make any necessary conforming changes to the Prospectus Summary as well.

Capitalization, page 53

- 11. Please tell us why it is appropriate to reflect the exercise of your Warrant as a pro forma adjustment. In your response, please tell us how the exercise of this Warrant is directly attributable to your IPO and factually supportable, as required by Item 11-02(B) (6) of Regulation S-X.
- 12. Please either remove cash and cash equivalents from your table or place a double underline under it to clearly segregate it from your capitalization.

Management's Discussion and Analysis of Financial Condition and Results of Operations Stock-Based Compensation and Fair Value of Ordinary Shares, page 59

- 13. Please update your discussion to include a table that discloses the terms of all equity issuances, including options, warrants, common stock, and preferred stock through the date of effectiveness. Please note that we are deferring a final evaluation of stock compensation and other costs recognized until the amendment containing the estimated offering price is filed. In addition, please revise your disclosure to provide:
 - A description of the valuation method and assumptions used to determine the fair value of your common stock that was used to value the equity issuances.
 - A description of whether the valuations were performed contemporaneously or retrospectively and if they were performed by a related party.
 - An explanation of why the fair value of your common stock changed from each grant date.
 - A description of each significant factor contributing to the difference between fair value at the grant date to the estimated IPO price.

• The intrinsic value of your vested and unvested options outstanding as of the most practicable date, based on the mid-point of your anticipated offering price range.

Business, page 65

- 14. We note that in several places in your prospectus in which you refer to prior clinical studies of aramchol, you characterize the drug as "safe." For example, on page 67, in discussing your Phase 1a study you state that "all doses proved to be safe" and on page 82 you state that the safety ... of aramchol has been demonstrated..." On page 68, you also list as one of your competitive strengths the fact that aramchol is "a safe, once-daily oral drug..." Because regulatory approval of aramchol is dependent on the agency making a determination (according to criteria specified in law and agency regulations) that a drug or biologic is both safe and effective, it is premature for you to describe aramchol, or any of the dosages administered, as safe. Accordingly, please delete this wording throughout your prospectus, as applicable.
- 15. Similarly, it is inappropriate at this stage of development to characterize aramchol or any drug candidate as "effective" in treating a disease indication if the FDA or comparable regulatory agency has not yet approved the drug for sale. As the efficacy of aramchol has yet to be confirmed by the FDA or other regulatory agency, you should revise your prospectus to remove any statement that could suggest efficacy has been confirmed. For example, we note your statement on page 67 that your Phase IIa clinical study demonstrated that aramchol "is 'effective' in reducing liver fat in a dose dependent manner."

Potential Phase III Program for Aramchol, page 75

- 16. You state that "[y]our current regulatory path for the development and submission of an application for regulatory approval of Aramchol for NASH ... was endorsed by BfArM and ANSM in September 2012" and that "the FDA Response provided a similar endorsement." Please revise to precisely describe the communications you received from BfArM, ANSM and the FDA that you have characterized as "endorsements."
- 17. You also state in the Prospectus Summary and Management's Discussion and Analysis that the FDA and the EMA have each recently confirmed that, if successful, your planned Phase IIb trial of aramchol may serve as a basis for Phase III pivotal trials of aramchol in the United States, Europe and Israel. Please revise your prospectus, as necessary, to clarify whether such confirmations were received in the form of correspondence. If not, please revise to describe the nature of such communications.
- 18. On page 75, you state that if the results of your Phase IIb study are statistically significant, it is possible that you may not be required to perform additional studies

> prior to commencing your pivotal Phase III trials. Please expand your disclosure to clarify whether the FDA informed you that, based on the results of your Phase IIb study, you may not be required to perform additional studies prior to your pivotal Phase III trials and, if so, describe any communications from the FDA to this effect. If you have not received any such communications, please explain the basis for your belief.

Phase IIa Trial: Aramchol Treatment in NAFLD or NASH Patients, page 76

19. In the tables that appear on pages 76-81 of your prospectus, several of the metrics used to assess the efficacy of aramchol are provided without any explanation or annotation to help the lay reader put the various clinical scores in context. For example, you provide an NAFLD activity score on page 76, the change in liver fat concentration by NMLS on page 78 and the change in endothelial function as measured by FMD on page 80. Yet, you have omitted adequate explanation that would allow readers who do not have the requisite scientific background to understand how these measurements are derived or what the respective values mean relative to each other. Please revise your disclosure accordingly.

Management

Compensation of Executive Officers and Directors, page 129

- 20. Please update your compensation disclosure to include the registrant's last completed fiscal year.
- 21. We note that you have disclosed the annual compensation of your CEO and Chief Medical Officer (pp. 133-134). Please supplementally advise us whether you have disclosed, or are required to disclose, in Israel the annual compensation on an individual basis of any of the other senior management members named in the registration statement. <u>See</u> Item 6.B of Form 20-F.

Principal Shareholders, page 137

- 22. Please disclose the number of your U.S. holders and the percentage of outstanding securities held by them. Please see Item 7.A.2 of Form 20-F.
- 23. We note on page 138 that shares held by Mr. and Mrs. Goldfarb and Medgal S.A. are to be aggregated with respect to voting rights and are thus deemed by Galmed to be beneficially held by Mr. and Mrs. Goldfarb. Please expand your disclosure to clarify that Mr. and Mrs. Goldfarb are the natural persons who exercise the voting and/or dispositive powers with respect to such shares owned by Medgal S.A. Alternatively, please identify the natural person or persons who exercise the voting and/or dispositive powers with respect to such shares, and include Medgal S.A. in the table on page 137.

Description of Share Capital Anti-takeover Measures Under Israeli Law, page 143

24. Please clarify whether Israeli law or your articles of association, in addition to the provisions mentioned, allow for the issuance of preferred stock or the adoption of other "poison pill" measures that could prevent a takeover attempt and thereby preclude shareholders from realizing a potential premium over the market value of their shares.

U.S. Federal Income Tax Consequences, page 152

25. Please delete your disclaimer that the U.S. federal taxation summary "is for general information purposes only and does not constitute tax advice" as it implies that an investor may not rely upon the tax information disclosed in the registration statement.

Where You Can Find Additional Information, page 167

26. Although you intend to file your Form 20-F annual report within 90 days after the end of your fiscal year, please disclose that, in any event, you are required to file your Form 20-F annual report within 120 days of your fiscal year's end.

Notes to Consolidated Financial Statements Note 9--Shareholders' deficiency C. Capital note, page F-20

27. Please disclose the terms governing conversion of the capital notes to ordinary shares.

D. Stock-based compensation, page F-20

28. Please revise your disclosure to clarify the exercise prices of your various options and warrants. In this regard, for example, you disclose in the last paragraph on page F-20 and in the table on page F-21 that the exercise price of the 331 options issued to the chairman of your Board of Directors is \$2.60 per share. In the second paragraph on page 129, you disclose that the exercise price is \$2,601.41 per share. As the header to your financial statement footnotes indicates that per share data is not in thousands, it appears that there is a discrepancy between the two amounts you disclose.

Underwriting

Lock-Up Agreements, page 160

29. Please state the number of shares covered by the lock-up agreements.

Signatures

30. Please include the signature of your principal accounting officer, or include the title of your principal accounting officer as part of the applicable officer's title.

Exhibits

- Please file the employment agreements between the company and each of Mr. Baharaff and Dr. Halperin as exhibits pursuant to Item 601(10)(iii) of Regulation S-K.
- 32. Please file the Confirmation and Release Letter from the Beneficiaries of the late Professor Tuvia Gilat as an exhibit pursuant to Item 601(10)(i) of Regulation S-K.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Frank Wyman at (202) 551-3660 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Matthew Jones at (202) 551-3786, Dan Greenspan at (202) 551-3623 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler Assistant Director

cc: Robert L. Grossman, Esq. Greenberg Traurig, P.A. 333 S.E. 2nd Avenue, Suite 4400 Miami, Florida 33131