

March 11, 2019

Mary Mast
Angela Connell
U.S. Securities and Exchange Commission
Division of Corporation Finance
Mail Stop 4720
100 F Street, N.E.
Washington, D.C. 20549

Re: Protalix BioTherapeutics, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2017
Filed March 6, 2018
Form 10-Q for the Quarterly Period Ended September 30, 2018
Filed November 7, 2018
File No. 001-33357

Ladies and Gentlemen:

Transmitted herewith is the response of Protalix BioTherapeutics, Inc. (the “Company” or “Protalix”) to the Staff’s comments to our Annual Report on Form 10-K for the year ended December 31, 2017 (the “Form 10-K”) and Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 (the “Form 10-Q”), which were set forth in the Staff’s letter dated February 13, 2019 (the “Second Comment Letter”) to Yossi Maimon, our Chief Financial Officer. The original comment letter was dated December 4, 2018, and our initial response was filed on December 27, 2018. For ease of reference, we have noted the Staff’s comments in bold-faced type and the responses in regular type.

Notes to the Consolidated Financial Statements

d. Revenue Recognition, page 8

1. We acknowledge your response to comment one. Please address the following as it relates to your determination that the performance obligations represented a single performance obligation since the license, clinical development and manufacturing and supply obligations were not distinct:

- **how your statement on page 2 of your response that Chiesi was not granted any other rights to, or benefits from, the intellectual property is consistent with Section 2.1b of the agreements. The agreements appear to give Chiesi the right to use Protalix Technology as necessary to (i) seek and obtain Regulatory Approval for the Licensed Product in the Field in the Territory.**

- **why the license and research and development services, either alone or combined, are not capable of being distinct from the manufacturing services pursuant to ASC 606-10-25-19a. In this respect, the subcontracting and sublicensing rights in Section 2.4 and step-in rights in Section 3.2 of the agreements appear to indicate there may be available resources outside of the company that could provide the research and development services and supplies. Refer also to Example 56, Case B in ASC 606-10-55-371 through 55-372. In this regard, we note in Case A that an approved drug is provided in the contract with manufacturing services, for which no other promised goods or services are included in the contract, which appears to be contrary to the company's facts and circumstances.**
- **why the license and research and development services, either alone or combined, are not separately identifiable from the supply obligation and thus do not meet the criteria in ASC 606-10-25-19b. In this regard, it appears due to the subcontracting and sublicensing rights, the license and research and development services are not interrelated with the manufacturing services pursuant to ASC 606-10-25-21c. Refer also to Example 56, Case B, ASC 606-10-55-372A.**

Response:

The Company reviewed its position in light of the Staff's comments and will change its accounting analysis of the arrangements with Chiesi Farmaceutici S.p.A. ("Chiesi") and related revenue recognition, as detailed below.

After review of the Staff's comments, and a subsequent reconsideration of applicable accounting guidance in ASC 606-10-25-14 through 25-21, the Company has concluded that the license and R&D services are not distinct promises and should be combined as a single performance obligation. However, the Company's obligation to manufacture product upon approval essentially represents an optional future purchase by Chiesi at a standalone selling price. Accordingly, in effect, the contract contains one performance obligation for the license and R&D services and an option for Chiesi to purchase manufactured product that does not represent a material right.

With respect to the license and R&D services, the rationale for a combined performance obligation is as follows: Chiesi cannot benefit from the license without the R&D services. The R&D services are highly specialized and depend completely on the supply of the drug that can only be produced by the Company. Chiesi cannot supply the drug for the clinical trials by itself or with the use of a third party (for example, a contract manufacturing organization) as the plant-based process is so complex and highly specialized that it requires specific infrastructure and know-how that only the Company and its employees possess. The license and R&D (including the supply of product for the clinical studies) are significantly affected by each other because Protalix would not be able to fulfill its promise by transferring each of the goods or services independently. Based on the foregoing and the factors set forth in ASC-10-25-21, specifically 25-21(c), the Company concluded that the license is not distinct from the R&D services.

Chiesi's option to purchase commercial product manufactured by Protalix, after receipt of regulatory approval for the drug, is at standalone selling prices (a market-based, tiered royalty arrangement common in the industry), and, therefore, does not represent a material right. As such, the manufacture and sale of drug product is not a performance obligation as of December 31, 2018. Upon receipt of regulatory approval, and at the request of Chiesi for Protalix to provide drug product, Protalix's commitment to manufacture and sell drug product would be accounted for, in effect, as a separate contract—a modification that adds distinct goods/services at standalone selling price—for purposes of revenue recognition under ASC 606. The performance obligation would begin after completion of the R&D services and receipt of regulatory approval for the drug.

The transaction price of the Ex-US agreement was \$50 million at contract inception, which was comprised of \$25 million of fixed consideration and an estimate of \$25 million of variable consideration for reimbursement of R&D services. However, as those reimbursements are subject to a cap, which is considerably less than the Company's expected R&D costs, this consideration essentially becomes fixed consideration. The transaction price of the US agreement was \$45 million at contract inception, which was comprised of \$25 million of fixed consideration and an estimate of \$20 million of variable consideration for R&D reimbursements, which are similarly capped, and, in effect fixed consideration.

With respect to the various R&D milestone payments, the Company estimates variable consideration using the most likely amount method. At contract inception and through December 31, 2018, no milestone payments were included in transaction price.

The method of measuring progress for the combined performance obligation (the license and the R&D services) is the cost-to-cost method, which the Company believes best depicts the pattern of transfer to the customer. Under the cost-to-cost method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected to be incurred upon satisfying the identified performance obligation. Under this method, revenue will be recorded as a percentage of the estimated transaction price based on the extent of progress towards completion.

The estimate of the Company's measure of progress and estimate of variable consideration to be included in the transaction price will be updated at each reporting date. For the portion of the performance obligation already satisfied, the change in transaction price will be reflected as a change in accounting estimate. The amount related to the unsatisfied portion will be recognized as that portion is satisfied over time.

Upon clarification of this position with the Staff, subject to the approval of its Audit Committee and Board of Directors, the Company intends to restate its 2018 quarterly financial statements, disclosing the reason for the restatement and its effect. With respect to the 2017 annual consolidated financial statements, the Company evaluated the materiality of the error from quantitative and qualitative perspectives, and concluded that the error was immaterial.

2. As it relates to your determination that revenue from the combined performance obligation should be recognized at a point in time upon the supply of the drug, please address the following:

- **Your response states that you intend to recognize revenue at the point in time in which Chiesi achieves control over batches supplied. However, you also state that you will recognize revenue as product is delivered to Chiesi based on the quantity supplied compared to the forecasted quantity of the drug to be supplied over the term of the agreements, which would appear to be an over time measurement. Please clarify this apparent inconsistency. Please also explain how you intend to estimate the forecasted quantity of the drug to be supplied over the term of the agreements and how this estimate would be deemed to be a reasonable measure of progress considering the guidance in ASC 606-10-25-36.**
- **Your response states that Protalix will “start satisfying its performance obligation only upon supply of the drug after issuance of regulatory marketing approvals.” Explain how you considered the contract duration guidance in ASC 606-10-25-3 which states that the guidance in this Topic should be applied to the duration of the contract (that is, the contractual period) in which the parties to the contract have present enforceable rights and obligations. In this regard, it would appear that the enforceable rights and obligations under these contracts began at their effective dates, which was October 19, 2017 for the Chiesi Ex-U.S. Agreement and July 23, 2018 for the Chiesi U.S. Agreement. Accordingly, it is unclear to us why an over time measurement of your performance obligation would not be recognized over the entire contractual period.**
- **Explain how you considered the guidance in ASC 606-10-25-27(c) in determining whether your performance obligation is being satisfied over time. In this regard, address the following:**
 - **Clarify whether your performance under the contracts create an asset with alternative future use. In this regard, explain whether you are contractually restricted from developing pegunigalsidase alfa (PRX-102) for your or any other entity’s benefit as long as the Chiesi agreements are in effect.**
 - **Explain whether you have an enforceable right to payment for performance completed to date under the contracts. In this regard, it would appear that you would have the full right to the non-refundable upfront payments (at a minimum) even in the event that the drug does not receive regulatory approval and enter the commercialization phase.**

Response:

As noted in the response to Question number 1, after reconsidering the performance obligations in the contract, the supply of product is an optional purchase. Please refer to the response to Question number 1.

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We thank you in advance for your time and attention to this response letter. Should you wish to discuss this response letter at any time, please do not hesitate to contact me at +972 (4) 902-8100 or YossiM@protalix.com or our counsel, Brian Hirshberg of Mayer Brown LLP at +1 (212) 506-2176 or bhirshberg@mayerbrown.com.

Sincerely,

/s/ Yossi Maimon
Yossi Maimon
Vice President and Chief Financial Officer
Protalix BioTherapeutics, Inc.

cc: Moshe Manor
Protalix BioTherapeutics, Inc.

Brian Hirshberg
Mayer Brown LLP