PROTALIX Biotherapeutics

December 27, 2018

Mary Mast
Angela Connell
U.S. Securities and Exchange Commission
Division of Corporate 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. to the Staff's comments to our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (the "Form 10-K") and Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018 (the "Form 10-Q"), which comments were set forth in the Staff's letter dated December 4, 2018 (the "Comment Letter") to Yossi Maimon, our Chief Financial Officer. 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. **You state that the development and manufacturing services for the Chiesi agreements are viewed as a single performance obligation and therefore the upfront payments, future research and development reimbursement payments and any potential additional development milestone payments under each agreement will be deferred until the commencement of commercial manufacturing. Please address the following:**

   · **Identify for us each of the promised goods or services in these agreements including the transfers of licenses and explain how you determined that you only had a single performance obligation under the guidance in ASC 606-10-25-14.**

Response: Protalix Ltd., our wholly-owned subsidiary, develops recombinant therapeutic proteins based on its proprietary ProCellEx® protein expression system. ProCellEx is a production system based on plant cell culture technology for the development, expression and manufacture of recombinant proteins. Protalix Ltd.'s research and development activities target the development of drugs to treat certain diseases using its unique technology in the manufacturing process of the drugs. It is the first company to gain U.S. Food and Drug Administration approval of a protein produced through plant cell-based expression. The ProCellEx platform is a proven alternative to mammalian cell-based production technology (the most common form of recombinant protein production), overcoming many of the disadvantages of mammalian cell-based production while offering significant production, regulatory and cost advantages.

Protalix Ltd. has entered into two separate agreements with Chiesi Farmaceutici S.p.A. ("Chiesi") with respect to the license and supply of pegunigalsidase alfa, our drug candidate for the treatment of Fabry disease that currently is under advanced stages of clinical development (the "drug" or the "product"): the Exclusive License and Supply Agreement dated as of October 17, 2017 covering all territories outside of the United States and the Exclusive U.S. License and Supply Agreement dated as of July 23, 2018 covering the United States (collectively, the "Chiesi Agreements"). Under the terms of the Chiesi Agreements, the parties have agreed to the following:

i) License – Chiesi was granted exclusive, non-transferrable, worldwide license rights to commercialize pegunigalsidase alfa. Chiesi was not granted any other rights to, or benefits from, the intellectual property of Protalix Ltd. (the "IP").

ii) Clinical development – Protalix Ltd. is responsible for continuing the actual clinical development of the product in order to obtain regulatory approvals for the drug. Chiesi did not receive any right to use the clinical data other than for commercialization purposes. Hence, Chiesi does not have the right to use the results of Protalix Ltd.'s clinical development activities with respect to the product for its own research and development activities in other areas or for other products.

iii) Manufacturing and supply – After a regulatory approval for the drug is obtained, Protalix is required to manufacture and supply the drug to Chiesi based on Chiesi's purchase orders. Chiesi will have no other way to obtain the product other than purchasing the product from Protalix Ltd.

ASC 606-10-25-14 states:

"At contract inception, an entity shall assess the goods or services promised in a contract with a customer and shall identify as a performance obligation each promise to transfer to the customer either:

a. A good or service (or a bundle of goods or services) that is distinct.
b. A series of distinct goods or services that are substantially the same and that have the same pattern of transfer to the customer (see paragraph 606-10-25-15)."

ASC 606-10-25-17 states:

“Performance obligations do not include activities that an entity must undertake to fulfill a contract unless those activities transfer a good or service to a customer.”

ASC 606-10-25-19 states:

“A good or service that is promised to a customer is distinct if both of the following criteria are met:

a. The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct).
b. The entity’s promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract).”

ASC 606-10-25-20 states:

“A customer can benefit from a good or service in accordance with paragraph 606-10-25-19(a) if the good or service could be used, consumed, sold for an amount that is greater than scrap value, or otherwise held in a way that generates economic benefits...”

The grant of non-transferrable commercialization rights and Protalix Ltd.’s commitment to complete the clinical development of the drug are not distinct actions and do not transfer any benefit to Chiesi prior to the commencement of commercial production of the drug, for the following reasons:

- Chiesi cannot benefit from the license on its own or together with other available resources. Chiesi does not have sublicensing rights (except for certain small territories) and has neither the right, the ability nor the know-how to continue the clinical development of the product (subject to certain, limited exceptions). Therefore, the license is not distinct.

- Completion of the clinical development is a condition precedent to Chiesi’s ultimate sale of the product. Chiesi cannot benefit in any other manner from the clinical development activities performed by Protalix Ltd. as Chiesi does not have the right to use any information obtained from Protalix Ltd.’s clinical development efforts, or from the license granted to Chiesi to use the clinical development information, for other indications that could be developed from the IP. Protalix Ltd. continues to be the owner of the IP and to be entitled to use the IP for its research and development activities in other areas and for the development of other drugs. Therefore, the clinical development activities are not capable of being distinct.

- Chiesi is obligated to acquire the product from Protalix Ltd. It cannot generate economic benefits from the commercialization license or from the completion of the clinical development in any way except from the ability to sell the finished product, which must be purchased from Protalix Ltd. Since the unique manufacturing process is crucial to the drug and only Protalix Ltd. can perform the manufacturing, no one else can produce the product and/or complete the clinical development.

Based on the above, the criterion in paragraph 606-10-25-19(a) is not met. Consequently, the license, the clinical development and the manufacturing services are not distinct activities and thus, we have accounted for the Chiesi Agreements as a single performance obligation. See also Example 56 to ASC 606 —"Identifying a Distinct License – case A".

In substance, we deem the Chiesi Agreements to be a transfer of specifically defined commercialization rights and a supply agreement for a drug pending approval in exchange for Chiesi's upfront contributions to Protalix Ltd.'s development costs, and additional payments of the ongoing purchase price of the product as stipulated in the Chiesi Agreements.

- **With reference to ASC 606-10-25-23 to 25-26, explain to us why revenue is deferred until commencement of commercial manufacturing and how you considered that you have already transferred the licenses and begun providing development services.**

Response: As described above, based on the unique facts and the terms of the Chiesi Agreements, we believe that each of the Chiesi Agreements should be viewed as a commercialization and distribution agreement as Chiesi will benefit from an agreement only upon the purchase of the drug from Protalix Ltd. and the subsequent sales of the drug.

Neither the grant of the license to commercialize the drug nor the continuation of the clinical development transfers any goods or services to Chiesi and, therefore, neither of these activities qualifies as a distinct performance obligation of Protalix Ltd.

Protalix Ltd. will start satisfying its performance obligation only upon supply of the drug after issuance of regulatory marketing approvals. All consideration received and to be received up to the commercialization phase relates to the ultimate supply of product to Chiesi and therefore are deferred and recognized only upon satisfaction of a single performance obligation, which is the supply of the drug.

- **Explain to us whether you intend to recognize revenue over time or at a point in time, and why with reference to ASC 606-10-25-30 or 25-31, as applicable.**

Response: As described above, we intend to begin recognizing revenue when entering into the commercial manufacturing/supply phase as product is delivered to Chiesi for commercial purposes. At that date, we intend to estimate the forecasted quantity of the drug to be supplied over the term of the Chiesi Agreements. Deferred revenue will be recognized based on the quantity supplied out of the total expected quantity. Hence, we intend to recognize revenue at a point in time at which Chiesi achieves control over batches supplied.

We intend to evaluate the need to expand the related disclosure in our financial statements included in future filings in order to further clarify the rational for the accounting for the consideration received under the Chiesi Agreements and the related revenue recognition.

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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