

March 11, 2016

U.S. Securities and Exchange Commission
Division of Corporation Finance
100 F Street, NE
Washington, D.C. 20549

Attention: Jim B. Rosenberg

Re: Mallinckrodt Public Limited Company
Form 10-K for the Fiscal Year Ended September 25, 2015
Filed November 24, 2015
Form 10-Q for the Quarterly Period Ended December 25, 2015
Filed February 2, 2016
File No. 001-35803

Dear Mr. Rosenberg:

This letter sets forth the responses of Mallinckrodt public limited company (“the Company”) to the comments of the staff (“the Staff”) of the Securities and Exchange Commission (“the Commission”) set forth in the Staff’s letter dated February 29, 2016, with respect to the above-referenced Form 10-K and Form 10-Q. Set forth below is the heading and text of each of the Staff’s comment followed by the Company’s response.

Form 10-K for the Fiscal Year Ended September 25, 2015
Risk Factors, page 23
General

- 1) ***We note recent media reports regarding the pricing of Acthar and the potential for increased scrutiny and government investigations regarding such pricing. We also note the substantial decrease in your stock price in November 2015 in response to the negative publicity. Please tell us what consideration you gave to disclosing the material risks to your company related to the public scrutiny of your Acthar pricing, including the material impact of any current or potential investigations or litigation.***

The Company gave careful consideration to the recent increase in media coverage and statements by officials regarding the pricing of pharmaceutical products in the United States generally (much of which has been focused on Turing Pharmaceuticals LLC and Valeant Pharmaceuticals International, Inc., rather than Acthar or the Company) in drafting the following risk factors included in the Form 10-K:

- “Our product concentration may materially adversely affect our financial condition and results of operations.” (page 27)
- “Cost-containment efforts of our customers, purchasing groups, third-party payers and governmental organizations could materially adversely affect our net sales and results of operations.” (pages 27-28)
- “Sales of our products are affected by the reimbursement practices of public and private insurers. In addition, reimbursement criteria or policies and the use of tender systems outside the U.S. could reduce prices for our products or reduce our market opportunities.” (page 28)
- “We may not achieve the anticipated benefits of price increases enacted on our pharmaceutical products, which may adversely affect our business.” (page 29)
- “We face significant competition and may not be able to compete effectively.” (page 30)

These risk factors disclose, among other things, that, “[i]n the U.S., there have been, and we expect there will continue to be, a number of state and federal proposals that limit the amount that third-party payers may pay to reimburse the cost of drugs, for example with respect to Acthar.” These risk factors also disclose that “[r]eimbursement of highly-specialized products, such as Acthar,” typically is reviewed on a case-by-case basis, sometimes by reference to coverage guidelines issued by the applicable insurance carrier, and that “[t]hese coverage guidelines are subject to on-going review by insurance carriers.”

Based on this assessment, the Company concluded that these risk factors sufficiently addressed the material risks associated with Acthar, including its pricing, given its significance within our comprehensive product portfolio.

While it is not possible to determine with certainty what caused the significant volatility in its stock price in November 2015 (ranging from a low of \$52.01 to a high of \$73.36), the Company believes a number of factors contributed. These include macro socio-economic concerns and a challenging U.S. media environment driven by U.S. presidential primaries. They also include incremental concerns related to ANI Pharmaceutical's purchase of dormant new drug applications for corticotropin products and speculation about new competition for Acthar in the U.S. market. In addition, on November 9, 2015 “Citron Research” issued a tweet alleging that the Company is a “far-worse offender of the reimb sys [than Valeant] - more to follow.” On the date of this tweet, the Company’s shares fell from an opening price of \$70.00 to an intraday low of \$52.01, recovering to a closing price of \$58.01. On November 10, 2015, Andrew Left, the executive editor of Citron Research and a well-known short-seller, appeared on CNBC’s “Fast Money” to discuss his allegations, but he did not produce any significant new information regarding the Company during this interview - in fact, the Company’s stock price climbed approximately 7% on November 10, 2015 following the interview. Citron Research also did not produce any additional information regarding the Company following the interview.

The Company believes that the allegations in the Citron Research tweet are unfounded and do not reflect actual risks to the Company.

The Company considered the risks associated with the volatility in its stock price in November 2015 and determined that the risk factors on pages 27-30 mentioned above, together with the risk factor on pages 40-41 captioned “Our share price may fluctuate significantly”, sufficiently addressed such risks.

Lastly, to the Company's knowledge, it was not the subject of any litigation or governmental or regulatory investigations regarding Acthar pricing in November 2015, and the Company determined that it did not face material risks related to such matters at that time. The Company continues to monitor this situation.

- 2) ***We note that in your Registration Statement on Form S-4 (333-196054) you refer investors to the risk factors in Questcor’s Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and Questcor’s Current Report on Form 8-K filed on July 10, 2014. These risk factors inform investors of potential risks relating specifically to Acthar, such as details of reimbursement rates for Acthar, limitations placed on coverage of Acthar by certain insurers, product safety of Acthar and adverse events reported by patients. Given that sales of Acthar represent approximately 30% of your total net sales, please tell us why you have not included similar risk factors in your current Form 10-K and provided more fulsome disclosure relating to Acthar specifically, such as the cost per vial.***

It is typical for a Form S-4 to incorporate all risk factors in each party’s prior periodic SEC filings, even though not all such risk factors would necessarily be material to the combined company. As indicated in Questcor’s Current Report on Form 8-K filed July 10, 2014 (the “Questcor 8-K”), approximately 95% of Questcor’s net sales in calendar years 2013, 2012 and 2011 were from Acthar, which we assume Questcor took into account when it drafted its risk factor disclosures. The Company carefully assessed Questcor’s risk factor disclosures in crafting its own risk factor disclosures following its acquisition of Questcor. In performing its assessment, the

Company took into account that Acthar represented 31% of consolidated net sales in fiscal year 2015 as compared with virtually all of Questcor's net sales in calendar years 2013, 2012 and 2011. Acthar represents one product in the Company's portfolio of Specialty Generics, Nuclear Imaging and Specialty Brands products, including those recently acquired through the acquisitions of Ikaria, Inc. in April 2015 and Therakos, Inc. in September 2015. Based on this assessment, the Company determined that the risk factor disclosures in the Form 10-K adequately addressed the material risks related to an investment in the Company, taking into account, among other things, the nature of the relevant risks and the significance of Acthar to the Company.

3) *We note that in your earnings call for the fourth quarter of 2015 you highlight your efforts to increase reimbursement through the use of six Specialty Pharmacies. Please tell us how the use of Specialty Pharmacies increases the reimbursement rate for Acthar.*

As noted by the Staff, and discussed during our earnings call for the fourth quarter of fiscal 2015, the Company strives to maintain or improve reimbursement rates with payers to ensure appropriate patient access for Acthar. To this end, the Company has begun and is investing in a strategy to generate additional clinical and health economic data regarding Acthar's use and providing that evidence to payers to demonstrate the benefits of Acthar to patients. Based on this clinical and economic evidence, the Company is working to sign contracts with payers to ensure Acthar is in a favorable formulary position. The Company believes that this strategy will improve reimbursement rates with payers and increase patient access to Acthar.

The same question that addressed Acthar reimbursement also included inquiry regarding the distribution of Acthar through specialty pharmacies and the Company's relationship with those specialty pharmacies. The Company wishes to clarify that we do not believe that the use of specialty pharmacies has a direct impact on reimbursement rates. The purpose of our comments during this earnings call was to provide better insight of our contractual relationship with and utilization of specialty pharmacies. Acthar is a highly specialized injectable product used in relatively small patient populations. As such it is not well suited for standard pharmacy stocking and distribution. The use of specialty pharmacies, which has now increased to nine, ensures that Acthar is available to patients in a timely manner. The Company notes that the specialty pharmacies we utilize are nationally-accredited, well-established, third-party entities of which we have no ownership or options to take an ownership position whatsoever.

Notes to Consolidated and Combined Financial Statements

Note 19: Commitments and Contingencies

Governmental Proceedings, page 118

4) *For each of the first two matters in this section you disclose that you cannot determine with certainty the ultimate outcome of the matter and that the ultimate resolution over amounts already accrued could have a material adverse effect on your financial condition, results of operations and cash flows. As ASC 450-20-25-2 requires only that a loss contingency be reasonably estimable, not determinable with certainty, tell us why you have not disclosed the reasonably possible loss or range of reasonably possible loss in excess of the amounts accrued as required by ASC 450-20-50-3 and 50-4. If you cannot reasonably estimate the possible loss or range of possible loss, tell us why not for each matter in your response and represent to us that you will specifically indicate this inability in future disclosures as required by ASC 450-20-50-4b.*

The Staff's comment refers to "the first two matters in this section" but we understand, based on conversations with Mr. Brunhofer, that you intended to refer to the matters described in the first and third paragraphs of the section. We note the applicability of ASC 450-20 to this disclosure. With respect to the first matter (Drug Enforcement Administration ("DEA") investigation), management has determined that while the overall outcome is unpredictable, a loss is probable, and a loss contingency accrual has been recorded for what management believes is the reasonably estimable loss in that matter. Although a loss in excess of the accrued

amount is reasonably possible, the amount or range of possible loss is not reasonably estimable for a number of reasons, including, without limitation, because: (1) there is very little case law interpreting the relevant portions of the Controlled Substances Act ("CSA") and the related regulations; and (2) there are no recent enforcement actions or settlements between the DEA and manufacturers of controlled substances to serve as a benchmark.

With respect to the second matter (Federal Trade Commission ("FTC") investigation), management has determined that the overall outcome is unpredictable, and while a loss is reasonably possible, the amount or range of possible loss is not reasonably estimable. Consequently, an accrual for loss contingency has not been recorded. The amount or range of possible loss is not reasonably estimable for a number of reasons, including, without limitation, because the FTC is still conducting its investigation.

In both matters, the Company continues to provide information to and conduct discussions with the government agencies in question in an effort to bring the matters to a conclusion. Future disclosures will specifically indicate why the Company cannot reasonably estimate the possible loss or range of loss in these matters as applicable, and as required by ASC 450-20-50-4b.

- 5) **Please tell us the nature of the medical affairs costs you reclassified to research and development expenses during the first quarter of fiscal 2016 as well as the nature of the medical affairs costs you continue to classify as selling, general and administrative expenses. For those costs you now classify as research and development expenses, tell us how these costs represent the discovery of new knowledge or the translation of new knowledge into new products or processes, consistent with the definitions of research and development, respectively, in ASC 730-10-20. Also see ASC 730-10-55-1 and 55-2.**

The Company's medical affairs group engages in various activities. During the first quarter of fiscal 2016 the Company determined that based upon the guidance in ASC 730 *Research and Development*, and consistent with industry practices, certain of the costs associated with the medical affairs group should be classified as research and development expenses. The most significant of these costs are presented below:

- Phase IV Studies and Investigator Initiated Research (“IIR”) - The Company’s medical affairs organization performs Phase IV and funds IIR studies to provide a framework for research that increases the understanding of diseases, disease management, or drug use and their related effects in a variety of patient populations. These studies further the understanding of how our products (including H.P. Acthar® Gel (repository corticotropin injection), OFIRMEV® (acetaminophen) injection, INOMAX® (nitric oxide) gas, for inhalation, Therakos® photopheresis and others) interact with these disease states, patient populations and treatment regimens.
- Grants and Fellowships (“Grants”) - The Company’s grants program funds independent studies by medical professionals that increases the understanding of diseases, disease management, or drug use and their related effects in a variety of patient populations.
- Pharmacovigilance - The Company's pharmacovigilance group is responsible for the collection, processing and analysis of adverse events for products in compliance with regulatory requirements. The goals of the pharmacovigilance department are to minimize or prevent harm to patients by identifying new safety concerns and/or hazards associated with the Company's products and to implement risk-minimization measures when appropriate.
- Medical Science Liaison (“MSL”) - The MSL organization delivers clinical and scientific data and clinical education to key thought leaders, professional societies, and practitioners focused on various disease states, including those associated with the Company’s products. The MSL organization is also responsible for engaging with the medical community regarding clinical and scientific data to obtain feedback on the published information and engage in dialogue.

The Company determined that certain costs incurred by the medical affairs group should continue to be classified within selling, general and administrative expenses as they do not meet the definition of research and development as defined in ASC 730 *Research and Development*. The most significant of these costs are presented below:

- Health Economic Outcomes Research (“HEOR”) - HEOR is performed to demonstrate the economic value of our currently approved products to prescribers, hospitals and payers. This research, and related publications, balance the cost of the Company’s products and treatment therapies with alternatives, in the context of overall healthcare savings that can be generated from the Company's products.
- Risk Evaluation and Mitigation Strategy (“REMS”) - A REMS may be required by the Food and Drug Administration as part of the approval of a new product, or for an approved product when new safety

information arises. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use.

The following summarizes the Company's consideration of each category of costs in light of the guidance included within ASC 730 *Research and Development*:

Description of Activity	Applicable Guidance Consideration
<i>Phase IV, IIR & Grants Programs</i>	
<p>These programs are aimed at medical research and clinical studies of various diseases, disease management, or the effect of drug use in a variety of patient populations - which may or may not currently be treated by our existing products. The results of this research are used by the Company and shared with the healthcare community to stimulate discussion of new ideas that could lead to new treatments in these disease states, enhancements to and new opportunities for our products, or development of new product opportunities.</p>	<p>The Company believes that these activities are consistent with “searching for applications of new research findings or other knowledge” and “the conceptual formulation and design of possible product or process alternatives”, which are included in ASC 730-10-55-1b and 55-1c, respectively, as examples of activities that are typically included in R&D.</p>
<i>Pharmacovigilance</i>	
<p>This activity is associated with gathering information about adverse reactions associated with our products. Information obtained through pharmacovigilance, which is an ongoing process, could lead to new knowledge that may result in the significant modification of existing products, modifications to the method of use for existing products or the development of new products to curb adverse reactions in patient populations.</p>	<p>The Company believes that these activities are consistent with “searching for applications of new research findings or other knowledge” and “the conceptual formulation and design of possible product or process alternatives”, which are included in ASC 730-10-55-1b and 55-1c, respectively, as examples of activities that are typically included in R&D.</p>
<i>MSL Program</i>	
<p>This activity is associated with providing information to and stimulating dialogue with experts and practitioners in various disease states. The dialogue with the medical community is utilized in identifying new areas of study, potential new indications for existing products, new formulations of existing products or identifying potential new drug candidates.</p>	<p>The Company believes that these activities are consistent with “searching for applications of new research findings or other knowledge” and “the conceptual formulation and design of possible product or process alternatives”, which are included in ASC 730-10-55-1b and 55-1c, respectively, as examples of activities that are typically included in R&D.</p>
<i>HEOR Data</i>	
<p>Research activities associated with HEOR data is primarily associated with generating data and information to support the selling and marketing of currently existing products by demonstrating the overall economic value of the Company’s products to patients, prescribers, hospital and payers.</p>	<p>The Company believes that these activities relate to the selling function of the entity, which as prescribed in ASC 730-10-15(c) shall be excluded from R&D.</p>
<i>REMS Program</i>	
<p>The monitoring of the safe and effective use of existing products is an FDA required activity. These activities include providing training on proper prescribing and monitoring of improper activities associated with the products related to the program.</p>	<p>The Company believes that these activities represent ongoing compliance costs associated with currently marketed products and do not provide significant information that can be utilized in future research and development. As such, these costs do not meet the definition of R&D as presented in ASC 730-10-20.</p>

As requested by the Staff, the Company acknowledges that:

- The Company is responsible for the adequacy and accuracy of the disclosure in its filings with the Commission under the Securities and Exchange Act of 1934, as amended (“Exchange Act Filings”);
- Staff comments or changes to disclosure in response to Staff comments do not foreclose the Commission from taking any action with respect to the Company’s Exchange Act Filings; and
- The Company may not assert Staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

If you have any questions regarding the foregoing, please contact Matthew K. Harbaugh, the Company’s Senior Vice President and Chief Financial Officer at (314) 654-2000.

Sincerely,
Mallinckrodt public limited company

By:/s/ Matthew K. Harbaugh
Matthew K. Harbaugh
Senior Vice President and Chief Financial Officer