

May 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 3, 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 set forth in the Staff’s letter dated April 13, 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 comments followed by the Company’s response.

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

- 1) With respect to your response to prior comment 1, we believe that your risk factors should be tailored to your specific circumstances and explain how the risks you identify have materially impacted your company. As currently drafted, many of the risk factors could apply to any issuer. For example, your risk factor on page 40 that your “share price may fluctuate significantly” does not disclose the specific incidents that have caused your share price to fluctuate materially, such as the tweet by a third party which caused a decline in share price on November 9, 2015. We note that another tweet by the same third party in March 2016 caused a similar decline in share price. In future filings starting with your next Form 10-Q, please revise your risk factors to disclose the specific impact of identified risks.**
- 2) Given Acthar’s significant contribution to revenues as discussed in prior comment 2, you should revise your risk factors to disclose how certain identified risks have materially impacted your company. Your risk factors on pages 27-30 only briefly mention Acthar and do not highlight that Acthar accounts for approximately one-third of your net sales and do not explain how these risks have previously impacted stock price and sales of Acthar. For example, we note that you have not disclosed Aetna’s denial of coverage for Acthar and the corresponding impact on revenues and share price, the adverse events related to Acthar (including the increase in adverse events from 2011 to 2013), the particular dependence of Acthar on the availability of reimbursement from insurers given its expense, or the negative publicity surrounding Acthar pricing. Please also clearly state in your risk factor on page 31 that the ongoing investigation by the Department of Justice relates to Acthar. We recognize that certain of these events occurred prior to your acquisition of Acthar, however these risks continue to appear relevant today. In future filings starting with your next Form 10-Q, please revise your risk factors to reflect your specific dependence on Acthar and the material risks related to this dependence.**

Company Response: As indicated on the Company's conference call with the Staff on April 25, 2016 (the "April Call"), the Company planned to (and did) include a new risk factor in its Form 10-Q filed on May 3, 2016 (the "Second Quarter 2016 Form 10-Q") regarding pricing pressure on certain of its products due to legal changes or changes in insurers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs. The new risk factor also highlights that Acthar represented 29.2% of the Company's net sales for the six months ended March 25, 2016. The full text of the risk factor included in the "Second Quarter 2016 Form 10-Q is as follows:

We may experience pricing pressure on certain of our products due to legal changes or changes in insurers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs, which could reduce our future revenue and profitability.

Recent public and governmental scrutiny of the cost of healthcare generally and pharmaceuticals in particular, especially in connection with price increases of certain products, could affect our ability to maintain or increase the prices of one or more of our products, which could negatively impact our future revenue and profitability. Certain press reports and other commentary have criticized the substantial increases in the price of Acthar that occurred, prior to our acquisition of the product. Acthar represented 29.2% of our net sales for the six months ended March 25, 2016. In addition, U.S. federal prosecutors recently issued subpoenas to another pharmaceutical company seeking information about its drug pricing practices, among other issues, and members of the U.S. Congress have sought information from certain pharmaceutical companies (not including Mallinckrodt) relating to drug price increases. We cannot predict whether any particular legislative or regulatory changes or changes in insurers' reimbursement practices may result from any such public scrutiny, what the nature of any such changes might be or what impact they may have on us. If legislative or regulatory action were taken or insurers changed their reimbursement practices to limit our ability to maintain or increase the prices of our products, our future revenue and profitability could be negatively affected.

The Company also revised the disclosure on page 23 of the Second Quarter 2016 Form 10-Q to clearly indicate that the ongoing investigation of Questcor's business practices by the Department of Justice relates to Acthar.

The Company has considered the Staff's comment with respect to the risk factor on page 40 that "your share price may fluctuate significantly" and continues to believe that it appropriately addresses the risks of volatility in the Company's share price. Notwithstanding that, the Company proposes to expand that risk factor in its next Form 10-Q to reference additional factors that could cause its share price to fluctuate. The modified risk factor would read as follows (new language is underlined):

Our share price may fluctuate significantly.

The market price of our ordinary shares may fluctuate significantly due to a number of factors, some of which may be beyond our control, including:

- actual or anticipated fluctuations in our results of operations;
- changes in earnings estimated by securities analysts or our ability to meet those estimates;
- perceived impacts to our results from acquisitions of products, licenses rights or businesses;
- the operating and share price performance of comparable companies;
- actual or anticipated sales of our ordinary shares;
- allegations by third parties (even if unsubstantiated) regarding our products or business practices;

- publicity and media reports regarding actual or potential competitive or other developments in the markets we serve;
- new regulations or legislation in the U.S. relating to the development, sale or pricing of pharmaceuticals or medical devices;
- political pressure to reduce the pricing of pharmaceuticals;
- continued consolidation in pharmacy networks and among insurers that may further increase their competitive market power;
- changes to the regulatory and legal environment in which we operate; and
- U.S. and worldwide economic conditions.

Third parties, some of whom may have taken investment positions that would increase in value if our share price declines (“short sellers”), may make allegations related to our products or business practices. These short sellers make a profit when our shares decline in value, and their actions and public statements, and the resulting publicity, may cause further volatility in our share price. In November 2015, one short seller publicly made assertions regarding Acthar that were not substantiated in any way. In March 2016 the short seller reiterated, again without any substantiation, many of the same assertions. On both occasions, the unsubstantiated assertions attracted media attention and our share price fluctuated. This volatility may cause the value of a shareholder’s investment to decline.

Volatility can also occur from short sellers becoming active in our stock. It is generally in the short seller’s interest for the price of a stock to decline. Prior to our acquisition of Questcor, Questcor experienced high levels of short interest in its stock. It has been alleged that short sellers may take various actions aimed at attempting to cause harm to a company’s business or reputation in an effort to cause such company’s stock to decline. Short sellers have recently been active in our stock.

In addition, when the market price of a company’s ordinary shares drops significantly, shareholders often institute securities class action lawsuits against the company. A lawsuit against us could cause us to incur substantial costs and could divert the time and attention of our management and other resources.

Furthermore, we cannot guarantee that an active trading market for our ordinary shares will continue to exist.

The Company respectfully advises the Staff that it believes that the risk factors included on pages 27 - 30 of the Annual Report on Form 10-K for the fiscal year ended September 25, 2015 (“the 2015 Form 10-K”), taken together with the new risk factor included in the Second Quarter 2016 Form 10-Q and the revised risk factor quoted above to be included in its next Form 10-Q, are appropriately tailored to the Company’s specific circumstances and adequately explain how these risks may impact the Company.

The Company believes that certain of the events referenced in comment 2, which occurred prior to the Company’s acquisition of Acthar, are not material to either the Company, with its roughly ten branded products and three business segments, or to the Acthar business as managed by the Company today, and that including such disclosures is unnecessary and potentially misleading to investors.

Potential Changes in Reimbursement by Insurers

The Company has disclosed the risks to the Company associated with changes in reimbursement rates in the 2015 Form 10-K, most prominently in the risk factor entitled “*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.” As noted in that risk factor, insurance policies and guidelines are subject to ongoing review by insurers. Coverage and reimbursement rates can change at any time (sometimes to the Company’s benefit and sometimes not). On its May 3, 2016 earnings call, the Company reported that it has continued to sign new payer agreements and has reached its initial goal to have greater than 50 percent of covered commercial lives under contract for Acthar. This is a significantly different business approach and model than that used by Questcor, which had no material contracts, relationships or interaction with public or private insurers.

Adverse Event Data on Acthar

The Company’s risk factor on page 23 of the 2015 Form 10-K states: “We are also required to report adverse events associated with our products to the FDA and other regulatory authorities. Unexpected or serious health or safety concerns associated with our products, including Acthar, could result in reduced sales of the affected products, product liability claims, labeling changes, recalls, market withdrawals or other regulatory actions, including withdrawal of product approvals, any of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.”

The Company believes that this risk factor is adequate to inform investors of the risks of unexpected or serious health or safety concerns associated with its products, including Acthar. Further, the Company believes that the inclusion of data related to frequency of adverse event reporting, for any of our products and especially for Acthar, may potentially be misleading to investors.

The FDA itself cautions on its website that data reported in the Adverse Event Reporting System (“FAERS”) does not demonstrate a causal link between the reported effect and the product at issue:

FAERS data do have limitations. First, there is no certainty that the reported event (adverse event or medication error) was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Further, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether or not an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S.

(<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/>)

The frequency of adverse event reports also does not necessarily correlate to a true increase in any particular side effect or event as each event counts as one report whether the report relates to a relatively minor event such as a headache or a more serious event such as anaphylaxis. Additionally, reporting frequency can be affected or influenced by extraneous circumstances such as publicity or a recent publication of relevant data, which is not necessarily associated with a new or increased health or safety concern.

The data gathered in adverse event reporting is, without significant case-by-case analysis to determine potential links to any drug or treatment, inherently unreliable as a proxy for a drug’s overall safety profile. An adverse event report made while a patient is taking a particular drug must be carefully analyzed before any causality can be determined. This typically includes physician review of detailed patient medical records when available. It would be necessary to assess a number of factors before any potential causality could be determined, such as concomitant medications (i.e, medications being used by the patient at the same time the patient is using one of our products) or comorbidities (i.e., the patient has one or more medical conditions in addition to the medical condition related to the patient’s use of our product), use of a product in a new patient population or therapeutic area or patient assistance programs involving solicitation of adverse event data.

Acthar is a product utilized by patients with serious medical conditions - often prescribed as third or fourth line treatment and only after other medications have become less effective or stopped working. Patients using Acthar frequently are using a variety of concomitant medications and are suffering from diseases in which co-morbidities are high. In patient populations of this sort, side effects and adverse events may be more common and Acthar usage and net sales are not likely to be materially impacted by rates of adverse event reporting in the FAERS database.

For the foregoing reasons, raw adverse event reporting data is a potentially misleading indicator of the safety risks of Acthar. Furthermore, any connection between the frequency of adverse event reports and the overall financial condition or results of operations of the Company would be even more attenuated. The Company believes that highlighting ebbs and flows in adverse event reporting would be potentially misleading to investors.

- 3) ***In addition, where a trend, demand, commitment, event or uncertainty is known, management must make two assessments. Refer to Section III. B of MD&A interpretive release 33-6835. Given the events discussed in the preceding comment and recent publicity regarding medications with dramatically increased prices, please provide us your analysis of these assessments supporting your conclusion that disclosure of the expected effects on future financial condition and results of operations regarding the uncertainty of maintaining Acthar's current revenue levels is not necessary.***

Company Response: The Company respectfully advises the Staff that it does not believe that any disclosure of the type described in the Staff's comment is required. In reaching this conclusion, the Company applies the framework set forth in Section III. B of MD&A interpretive release 33-6835 (the "MD&A Interpretive Release"), which states:

"A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation. ...

Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:

- (1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.
- (2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur."

Set forth below is an application of the above framework to the matters cited in the Staff's comment.

Potential Changes in Reimbursement by Insurers

The Company does believe that adverse changes in insurer reimbursement policies are possible, and accordingly has disclosed the risks to the Company associated with changes in reimbursement rates in the 2015 Form 10-K, most prominently in the risk factor entitled "*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.*" However, while such changes may be possible, the Company does not believe that material adverse changes in reimbursement policies by public or private insurers are reasonably more likely to occur with respect to Acthar than any other drug products, and further, if they did occur, the Company does not

believe that they would be reasonably likely to have a material effect on the overall financial condition or results of operations of the Company. As noted in that risk factor, insurance policies and guidelines are subject to ongoing review by insurers. Coverage and reimbursement rates can change at any time (sometimes to the Company's benefit and sometimes not). Furthermore, as noted above in the response to comment #2, the Company has continued to sign new payer agreements with respect to Acthar. The Company believes that any attempt to predict the potential likelihood or impact of material adverse changes in reimbursement policies related to any specific drug would be speculative and potentially misleading to investors.

Adverse Event Data on Acthar

The Company is not able to determine whether a material increase in the frequency of reported adverse event data with respect to Acthar is reasonably likely to occur. Assuming that such a material increase did occur, the Company does not believe, for the reasons set forth above in the response to comment #2, that it would be reasonably likely to have a material effect on the financial condition or results of operations of the Company.

Press Coverage of Drug Price Increases

The Company acknowledges that increased public scrutiny of drug price increases involves a potential risk to the Company, and accordingly included a new risk factor on this topic in its Second Quarter 2016 Form 10-Q. However, the Company does not believe that increased press coverage of drug price increases is required to be addressed in its MD&A.

Press coverage in and of itself is not a financial risk to the Company; financial risk could only arise from adverse changes in law or regulation or regulatory policies, or in insurance policies or guidelines, that result from increased public scrutiny of drug prices.

The Company cannot predict whether any such changes may result from the recent increase in media focus, what form any such changes might take or what the effect of any such changes on Acthar revenue might be. Accordingly, while such downstream changes in law, regulation, regulatory policy or industry practice may be possible, the Company does not believe that material adverse changes are reasonably likely to occur, or, if they did occur, that they would be reasonably likely to have a material effect on the overall financial condition or results of operations of the Company. Any prediction as to any such matters would be speculative and may mislead investors as to the relevance of the current public debate to the Company and Acthar. The Company also notes that much of the public scrutiny regarding drug pricing has focused on material increases in pricing shortly after a company acquires a drug. By contrast, the Company has not materially increased the price of Acthar since its acquisition of Acthar (through its acquisition of Questcor Pharmaceuticals, Inc.) in 2014.

- 4) ***We acknowledge your response to prior comment 5. Please tell us whether any of your Phase IV Studies and/or Investigator Initiated Research are designed to and/or result in increased marketing claims against competing products. If so, please tell us why these costs are not more appropriately classified as selling and marketing expenses.***

The Company's Phase IV and Investigator Initiated Research ("IIR") studies are not designed for the purpose of generating marketing claims against competing products. The primary purpose of these studies is to expand the understanding of the products utilized in these studies in appropriate patient populations and facilitate discussion and research within the healthcare community. The Company acknowledges that the results of these studies may occasionally yield information that compares its products against other treatment alternatives. However, these instances are indirect consequences of its Phase IV and IIR studies. The Company does not believe that these indirect results should be determinative in the classification of the expenses within the financial statements. The Company's view is based on the fact that any information that may be utilized in the selling and marketing efforts is not the intended purpose of these studies and is often not known until well after the original costs are incurred and recognized in its financial statements.

Further, the Company notes that the majority of its Phase IV and IIR studies were incurred on products for which it believes there are few, if any directly competing products. For example, the Company notes that its Acthar product is generally utilized as a third or fourth line treatment when alternative treatments have either failed or are no longer as effective as they once were in producing the desired outcomes for patients. As such, these studies associated with this product focus on the efficacy of the product and attempt to better understand how it interacts with various disease states - including those for which the product is not currently marketed.

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

Sincerely,
Mallinckrodt public limited company

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