

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

June 19, 2014

Via E-mail
Peter G. Edwards, Esq.
Senior Vice President and General Counsel
Mallinckrodt plc
675 James S. McDonnell Blvd.
Hazelwood, MO 63042

Re: Mallinckrodt plc Registration Statement on Form S-4

> Filed May 16, 2014 File No. 333-196054

Dear Mr. Edwards:

We have the following additional comments on the above referenced registration statement. 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

General

- 1. We note your references throughout the S-4 to the potential advantages of the merger with Questcor and the advantages relating to the acquisition of Questcor's product, Acthar. In particular, we note the following:
 - Your disclosure on page 101 that the merger would provide a strong platform to support the expansion of Acthar into new therapeutic areas;
 - The prospective financial information on page 128 relating to patient population, market size, market share, dosing and pricing for Acthar in each of its approved indications and estimates of prospective sales; and
 - The disclosure on page 229 that the entry into the merger agreement with Questcor was driven by the 19 approved indications for Acthar, and your discussion of the acquisition of Acthar as a competitive strength on page 230.

In light of these disclosures, we believe you should also discuss the material risks relating to Questcor and Acthar that are necessary to put the disclosure in context. Specifically, address risks relating to the number of significant "adverse events" in recent years among users of Acthar and material changes in health insurers' reimbursement policies on Acthar. In this regard, we refer you to our comments below on Questcor's 10-K for the fiscal year ended December 31, 2013, which you incorporate by reference.

Questcor Form 10-K for the fiscal year ended December 31, 2013

<u>Business</u>

Overview, page 3

2. We note your disclosure indicating that Acthar is approved by the FDA for the treatment of nineteen indications. We further note your disclosure in the risk factor on page 10 indicating that "there is limited clinical evidence on the efficacy of Acthar for its on-label indications." In your business section, disclose the relevant history of Acthar's development and commercial use and explain how you are able to commercialize the product in 19 on-label indication with only limited clinical evidence of efficacy. Also identify in this section for which of the nineteen indications any substantial clinical evidence of efficacy exists, and if material to put the disclosure in context, the percentage of your sales generated by the indications that have "substantial clinical evidence of efficacy." Include similar clarifying disclosure in the risk factor on page 10.

Risk Factors

"We may be negatively affected by lower reimbursement levels," page 10

3. We note the disclosure concerning the extent to which you may be negatively affected by lower reimbursement levels. Expand the disclosure to describe in specific terms the extent to which you have been and could be affected. In this regard, we note a December 29, 2012 New York Times article discussing reimbursement levels for Acthar and Aetna's September 2012 decision to limit reimbursement of Acthar to cover only treatment for infantile spasms. Further, a June 13, 2014 New York Times article notes that Cigna recently changed its reimbursement policy on Acthar to remove coverage for multiple sclerosis in adults. Disclose these events and describe the attendant impacts. Also discuss any other decisions or ongoing deliberations by third party payors that could limit reimbursement for Acthar, whether through private insurers or government programs such as Medicare, Medicaid or TRICARE.

"We are subject to significant ongoing regulatory obligation and oversight...," page 19

4. You disclose that Acthar accounted for approximately 95% of your net sales in 2013. The June 13, 2014 New York Times article discusses adverse events reported to the FDA's Adverse Event Reporting System (Faers) since 2012, including 20 deaths and 6

disabilities among patients using Acthar in which Acthar was recorded as "suspect." In light of your disclosure in this risk factor, please disclose the following:

- the total number of adverse events relating to Acthar, whether documented by you or reported by others, that occurred during the past three years, including the type of adverse event, its severity, and the indication for which Acthar was prescribed relative to a given adverse event; and
- the number of adverse events in which the FDA considered use of Acthar "suspect."

Additionally, please advise us whether you have received any communications from the FDA regarding adverse events to date and if so, tell us the substance of such communications.

Management's Discussion & Analysis Results of Operations, pages 32-33

- 5. Please discuss the extent to which the reimbursement issues discussed above are a known trend or uncertainty that has had or that you reasonably expect will have a material unfavorable impact on net sales or revenues, income from continuing operations or financial condition. As part of this, quantify, to the extent possible, the number of patients prescribed Acthar in 2012 and 2013 that were covered by Aetna, Cigna or other payors that have limited or are considering limiting reimbursement. Also disclose the sales attributable to those patients in those years.
- 6. Similarly, disclose how the reported adverse events (also discussed above) may have or could potentially affect your historical and future results or financial condition.

Notes To Consolidated Financial Statements 2. Acquisitions

Acquisition of Synacthen, page 69

- 7. Please refer to our discussion on June 16, 2014. Identify the intangible asset you acquired, the alternative manner in which it will be used and provide an analysis supporting your conclusion that it has "alternative future uses." Specifically address the following:
 - why the use of the intangible asset was not contingent on its further development subsequent to the acquisition date, and
 - why you expected that the company would use the acquired intangible asset in the alternative manner and the anticipated economic benefit from that use.

In your analysis, please identify and distinguish current projects from future projects. Please also provide contextual discussion about your "reasonably expected" assessment, notwithstanding sales elsewhere in the world. In this regard, discuss how your assessment contemplated:

- that the intangible asset has never been developed for approval for patients in the United States;
- the development timetable;
- the uncertainty of FDA approval; and
- the effects that negative development results would have on the research and development projects identified at the acquisition date to be commenced at a future date.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Act of 1933 and all applicable Securities Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please refer to Rules 460 and 461 regarding requests for acceleration. We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Scott Wuenschell at (202) 551-3705 or Mary Mast at (202) 551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Austin Stephenson at (202) 551-3192 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler Assistant Director

cc: Joel H. Trotter, Esq. Latham & Watkins LLP

> Benjamin M. Roth, Esq. Wachtell, Lipton, Rosen & Katz