Questcor Pharmaceuticals, Inc. 1300 North Kellogg Drive, Suite D Anaheim, California 92807

July 3, 2014

VIA EDGAR

Scott Wuenschell Securities and Exchange Commission Division of Corporate Finance 100 F Street, N.E. Washington, D.C. 20549

> Re: Questcor Pharmaceuticals, Inc. Form 10-K for the Fiscal Year Ended December 31, 2014 Filed February 26, 2014 Response dated June 24, 2014 File No. 001-14758

Dear Mr. Wuenschell:

We are responding to the U.S. Securities and Exchange Commission (the "Commission") Staff's (the "Staff's") comments regarding the abovereferenced filing and response letter of Questcor Pharmaceuticals, Inc. ("Questcor" or the "Company") included in the Staff's comment letter dated July 1, 2014, addressed to Questcor and Mallinckrodt plc ("Mallinckrodt"), regarding Mallinckrodt's Registration Statement on Form S-4, filed on May 16, 2014 (File No. 333-196054) (the "Form S-4"), Questcor's Form 10-K for the Fiscal Year Ended December 31, 2014, filed February 26, 2014 (File No. 001-14758) and Questcor and Mallinckrodt's Response Letters, each dated June 24, 2014, to the Staff's comment letter dated June 23, 2014. We have set forth below our response to comments 2-10 raised in the letter. Mallinckrodt is responding to comment 1 in the letter under separate cover. For ease of reference, we have included each of the Staff's comments in its entirety in bold and italicized text preceding our response.

Questcor's Response Letter dated June 24, 2014

- 2. We note your response to our prior Comment 2. Please expand your proposed "Business" disclosure to address the following points:
 - Explicitly disclose, if true, that clinical trials were not required in 1952 when Acthar was approved for use in fifty different indications;
 - Compare the efficacy evidence required by the FDA in 2010 to the evidence presented in 1952 resulting in the elimination of approximately thirty indications; and

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Clarify why the law does not require controlled clinical trials for Acthar as it does for "more recently approved" pharmaceutical products.

The Company acknowledges the Staff's comment. For purposes of addressing the Staff's comment, the Company proposes to revise the previously proposed additional "Business" disclosure to be included in a Current Report on Form 8-K that will be incorporated by reference into the Form S-4.

The revised "Business" disclosure would read as follows (revisions marked in bold and underlined text):

"Acthar was originally approved by the FDA in 1952, for the treatment of approximately 50 different medical conditions, or "indications." This was prior to the enactment of the 1962 Kefauver Harris Amendment, or the "Drug Efficacy Amendment," to the Food, Drug, and Cosmetic Act, which introduced the requirement that drug manufacturers provide proof of the effectiveness (in addition to the previously required proof of safety) of their drugs before approval. As such, the FDA's original approval in 1952 was based on safety; clinical trials evaluating efficacy were not required. In the 1970s the FDA reviewed the safety and efficacy of Acthar during its approval of Acthar for the treatment of acute exacerbations in Multiple Sclerosis (MS) and evaluated all other previous indications on the label through the process called DESI – Drug Efficacy Study Implementation. In this process the medical and scientific merits of the label and each indication on the label were evaluated based on publications, information from sponsors, and the judgment of the FDA. The label obtained after the DESI review and the addition of the MS indication is the Acthar label that was used until the most recent changes in 2010.

In 2010, in connection with its review of our supplemental New Drug Application, or sNDA, the FDA again reviewed evidence of safety and efficacy, added the treatment of Infantile Spasms (IS) to the label of approved indications, and maintained its approval of Acthar for the treatment of acute exacerbations in MS and 17 other indications, including proteinuria in the Nephrotic Syndrome without uremia of the idiopathic type or that due to lupus erythematosus, certain rheumatology-related indications and respiratory manifestations of symptomatic sarcoidosis. In conjunction with its decision to retain these indications on a modernized Acthar label, the FDA eliminated approximately 30 indications from the label. The FDA review included a medical and scientific review of Acthar and each indication (for example, an evaluation of the pathophysiology associated with each indication and the known and potential mechanism of action of Acthar for each indication) and an evaluation of available clinical and non-clinical literature that had become

available through the date of the review. The FDA did not require us to perform additional clinical trials for Acthar.

FDA approval of Acthar for the treatment of specific indications allows Questcor to promote Acthar, under regulations provided by the FDA for such marketing, to physicians for such indications. Since 2008, Questcor has grown its field force of Acthar Specialists in order to increase physician awareness of the availability of Acthar to treat certain of its on-label indications. The Company's promotional efforts surrounding Acthar to increase awareness of, and familiarity with, Acthar is monitored by our regulatory, compliance and legal departments and is subject to FDA review.

Ultimately, each physician must decide for himself or herself whether the patient's medical condition warrants the use of Acthar. In making that decision, the physician considers various forms of evidence as to the safety and efficacy of Acthar for each specific patient. Because Acthar was originally approved in 1952, prior to the 1962 Drug Efficacy Amendment, the evidence of the safety and efficacy of Acthar does not include clinical trials except for the IS and MS indications. By contrast, clinical trials have been required to establish both safety and efficacy for drugs approved since 1962. However, evidence as to safety and efficacy is not limited to clinical trials. Evidence can come in other forms such as prospective clinical datasets generated by third parties through independent clinical trials and case series or retrospective case reviews involving small numbers of patients. The approved indications for which Acthar is promoted and which generate a significant amount of the Company's revenues typically include clinical evidence of this type. Physicians may also base treatment decisions on their own clinical experience, or the clinical experience of their peers, in prescribing a drug. Physicians likely consider other factors as well, including the availability and relative safety and efficacy of other therapies and, if applicable, the patient's history on any such other therapies. In many cases where Acthar is a treatment option, the patients are extremely ill or debilitated from their condition. In IS, Acthar is a leading therapy, and one of only two FDA-approved therapies. For other indications, Acthar is often used as a "rescue" therapy after a patient has not adequately responded to, or had difficulties with, other treatment regimens."

3. In your response to prior Comment 2, you include proposed risk factor disclosure that references "ongoing" clinical trials for Acthar. If these ongoing clinical trials relate to existing approved indications for Acthar, please clarify. If they do not, please delete the reference.

The Company acknowledges the Staff's comment. For purposes of addressing the Staff's comment, the Company proposes to revise the previously proposed "Risk Factor" disclosure to be included in a Current Report on Form 8-K that will be incorporated by reference into the Form S-4.

The revised "Risk Factor" disclosure would read as follows (revisions marked in bold and underlined text):

"Substantially all of our net sales and profits are derived from Acthar.

For the year ended December 31, 2013, approximately 95% of our total net sales were attributable to the sale of Acthar for the treatment of the following on-label indications: Nephrotic Syndrome, certain rheumatology-related conditions, MS exacerbations in adults and IS. We expect to continue to rely on sales of Acthar for these indications for a significant percentage of our net sales and profits for the foreseeable future.

In 2010, the FDA completed its review and modernization of the Acthar label, which led to Acthar maintaining its approval for 19 indications. However, relative to other more recently approved pharmaceutical products, evidence of such efficacy for Acthar does not include clinical trials except for the IS and MS indications. Despite the recent significant increase in Acthar prescriptions for on-label indications, this limited clinical efficacy profile could impact future sales of Acthar. <u>Questcor has commenced Phase 4 clinical trials in an effort to supplement the non-clinical evidence supporting the use of Acthar in the treatment of the on-label indications of Idiopathic <u>Membraneous Nephropathy and Systemic Lupus Erythematosus</u>. The completion of ongoing or future clinical trials to provide further evidence on the efficacy of Acthar in the treatment of its approved indications could take several years to complete and will require the expenditure of significant time, financial and management resources and a clinical trial may not result in data that supports the use of Acthar to treat any of its approved indications. In addition, a clinical trial to evaluate the use of Acthar to treat indications not on the current Acthar label may not provide a basis to pursue adding such indications to the current Acthar label. Our efforts to receive approval for new indications to add to the current Acthar label would require one or more additional clinical studies and the preparation and submission of a sNDA with the FDA, and any submission may not ultimately be approved by the FDA.</u>

The demand for Acthar to treat NS, rheumatology related conditions, MS exacerbations, IS, and respiratory manifestations of symptomatic sarcoidosis is subject to significant short-term variability. We believe that investors should consider our results over several quarters when analyzing our performance. We believe that this variability in demand can be caused by several factors, including the following:

• <u>Small Number of Prescriptions. Acthar is approved to treat patients with rare diseases. Therefore, the number of prescriptions</u> for Acthar is small relative to many other drug products that are used for larger patient populations. As a result, prescriptions and sales for Acthar can have greater variability from quarter to quarter.

- MS Exacerbation Seasonality. The incidence of MS exacerbations is potentially higher in the summer months, possibly due to warmer weather, as well as during the holiday season, possibly due to increased stress.
- Insurance Plan Annual Enrollment. In prior first quarter periods, there were temporary reductions in the number of paid and shipped prescriptions for Acthar due to a slowdown in the processing of insurance coverage. Based on discussions with our reimbursement hub, as well as personnel at specialty pharmacies that process and ship Acthar prescriptions, we believe these slowdowns may have been due to additional insurance coverage verification activities required as a result of annual insurance plan re-enrollment.

Recommended treatment regimens among physicians prescribing Acthar for use in treating NS, rheumatology related conditions, MS exacerbations, IS and respiratory manifestations of symptomatic sarcoidosis vary within each therapeutic area. If physicians prescribe a lower number of vials for the treatment of any of these indications, our net sales of Acthar could decline. Additionally, we are aware that some prescriptions are initially for a lower number of vials than is necessary to complete the physician's recommended treatment regimen, and allow for one or more prescription refills. If patients do not obtain their refill prescriptions in order to complete their recommended treatment regimens, our net sales from the sale of Acthar would be negatively impacted. We may not be able to increase prescription levels by enough to offset any decline in vials per prescription.

If the sales of or demand for Acthar declines, if third-party payers refuse to provide, or make it substantially more difficult to obtain, reimbursement for purchases of Acthar, if a greater proportion of our Acthar unit sales is comprised of product dispensed to Medicaid eligible patients or if vials sourced through various patient assistance programs increase as a percent of total shipments, our net sales of Acthar would be negatively impacted. If the cost to produce Acthar increases, our gross margins on the sale of Acthar could decline. If our net sales or gross margins from the sale of Acthar decline, our ability to generate profits would be harmed."

4. In your proposed risk factor disclosure, you state that "demand for Acthar...is highly variable, and we cannot predict whether we will continue to generate significant net sales from sales of Acthar." Please explain the specific factors affecting such observed variability.

The Company acknowledges the Staff's comment. For purposes of addressing the Staff's comment, the Company proposes to revise the previously proposed "Risk Factor" disclosure to

be included in a Current Report on Form 8-K that will be incorporated by reference into the Form S-4. The Company refers the Staff to the third paragraph of the revised "Risk Factor" disclosure proposed in its response to comment 3 above.

5. We note your response to our prior Comment 3. Please expand the proposed risk factor disclosure to explain Aetna's September 2012 decision to limit reimbursement to cover only treatment for infantile spasms. Also disclose the percent of Acthar prescriptions attributable to Tricare where your proposed disclosure mentions the December 2013 Tricare coverage policy bulletin.

The Company acknowledges the Staff's comment. For purposes of addressing the Staff's comment, the Company proposes to revised the previously proposed "Risk Factor" disclosure to be included in a Current Report on Form 8-K that will be incorporated by reference into the Form S-4.

The revised "Risk Factor" disclosure would read as follows (revisions marked in bold and underlined text):

"We may be negatively affected by lower reimbursement rates.

Our ability to generate pharmaceutical net sales is affected by the availability of third party reimbursement for Acthar, and our ability to generate net sales will be diminished if we fail to maintain an adequate level of reimbursement for Acthar from such third party payers.

Acthar is a very low-volume, highly-specialized pharmaceutical product and the sale of Acthar depends in part on the availability of reimbursement from insurers, including state and federal health care plans such as Medicare and Medicaid, as well as managed care providers and private insurance plans. Like other very low-volume, highly specialized pharmaceutical products, Acthar is expensive relative to other types of pharmaceutical products, with the cost per vial being approximately \$31,000 (this is the amount Questcor invoices its specialized distributor; the Company does not have visibility into the mark-ups applied by specialized pharmaceus). In 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, including Acthar. We believe the increasing emphasis on managed care in the U.S. has and will continue to put pressure on the usage of Acthar. In addition, current third party reimbursement policies for Acthar may change at any time and such changes could include, among other things, required pre- authorizations, lower reimbursement or the loss of insurance coverage. For example, in 2012 Aetna issued a policy update that appeared to remove coverage for Acthar

for multiple approved indications and limit coverage to West Syndrome (infantile spasms). However, Aetna like most health insurers, offers plans with varying levels of coverage. In its most recent policy update (June 2014) Aetna clarified that certain Aetna plans cover all FDA-approved indications for Acthar. For patients with those plans, the 2012 policy update would not apply. Like most insurance carriers, Aetna provides approval of Acthar on a patient-by-patient basis, after careful review of prior authorization submission, and appeal submission, if applicable. However, negative changes in policies or practices of third party payers or third party payers' refusal to reimburse for Acthar may reduce the demand for, or the price of, Acthar, which could result in slower growth in Acthar sales or even lower Acthar net sales overall.

Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologicals, have been reduced by 2% under sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, Pub. L. No. 112-25, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240. The Bipartisan Budget Act of 2013, Pub. L. No. 113-67, extended the 2% reduction to 2023. Medicare Part D plans may seek discounts from us if Congress does not modify these sequestrations in the future. Other legislative or regulatory cost containment provisions, as described below, could have a similar effect. This may negatively impact our net sales. In December 2013, Tricare issued a coverage policy bulletin for Acthar restricting the use of Acthar to infantile spasms and limited other cases. The use of Acthar by patients enrolled in Tricare may decrease as a result of this coverage decision. Based on information available to the Company, prescriptions for Acthar covered by Tricare represented approximately 3.1% of the total patients prescribed Acthar for the year ended December 31, 2013.

Reimbursement of highly-specialized products, such as Acthar, is typically reviewed and approved or denied on a patient-by-patient, caseby-case basis, after careful review of details regarding a patient's health and treatment history that is provided to the insurance carriers through a prior authorization submission, and appeal submission, if applicable. During this case-by-case review, the reviewer may refer to coverage guidelines issued by that carrier. These coverage guidelines are generally updated annually, semi-annually, or spontaneously by insurance carriers. Because of the large number of carriers, there is a large number of guideline updates issued each year.

For the past several years, the overall reimbursement rates (i.e., the percentage of prescriptions approved for insurance coverage out of the total number reviewed for coverage) for Acthar across all third party payers have remained favorable and relatively consistent. <u>Specifically, based on information available to the Company, the overall reimbursement rate for Acthar across all third party payers was approximately 94%, 91% and 89% for the years ended 2011, 2012 and 2013, respectively. The Company views these rates as favorable because they indicate that significantly more prescriptions are being approved than are being denied, meaning that a high level of patients who are being prescribed Acthar are receiving insurance coverage for such prescriptions upon completion of the insurance review process. We also view these rates as relatively consistent given that the overall reimbursement rates have not fluctuated significantly over the three year period. The Company believes that reimbursement rates for Acthar have remained favorable and relatively consistent in large part because Acthar is generally reserved by physicians for patients with more severe forms of the medical conditions for which the drug is being prescribed, the patient has often not properly responded to other therapies and Acthar is approved by the FDA for that medical condition. Notwithstanding the reimbursement experience of Acthar in recent years, there can be no assurance that the reimbursement rates for Acthar will not decline in the future due to, among other possible events, policy changes by third party payers.</u>

We are unable to predict what additional legislation or regulation or changes in third party coverage and reimbursement policies may be enacted or issued in the future or what effect such legislation, regulation and policy changes would have on our business."

6. In response to prior Comments 3 and 5, your proposed disclosure indicates that the overall reimbursement rate for Acthar has remained "favorable and relatively consistent." Please quantify the overall rate of reimbursement for the last three completed fiscal years and disclose what you mean by "favorable and relatively consistent" wherever you so describe your reimbursement rate.

The Company acknowledges the Staff's comment. For purposes of addressing the Staff's comment, the Company proposes to revise the proposed "Risk Factor" and "Management's Discussion & Analysis—Results of Operations" disclosures to be included in a Current Report on Form 8-K that will be incorporated by reference into the Form S-4. The revised "Risk Factor" disclosure would read as indicated in the fifth paragraph of the proposed "Risk Factor" disclosure in the Company's response to comment 5 above. The revised "Management's Discussion & Analysis—Results of Operations" disclosure would read as indicated in the proposed disclosure in the Company's response to comment 9 below.

7. In response to prior Comment 3, your proposed risk factor disclosure states that Acthar is a very low-volume, highly specialized pharmaceutical product. Please also disclose the per-vial cost of Acthar.

The Company acknowledges the Staff's comment. For purposes of addressing the Staff's comment, the Company proposes to revise the proposed "Risk Factor" and refers the Staff to the second paragraph of the revised "Risk Factor" disclosure proposed in its response to comment 5 above.

8. We note your response to our prior Comments 4 and 6, in which you state that adverse events relating to Acthar are not material. However, the table included in your response at the bottom of page 9 indicates that adverse events as a percentage of prescriptions have doubled during the last three years. This information appears to represent a significant trend and as such, a material risk. We believe you should disclose the number of adverse events as a percentage of prescriptions over the past three years in proposed risk factor disclosure.

The Company acknowledges the Staff's comment but respectfully disagrees with the Staff's view that the information referenced in the Staff's comments represents a material risk. For purposes of addressing the Staff's comment, the Company proposes to add a "Risk Factor" disclosure in a Current Report on Form 8-K that will be incorporated by reference into the Form S-4. The Company will retain this risk factor in future 10-K filings if this information is material.

The additional "Risk Factor" disclosure would read as follows (revisions marked in bold and underlined text):

"Product Safety

Negative health outcomes for patients using Acthar could (1) lessen the frequency with which physicians decide to prescribe Acthar, (2) encourage physicians to stop prescribing Acthar to their patients who previously had been prescribed Acthar, (3) cause reportable serious adverse events and give rise to product liability claims against us, and (4) result in our need to withdraw or recall Acthar from the marketplace.

Patients who use Acthar already often have severe and advanced stages of disease and known as well as unknown significant pre-existing and potentially life-threatening health risks, including, for example, congestive heart failure, diabetic mellitus, chronic kidney failure, encephalopathies, and seizures. Additionally, Acthar is often used to treat certain auto-immune conditions and is known to impact the immune system, creating risk for the increased potential of infection in patients while taking Acthar. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to Acthar. Such events could subject us to costly litigation, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to

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market Acthar, or materially impact our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to Acthar, the investigation into the circumstance may be time consuming or inconclusive. These investigations may interrupt our sales efforts or impact and limit the type of regulatory approvals Acthar receives or maintains.

<u>From January 1, 2011 to December 31, 2013, 1,022 patients have reported an adverse event while on Acthar and 3,100 adverse events have been reported by these patients. The number of patients reporting an adverse event as a percentage of prescriptions was 4.8%, 4.9%, and 3.0%, respectively, for the years ended 2013, 2012 and 2011. The number of adverse events reported per year among patients reported to have been using Acthar as a percentage of prescriptions was 13.7%, 15.8% and 9.1%, respectively, for the years ended 2013, 2012 and 2011. The number of adverse events reported per year among patients reported to have been using Acthar as a percentage of prescriptions was 13.7%, 15.8% and 9.1%, respectively, for the years ended 2013, 2012 and 2011. These adverse events are based on reports to the Company and the FDA. As the FDA's FAERS website points out, "there is no certainty that the reported event (adverse event or dedication 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." For these and other reasons, the FDA states "FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population." Also, the types of adverse events that have occurred are consistent with the current safety profile of Acthar as presented in its prescribing information, no new safety signals have occurred, and we continue to comply with all appropriate safety, surveillance and reporting required by the FDA.</u>

Since 2011, Questcor has continued to launch sales/promotional efforts to new specialty physician audiences related to an increasing number of on-label indications. These efforts included an increase in promotion to nephrologists beginning in late 2011, a new promotional effort to rheumatologists focusing on dermatomyositis/polymyositis beginning in 2012, and a further increase in promotion to rheumatologists for DM/PM and other rheumatology-related indications beginning in early 2013. More recently, we began a new promotional effort to pulmonologists for respitory manifestations of symptomatic sarcoidosis in early 2013 and in June 2014 we increased our promotional efforts in rheumotology for SLE. Typically there is an expected increase in the reporting rate of adverse events associated with the increased use of the product in the new patient population.

We believe the increase in reported adverse events as a percentage of total prescriptions from 2011 to 2013 is primarily attributable to the fact that prior to 2012, the primary use of Acthar was for the treatment of infantile spasms or acute exacerbations in MS. In general, the number of concomitant medications (i.e., medications being used by the patient at the same time the patient is using Acthar) 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 Acthar) for these two patient populations, particularly MS, is relatively small and stable. However, for nephrology and rheumatology patients, the

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patients generally have a significant number of comorbidities, and are usually taking multiple concomitant medications. Many of the patients are on multiple other medications such as immunosuppressants, antihypertensives, diuretics, etc. These medications may also be associated with adverse events similar to those reported for Acthar, such as infections, hypertension, renal changes, weight changes etc. Regardless of other medications or comorbidities that may be present in a patient report, any adverse event report received by Questcor is reported to the FDA even if other medications or comorbidities may also be present and could be potentially contributing to the adverse event report.

9. We note your response to our prior Comment 5. In your proposed disclosure, you should quantify the number of patients prescribed Acthar in 2012 and 2013 that were covered by Aetna, Cigna, and Tricare, and any other payors that have limited or are considering limiting reimbursement. Also disclose the sales attributable to those patients in those years.

The Company acknowledges the Staff's comment. For purposes of addressing the Staff's comment, The Company proposes to address the Staff's comment with additional disclosure in a Current Report on Form 8-K that will be incorporated by reference into the Form S-4.

This disclosure would read as follows:

"Overall, reimbursement rates for Acthar across all third party payers have remained favorable and relatively consistent over the last several years. However, reimbursement rates will vary by indication and third party provider and may change due to various factors, including policy updates by third party payers or changes to the procedures used by third party payers to approve medically necessary prescriptions for reimbursement. These policy updates could negatively impact our business. For example, Aetna, Cigna, Tricare and United Healthcare have issued recent policy updates for Acthar, and these updates may negatively impact our business or the impact to such policy changes may be unknown at this time. Based on information available to the Company, the prescriptions for Acthar covered by Aetna, Cigna, Tricare and United Healthcare represented approximately 5.1%, 4.2%, 3.1% and 10.9%, respectively, of the total prescriptions for Acthar for the year ended December 31 2012 and approximately 3.6%, 3.5%, 3.1% and 10.5%, respectively, of the total prescriptions for Acthar for the year ended December 31 2013. Based on information available to the Company, approximate net sales attributable to patients covered by Aetna, Cigna, Tricare and United Healthcare represented approximately 4.8%, 4.4%, 2.9% and 11.5%, respectively, of the total net sales for Acthar for the year ended December 31, 2012 and approximately 3.3%, 3.8%, 2.8% and 11.3%, respectively, of the total net sales for Acthar for the year ended

December 31, 2013. However, based on information available to the Company, the overall reimbursement rate for Acthar across all third party payers was approximately 94%, 91% and 89% for the years ended 2011, 2012 and 2013, respectively. See the section titled "*We may* be negatively affected by lower reimbursement rates" above. Like most manufacturers of specialty drugs, Questcor faces challenges in the modern reimbursement and health care environments. To address these challenges, Questcor has experienced personnel whose focus is to interact with payers on an ongoing basis. Through our ongoing efforts, the number of Acthar prescriptions covered by insurance has continued to grow from 2012 to the present, from 6,993 prescriptions overall in 2012 to 8,963 in 2013. Significant growth in the number of Acthar prescriptions covered by insurance is continuing through the first half of 2014 as well."

10. Please refer to our discussion on July 1, 2014. Please tell us if you acquired more than one intangible asset in connection with the Novartis License Agreement. If you believe you acquired more than one intangible asset, please provide us an analysis explaining how you determined the relative fair value assigned to each intangible asset based on market participant assumptions.

After considering the content of our call on July 1, 2014, Questcor acknowledges that it did acquire two intangible assets: Synacthen and Synacthen Depot. In future filings we will clarify in our disclosures as to when we are referring to the Synacthen Depot product and when we are referring to the Synacthen product. As described below, based on the facts known or knowable at the time of the transaction, had Questcor accounted for Synacthen and Synacthen Depot as separate intangible assets, it would have assigned 0% of the purchase price to Synacthen and 100% to Synacthen Depot under ASC 805-50-30-3.

During the negotiation process with Novartis, Questcor considered the fair value of Synacthen, a short-acting diagnostic product, and determined that the product did not have value to Questcor or to any other market participant. Questcor respectfully submits the following information in support of this view:

<u>Market Participant Dynamics</u>. The primary use of short-acting tetracosactide (also referred to as cosyntropin), the active pharmaceutical ingredient in Synacthen, is to test adrenal gland function by measuring the adrenal gland's secretion of cortisol. There are several causes of low cortisol levels. For example, Addison's disease is a disorder where a person's adrenal glands produce too little steroid. Physicians test for this condition, as well as others involving low cortisol levels, by administering short-acting tetracosactide and measuring resulting adrenal cortisol production. The market leading short-acting tetracosactide product is the branded product Cortrosyn, which was approved by the U.S. Food and Drug Administration, or FDA, in 1970 and is currently

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owned by Amphastar Pharmaceuticals, Inc. In 2012, Amphastar generated approximately \$13.8 million in sales from Cortrosyn, but was believed to be losing market share to two generic diagnostic products, owned by two of the leading generics companies: Sandoz (a Novartis subsidiary) and Mylan Inc. Cortrosyn's loss of market share has been confirmed: in its first-quarter ended March 31, 2014, Amphastar generated revenue from Cortrosyn of approximately \$2.4 million, indicating an annual revenue run-rate of approximately \$9.6 million (30% less than 2012).

A market participant could attempt to obtain FDA approval for Synacthen and then attempt to use its brand to compete in the branded portion of the market against Cortrosyn or could choose to compete directly with the generic products based solely on price. Questcor believed that competing with the embedded branded product, Cortrosyn, would be difficult since Synacthen has no material differentiating features relative to Cortrosyn. Questcor believed that a market participant would also face the difficult prospect of attempting to take share from the first branded product in a shrinking market. Confirming this view, Amphastar has recognized the challenging nature of the market for Cortrosyn in its recent prospectus for its initial public offering: "In addition, due to intense pricing competition in the pharmaceutical industry, we have experienced significant declines in the per unit pricing and gross margins attributable to several of our products, including ... Cortrosyn ... We expect this pricing pressure to continue in future periods."

<u>Market Participation Assumptions and Economic Analysis</u>. Questcor analyzed entering the market with Synacthen as a branded competitor and alternatively as a generic competitor.

<u>As a Branded Competitor</u>: In its internal discounted cash flow / net present value model for the transaction, Questcor did not assign any value to the short-acting Synacthen. On a standalone basis, Questcor has determined that the net present value for Synacthen is negative. This analysis is based on the following assumptions:

- 3% branded price erosion year over year, which is in alignment with Amphastar's disclosures in its public documents and consistent with the entry of a competing branded drug (Synacthen);
- Capture of 33% of the branded market within three years post-launch;
 - Net sales ranging \$1.5 million to \$2.2 million per year
- Gross margin of 90%;
- 20% sales and marketing expense burden post-launch;
- 5% general and administrative expense burden post-launch;

- Two regulatory full time equivalent employees; and
- Development costs of \$5.25 million pre-launch with \$100,000 annually post-launch.

Based on the assumptions identified above, the resulting net present value is negative and would not warrant the assignment of any value to the short-acting Synacthen. We arrived at this same conclusion using different assumptions in a sensitivity analysis.

<u>As a Generic Competitor</u>: The generic companies compete on price and discount generic short-acting tetracosactide by approximately 15% to 20% relative to Cortrosyn. Thus, while the costs to get FDA approval and operate the business would be approximately the same, the revenue would be lower. As such, however poor the economics were for a new branded product, they were even worse in the generic component of the market.

<u>Conclusion</u>: Therefore, had Questcor accounted for Synacthen and Synacthen Depot as separate intangible assets, it would have assigned 100% of the purchase price to Synacthen Depot (or \$196 million) and 0% to Synacthen (or \$0).

<u>Novartis' Views in the Deal</u>. Interestingly, Novartis' own subsidiary Sandoz is the owner of one of the generic products, for which it obtained FDA approval in 2008. Questcor believes that Novartis would not have created a potential competitor for Sandoz and, therefore, must have recognized that it would not make economic sense for a third party to seek approval and commercialization of Synacthen.

Pursuant to your request, the Company acknowledges that: (i) it is responsible for the adequacy and accuracy of the disclosure in its filings; (ii) Staff comments or changes to disclosure in response to Staff comments do not foreclose the Commission from taking any action with respect to the filings; and (iii) 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.

Please contact me at (714) 786-4201 or Joel H. Trotter of Latham & Watkins LLP at (202) 637-2165 should you have further comments or if you require any additional information.

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Respectfully yours,

/s/ Rajesh Asarpota Rajesh Asarpota Senior Vice President, Chief Financial Officer

cc: Jeffrey P. Riedler, the Commission Mary Mast, the Commission Austin Stephenson, the Commission Michael Mulroy, Questcor Pharmaceuticals, Inc.
R. Scott Shean, Latham & Watkins LLP Joel H. Trotter, Latham & Watkins LLP Adam O. Emmerich, Wachtell, Lipton, Rosen & Katz Benjamin M. Roth, Wachtell, Lipton, Rosen & Katz