

QUESTCOR PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 02/16/12 for the Period Ending 02/16/12

Address	1300 NORTH KELLOGG DRIVE SUITE D ANAHEIM, CA 92807
Telephone	714-786-4200
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Sector	Healthcare
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

**PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): February 16, 2012

QUESTCOR PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

California
(State or Other Jurisdiction
of Incorporation)

001-14758
(Commission
File Number)

33-0476164
(I.R.S. Employer
Identification No.)

**1300 Kellogg Drive, Suite D, Anaheim,
California**
(Address of Principal Executive Offices)

92807
(Zip Code)

Registrant's telephone number, including area code: (714) 786-4200

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01. Regulation FD Disclosure.

Commencing on February 16, 2012, Questcor Pharmaceuticals, Inc. (the "Company") will utilize an updated presentation for investor relations purposes. The presentation includes the following update regarding prescription information for the Company's primary product, H.P. Acthar Gel (repository corticotropin injection) ("Acthar") for January 2012, based on the most recent data available to the Company at the time of this filing:

- For acute exacerbations of multiple sclerosis ("MS"), the number of paid prescriptions was between 330 and 345 for January 2012.
- For proteinuria in nephrotic syndrome of the idiopathic type ("NS"), the number of paid prescriptions was between 70 and 75 for January 2012.
- For infantile spasms ("IS"), the number of paid prescriptions was between 45 and 50 for January 2012.

The Company is also disclosing the following unaudited balance sheet information as of January 31, 2012:

- Cash, cash equivalents and short-term investments: \$214 million.
- Accounts receivable: \$45 million

Risk Factor Regarding Volatility of Prescription Levels

The number of paid prescriptions for Acthar in each therapeutic area is volatile and the Company cautions investors to not view data for a single month or a single quarter as representative of a trend or otherwise being predictive of future results. The Company believes that investors should consider the Company's results over several quarters when analyzing the Company's performance.

Important, Previously Disclosed Information Regarding Prescriptions and Net Sales

Net sales of Acthar are derived from the Company's sales of vials to CuraScript Specialty Distributor ("CuraScript SD"), which in turn sells Acthar primarily to specialty pharmacies. These specialty pharmacies place orders to CuraScript SD based on their respective levels of sales and inventory practices. End-user demand for Acthar results from physicians writing prescriptions to patients for the treatment of MS exacerbations, NS, IS and various other conditions. Physicians do not purchase Acthar for resale to patients. Instead, patients purchase Acthar directly from specialty pharmacies after receiving a prescription and, typically, arranging for third party reimbursement (government or commercial insurance) – often after satisfying a prior authorization requirement imposed by their insurance carrier.

Recommended treatment regimens among physicians prescribing Acthar vary within each therapeutic area. Due to various factors, including inventory levels at both the specialty pharmacies and at CuraScript SD, the duration of treatment regimens and the timing of the placement of refill prescription orders, there is typically a delay between changes in prescription levels and changes in the levels of orders the Company receives from CuraScript SD. Additionally, treatment regimens, and patient compliance with physician-recommended treatment regimens, may vary over time.

The Company's ability to accurately determine the number of prescriptions is subject to the following important notes:

- (1) Because Acthar prescriptions are filled at specialty pharmacies, the Company does not receive complete information regarding either the number of prescriptions or the number of vials by therapeutic area for all of the patients being treated with Acthar. However, the Company is able to monitor trends in payer mix and areas of therapeutic use for new (non-refill) Acthar prescriptions based on data the Company receives from its reimbursement support center. The Company estimates that over 90% of new Acthar prescriptions are processed by this support center, but believes that very few refill prescriptions are processed there.
- (2) Prescription figures include related conditions for each therapeutic area. Related conditions are diagnoses that are either alternative descriptions of the medical condition or are closely related to the medical condition

referenced above. For example, a prescription for “Demyelinating disease of the central nervous system” would be included as an MS-related condition for purpose of the updated prescription information provided above. About 5% of the prescriptions referenced for a specific indication are for related conditions.

(3) A new prescription may or may not represent a new patient or a new therapy for the patient receiving the prescription. The Company uses business rules to determine whether a prescription should be classified as new for counting purposes. From time to time, the Company may modify these rules.

The presentation is furnished under this Item 7.01 pursuant to Regulation FD and is included as Exhibit 99.1 to this Current Report on Form 8-K. The presentation will also be made available on the Company’s website at www.questcor.com. In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<i>Exhibit No.</i>	<i>Description</i>
99.1	Questcor Pharmaceuticals, Inc. Investor Presentation dated February 16, 2012.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 16, 2012

QUESTCOR PHARMACEUTICALS, INC.

By: /s/ Michael Mulroy
Michael Mulroy, Chief Financial Officer &
General Counsel

EXHIBIT INDEX

Exhibit No.

Description

99.1

Questcor Pharmaceuticals, Inc. Investor Presentation dated February 16, 2012.

NASDAQ **QCOR**

February 16, 2012

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Safe Harbor Statement

Except for the historical information contained herein, this presentation contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All such statements have been made pursuant to the Private Securities Litigation Reform Act of 1995, as amended. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "if," "should," "forecasts," "intends," "exploring," "expects," "plans," "appears," "grows," "believes," "estimates," "predicts," "potential," "continue" or "trends" or the negative of such terms and other comparable terminology. These statements are only predictions. Actual events or results may differ materially. Factors that could cause or contribute to such differences include, but are not limited to, the following: Our reliance on Acthar for substantially all of our net sales and profits; Reductions in vials used per prescription resulting from changes in treatment regimens by physicians or patient compliance with physician recommendations; The complex nature of our manufacturing process and the potential for supply disruptions or other business disruptions; The lack of patent protection for Acthar; and the possible FDA approval and market introduction of competitive products; Our ability to generate revenue from sales of Acthar to treat on-label indications associated with NS, and our ability to develop other therapeutic uses for Acthar including SLE; Research and development risks, including risks associated with Questcor's work in the area of nephrotic syndrome and potential work in the area of SLE, and our reliance on third-parties to conduct research and development and the ability of research and development to generate successful results; Regulatory changes or other policy actions by governmental authorities and other third parties in connection with U.S. health care reform or efforts to reduce federal and state government deficits; Our ability to receive high reimbursement levels from third party payers; An increase in the proportion of our Acthar unit sales comprised of Medicaid-eligible patients and government entities; Our ability to estimate reserves required for Acthar used by government entities and Medicaid-eligible patients and the impact that unforeseen invoicing of historical Medicaid prescriptions may have upon our results; Our ability to operate within an industry that is highly regulated at both the Federal and state level; Our ability to effectively manage our growth, including the expansion of our NS selling effort, and our reliance on key personnel; The impact to our business caused by economic conditions; Our ability to protect our proprietary rights; Our ability to maintain effective controls over financial reporting; The risk of product liability lawsuits; Unforeseen business interruptions; Volatility in Questcor's monthly and quarterly Acthar shipments and end-user demand, as well as volatility in our stock price; and Other risks discussed in Questcor's annual report on Form 10-K for the year ended December 31, 2010, and other documents filed with the Securities and Exchange Commission.

The risk factors and other information contained in these documents should be considered in evaluating Questcor's prospects and future financial performance.



Questcor

A biopharmaceutical company whose product, Acthar, helps patients with serious, difficult-to-treat medical conditions

Questcor Overview

Flagship Product: H.P. **Acthar**[®] GEL
(repository corticotropin injection) 80 U/mL

- 19 approved indications

Key Markets*:

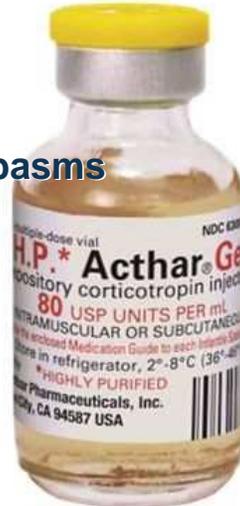
- Multiple Sclerosis, Nephrotic Syndrome, Infantile Spasms
- Several billion dollar market opportunity

Strategy:

- Continue to grow Acthar sales in each key market
- Develop other on-label markets for Acthar

Financials:

- Profitable, cash flow positive, \$214M** in cash, debt-free



*In this presentation, the terms "Multiple Sclerosis," "Nephrotic Syndrome" and "Infantile Spasms," and their abbreviations, refer to the on-label indications for Acthar associated with such conditions. Investors should refer to the FDA approved Acthar label, which can be found at <http://www.acthar.com/files/Acthar-PI.pdf>. **As of 01/31/12

Questcor Strategy Pursue Acthar Markets

Multiple Sclerosis (MS)

Nephrotic Syndrome (NS)

Infantile Spasms (IS)

Systemic Lupus Erythematosus

Acthar and Multiple Sclerosis (MS)

Neurodegenerative disorder

Acute treatment for relapses

Patient reported
response to IV Steroids*

43% get better or
much better

27% get only a
little better

30% stay the same
or get worse

Potential
target for

Acthar[®]

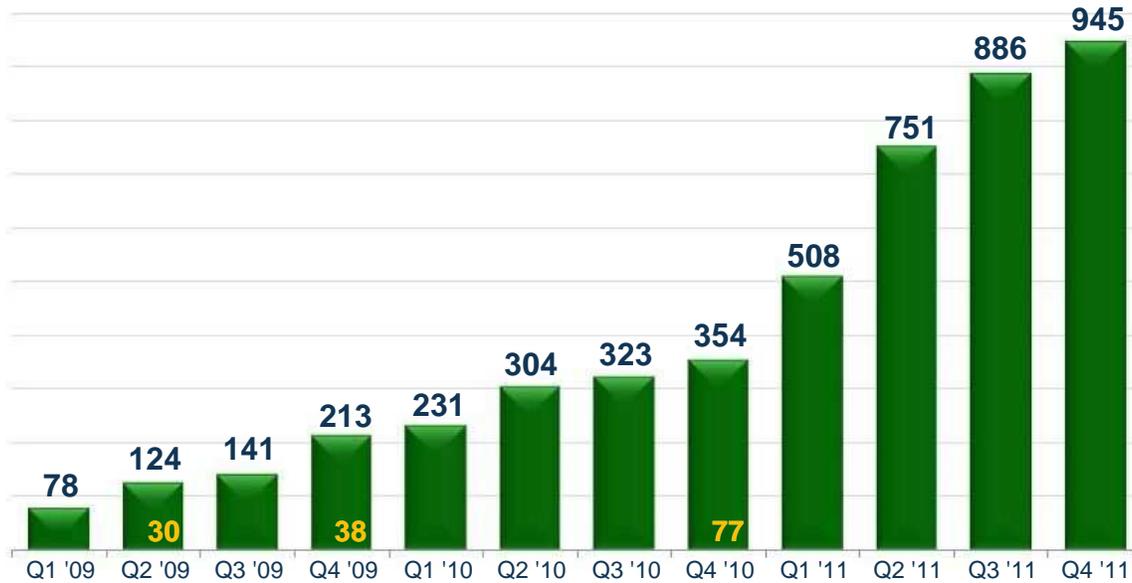
*Nickerson, et al (2011)



ACTHAR is approved for MS exacerbations, without reference to first line or second line use but is generally positioned as second line as a matter of marketing strategy. See <http://www.acthar.com/files/Acthar-PI.pdf> for details.

MS Scripts-Record of Consistent Growth

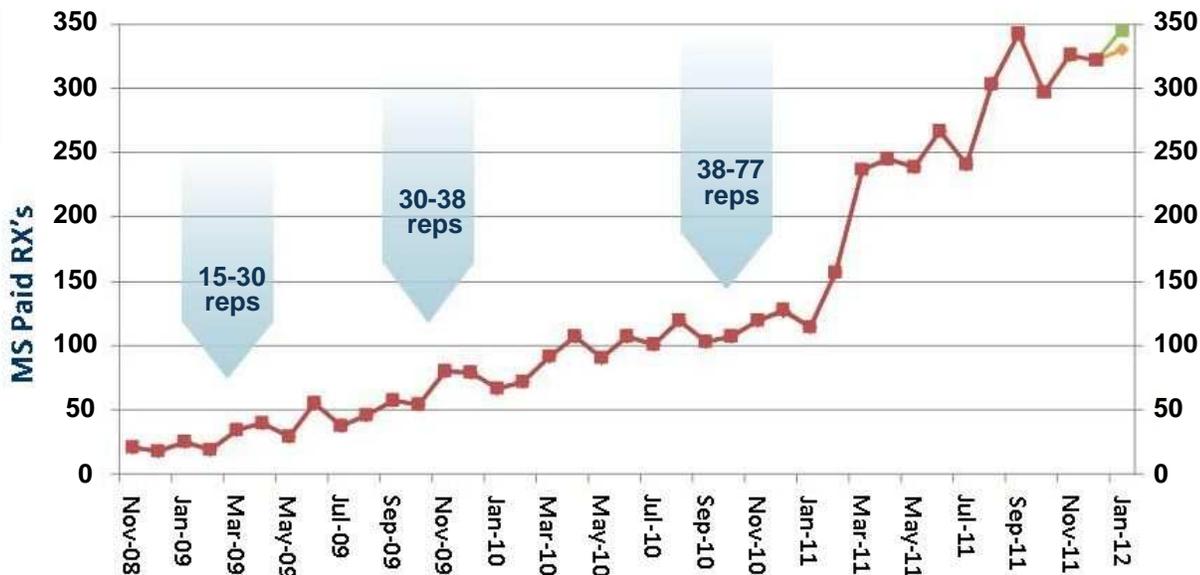
Paid Rx's



Notes: Historical trend information is not necessarily indicative of future results. Acthar is marketed for the on-label indication of MS exacerbations in adults, though the chart includes "Related Conditions" - diagnoses that are either alternative descriptions of the condition or are closely related to the medical condition which is the focus of the chart. About 5% of the prescriptions in the tables are for related conditions. Yellow numbers in the bars show the number of MS sales representatives making calls for the majority of the quarter.



Monthly MS Scripts History

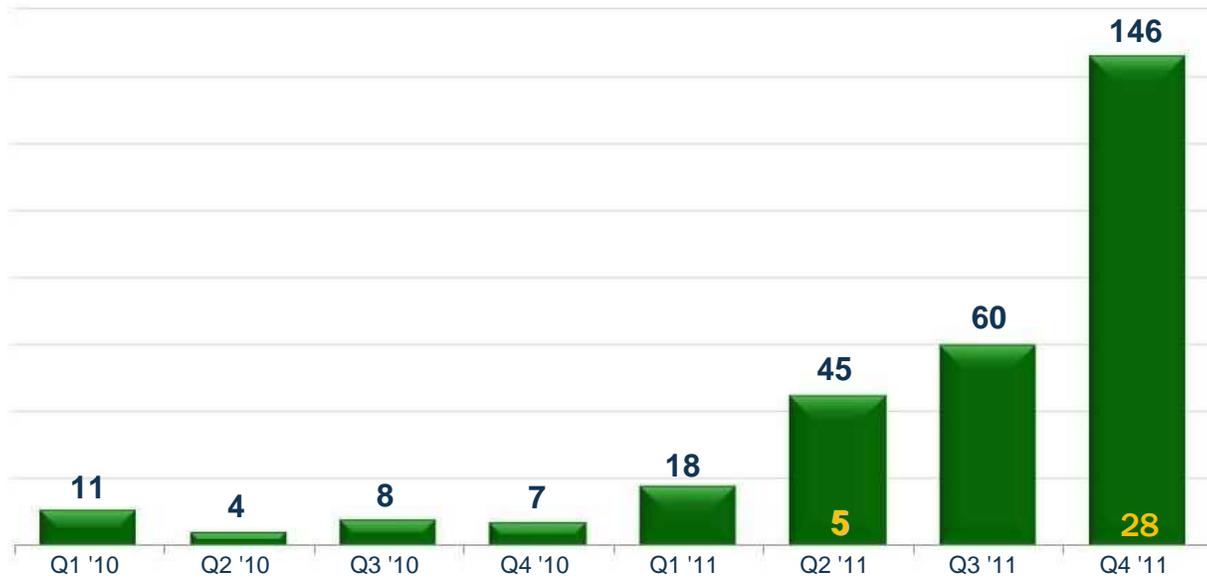


Notes: Historical trend information is not necessarily indicative of future results. Acthar is marketed for the on-label indication of MS exacerbations in adults, though the chart includes "Related Conditions" - diagnoses that are either alternative descriptions of the condition or are closely related to the medical condition which is the focus of the chart. About 5% of the prescriptions in the tables are for related conditions.

Acthar and Nephrotic Syndrome (NS)

- Characterized by excessive spilling of protein from the kidneys into the urine (proteinuria)
- Can result in end-stage renal disease (ESRD), dialysis, transplant
- Acthar is approved “to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus”
- Significant unmet need
 - Few treatment options
 - Goal of therapy is the significant reduction of proteinuria

NS Scripts-Strong Q4 Growth



Yellow numbers in the bars show the number of NS sales representatives making calls for the majority of the quarter. Q3'11 included expansion and training of new sales people.

Paid Rx's



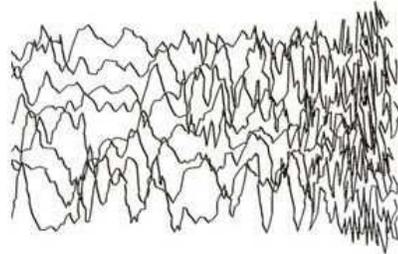
Notes: Historical trend information is not necessarily indicative of future results. Chart includes "Related Conditions" - diagnoses that are either alternative descriptions of the condition or are closely related to the medical condition which is the focus of the chart.

Acthar and Infantile Spasms (IS)

- FDA approval 10/15/10
- Devastating, refractory form of childhood epilepsy
- IS not responsive to standard anti-epileptic drugs
- Unsuccessful treatment may leave infant with permanent developmental disabilities
- Considered a medical emergency
- Ultra-rare orphan disorder
- About half of IS patients receive Acthar via Acthar patient support programs and Medicaid

IS Scripts-Higher numbers in H2 2011

- Acthar currently used to treat 40-50% of IS patients
- Targeting select institutions
- Significant variability in quarterly Rx's
- Q4-2011 paid Rx's above historic range



Systemic Lupus Erythematosus (Lupu

- **High unmet need; difficult to treat**
- **Serious health risk if unsuccessfully treated**
- **Multiple on-label indications for Acthar**
 - Exacerbations
 - Maintenance therapy
 - Lupus nephritis
- **Large patient population**

Financials

Profitable

Debt Free

Cash Flow Positive

Q3-2011 Financial Results

Record Net Sales (up 91%) and Solid Earnings (EPS up 94%)

	Q3 –2011	Q3 –2010
Net Sales (\$M)	\$59.8	\$31.3
Gross Margin	94%	93%
Operating Income (\$M)	\$33.6	\$16.8
Fully Diluted, GAAP EPS	\$0.35	\$0.18

- Third quarter vials shipped: 2,910
- Third quarter cash flow from operations: \$32.6M
- Channel inventory estimated to be within historic range
- Medicaid reserves continue to appear adequate
- No shares repurchased

Questcor is Cash Flow Positive

	01/31/12
Cash / ST Investments	\$214M*
Accounts Receivable	\$45M

*After return of \$78 million of cash to shareholders through share repurchases.

Debt-free balance sheet

Share Repurchases: 15 Million Shares

- 2.2 Million Preferred share buyback
- 13.2 Common share buyback
- **\$78 million returned to shareholders in stock buybacks**
- 63.6 million shares currently outstanding
- 4.3 million shares remain on buyback authorization

Repurchased shares significantly improved EPS

Preliminary Q4-2011 Metrics

- 3,360 Vials Shipped
- Net sales of approximately \$75 million
- Operating expenses expected to be up 20-30% from Q3-2011
- Operating income of approximately \$41 million to \$43 million
- Paid Rxs Q4-11 and January 2012 (estimated)

DX	Q4-11	January 2012
MS	945	330-345
NS	146	70-75
IS	120	45-50

Notes: Paid Rx information based on internal estimates. The table includes "Related Conditions" - diagnoses that are either alternative descriptions of the condition or are closely related to the medical condition which is the focus of the chart. About 5% of the prescriptions in the tables are for related conditions.

How Does Acthar Work?

- Acthar treats autoimmune conditions across a variety of organ systems (CNS, kidney, etc.)
- Acthar appears to modulate the immune system and associated inflammatory response through binding to melanocortin receptors
- The primary melanocortin peptide (ACTH) in Acthar binds to all 5 melanocortin receptors (MCR1-5); other active peptides are in Acthar as well
 - Indirect effect: Acthar triggers the production of corticosteroids and adrenal compounds through binding to MCR2 receptors
 - Direct effect: Acthar acts directly at the cellular level by binding to melanocortin receptors on immune cells and cells in the targeted tissues (e.g., kidney podocytes)
- All the active ingredients of Acthar have yet to be fully characterized and the mechanism of action and pharmacokinetic profile of Acthar are not fully known

Biosimilar Pathway Difficult/Impossible

- **Difficult/impossible to reverse engineer ACTHAR**
 - Not well characterized
- **Complex pharmacology**
 - Not well characterized
- **Clinical trial(s) required**

Acthar Market Opportunity

Market	Rx Value	Market Size
MS	\$40-50K	\$1B+
NS	\$150-250K	\$1B+
IS	\$100-125K	\$100M
Lupus	Unknown	Unknown
Other	Various	Unknown
Total		\$2B+

NS Business Already Significant

Market	Approximate Annualized Net Sales Run Rate*	Approximate Annualized Level of Business**
MS	\$145-160M	\$145-160M
NS	\$60-70M	\$100-110M
IS	\$40-50M	\$40-50M

Note: Figures do not represent actual net sales ranges for the quarter or year ended December 31, 2011

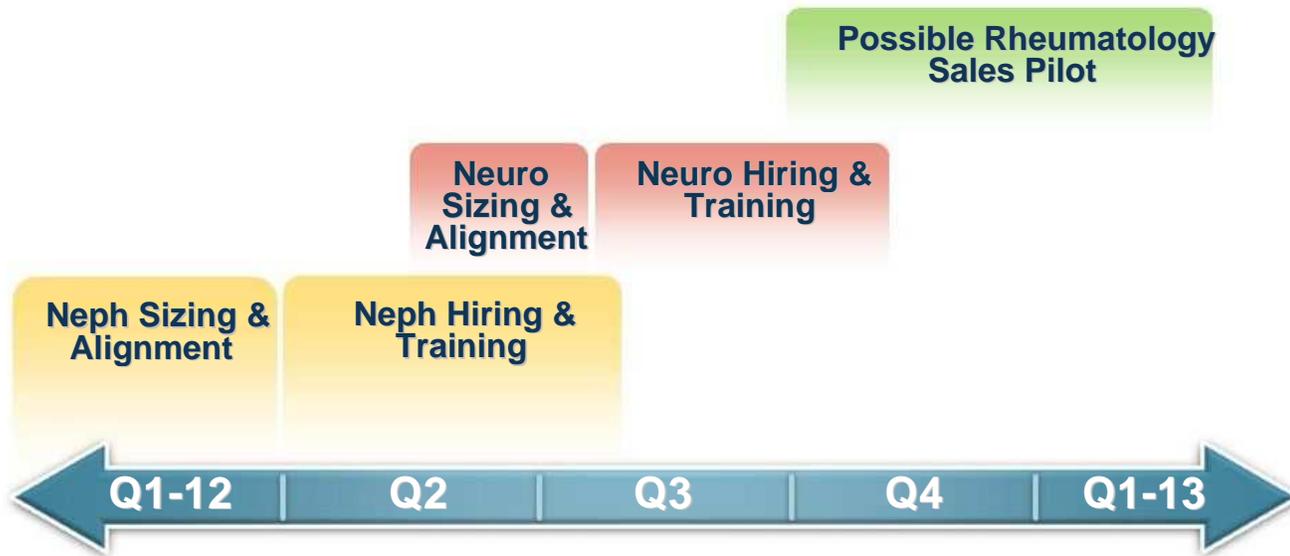
* Figures based on estimates of vials shipped to patients within each therapeutic area in the quarter, multiplied by 4.

** Figures represent Q4-2011 new paid prescriptions times estimated vials per script over treatment regimen, multiplied by 4.

Strategic Plan- Focus on the Embedded Pipeline in Acthar

- **Expand NS promotion effort**
- **Expand MS promotion effort**
- **Maintain IS promotion effort**
- **Develop pilot rheumatology promotion activity**
- **Develop other markets for Acthar**
 - Acthar is its own pipeline with many other on-label indications and many possible other therapeutic uses
 - Further define and develop the unique characteristics of Acthar
- **No unrelated business development efforts planned**

Sales Force Expansion- Preliminary Outlook for 2012



Investment Highlights

Acthar has sustainable competitive advantages-without FDA approval risk

Acthar is approved for 19 indications-many in large markets with sizable unmet need

Sales in MS and NS are growing rapidly, yet market penetration is low

Developing new vertical markets

High margins provide good operating leverage

Profitable, cash flow positive, no debt

NASDAQ **QCOR**

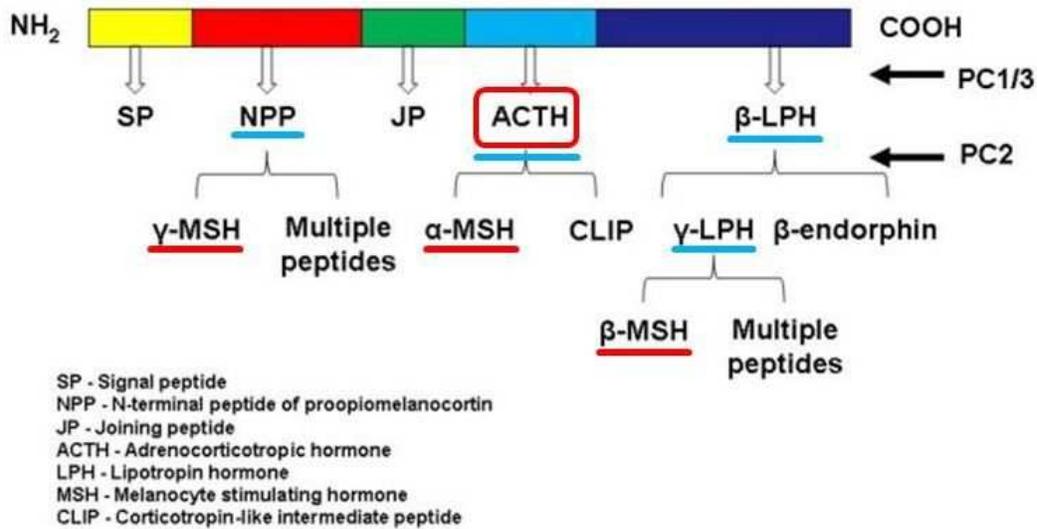
February 16, 2012

Leerink Swann



ACTH is a Melanocortin Peptide Derived from Pro-opiomelanocortin (POMC) in the Pituitary

Pro-opiomelanocortin Precursor Polypeptide



Affinity of Melanocortin Peptides and Distribution of Receptor Subtypes

MCR	Prevalent Tissue/Cells with Receptor
MC1R	Podocytes Renal Mesangial Cells Endothelial Cells (Glomerular, Tubular, Vascular) Tubular Epithelial Cells Macrophages Melanocytes Immune/Inflammatory Cells Keratinocytes CNS
MC2R	Adrenal Cortex (Steroidogenesis), Adipocytes

Affinity of Melanocortin Peptides and Distribution of Receptor Subtypes

MCR	Prevalent Tissue/Cells with Receptor
MC3R	CNS Macrophages
MC4R	Podocytes Renal Mesangial Cells (?) Endothelial Cells (Glomerular, Tubular) Tubular Epithelial Cells CNS
MC5R	CNS Exocrine Glands Lymphocytes Podocytes

MOA of Acthar in N

Acthar, Melanocortin Peptides

