QUESTCOR PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

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Address	1300 NORTH KELLOGG DRIVE SUITE D ANAHEIM, CA 92807
Telephone	714-786-4200
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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): July 10, 2014

QUESTCOR PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

California	**001-14758**	**33-0476164**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

1300 Kellogg Drive, Suite D, Anaheim, California	**92807**
(Address of Principal Executive Offices)	**(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))

ITEM 8.01 OTHER EVENTS

Questcor Pharmaceuticals, Inc. (the " Company ") is filing this Current Report on Form 8-K in connection with the preparation of the Registration Statement on Form S-4 of Mallinckrodt plc ("Mallinckrodt") (File No. 333-196054) (the " Registration Statement "), which includes the Company's Proxy Statement relating to its pending merger transaction with Mallinckrodt. This Current Report on Form 8-K revises the disclosure contained within the following items in the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2013 (the " 2013 Form 10-K "):

- Part I, Item 1. Business
- Part I, Item 1A. Risk Factors
- Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The preceding information is filed hereunder as Exhibit 99.1 which is incorporated herein by reference.

All revisions to the 2013 Form 10-K relate solely to the items set forth above. These revisions have no effect on the Company's previously reported results of operations, financial position, or cash flows. The information in this Current Report on Form 8-K should be read in conjunction with the 2013 Form 10-K (except for the items revised herein), which was previously filed with the Securities and Exchange Commission. All other information in the 2013 Form 10-K remains unchanged and neither the items set forth above nor any other items in the 2013 Form 10-K have been updated for events occurring after December 31, 2013, except as expressly set forth in Exhibit 99.1. For significant developments since December 31, 2013, refer to subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

The information in this Current Report on Form 8-K is deemed incorporated by reference into the Company's registration statements filed under the Securities Act of 1933, as amended, and will also be incorporated by reference into the Registration Statement.

Cautionary Statement Regarding Forward-Looking Statements

Statements in this document that are not strictly historical, including statements regarding the proposed acquisition, the expected timetable for completing the transaction, future financial and operating results, benefits and synergies of the transaction, future opportunities for the combined businesses and any other statements regarding events or developments that we believe or anticipate will or may occur in the future, may be "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve a number of risks and uncertainties. There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements. These factors include risks and uncertainties related to, among other things: general economic conditions and conditions affecting the industries in which Mallinckrodt and the Company operate; the commercial success of Mallinckrodt's and the Company's products, including H.P. Acthar ® Gel; Mallinckrodt's and the Company's ability to protect intellectual property rights; the parties' ability to satisfy the merger agreement conditions and consummate the merger on the anticipated timeline or at all; the availability of financing, including the financing contemplated by the debt commitment letter, on anticipated terms or at all; Mallinckrodt's ability to successfully integrate the Company's operations and employees with Mallinckrodt's existing business; the ability to realize anticipated growth, synergies and cost savings; the Company's performance and maintenance of important business relationships; the lack of patent protection for Acthar, and the possible United States Food and Drug Administration ("FDA") approval and market introduction of additional competitive products; the Company's reliance on Acthar for substantially all of its net sales and profits; the Company's ability to continue to generate revenue from sales of Acthar to treat on-label indications associated with nephrotic syndrome, multiple sclerosis, infantile spasms or rheumatology-related conditions, and the Company's ability to develop other therapeutic uses for Acthar; volatility in the Company's Acthar shipments, estimated channel inventory, and end-user demand; an increase in the proportion of the Company's Acthar unit sales comprised of Medicaid-eligible patients and government entities; the Company's research and development risks, including risks associated with the Company's work in the area of nephrotic syndrome and Lupus, the Company's efforts to develop and obtain FDA approval of Synacthen Depot; Mallinckrodt's ability to receive procurement and production quotas granted by the

U.S. Drug Enforcement Administration; Mallinckrodt's ability to obtain and/or timely transport molybdenum-99 to our technetium-99m generator production facilities; customer concentration; cost-containment efforts of customers, purchasing groups, third-party payors and governmental organizations; Mallinckrodt's ability to successfully develop or commercialize new products; competition; Mallinckrodt's ability to integrate acquisitions of technology, products and businesses generally; product liability losses and other litigation liability; the reimbursement practices of a small number of large public or private issuers; complex reporting and payment obligation under healthcare rebate programs; changes in laws and regulations; conducting business internationally; foreign exchange rates; material health, safety and environmental liabilities; litigation and violations; information technology infrastructure; and restructuring activities. Additional information regarding the factors that may cause actual results to differ materially from these forward-looking statements is available in (i) Mallinckrodt's SEC filings, including its Annual Report on Form 10-K for the fiscal year ended September 27, 2013 and Quarterly Reports on Form 10-Q for the quarterly periods ended December 27, 2013 and March 28, 2014; (ii) the SEC filings of Cadence Pharmaceuticals, Inc., which was acquired by Mallinckrodt on March 19, 2014, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2013; and (iii) the Company's SEC filings, including the 2013 Form 10-K (and the amendment thereto on Form 10-K/A) and its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014. The forward-looking statements made herein speak only as of the date hereof and none of Mallinckrodt, the Company or any of their respective affiliates assumes any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.

Important Information for Investors and Shareholders

This Current Report on Form 8-K does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. In connection with the proposed transaction between Mallinckrodt and the Company, Mallinckrodt filed with the Securities and Exchange Commission (the " SEC ") on May 16, 2014 a registration statement on Form S-4 that includes a preliminary joint proxy statement of Mallinckrodt and the Company and also constitutes a preliminary prospectus of Mallinckrodt. The registration statement is not yet effective. The definitive joint proxy statement/prospectus will be delivered to shareholders of Mallinckrodt and the Company. INVESTORS AND SECURITY HOLDERS OF MALLINCKRODT AND THE COMPANY ARE URGED TO READ THE DEFINITIVE JOINT PROXY STATEMENT/PROSPECTUS AND OTHER DOCUMENTS THAT WILL BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and security holders will be able to obtain free copies of the registration statement and the definitive joint proxy statement/prospectus (when available) and other documents filed with the SEC by Mallinckrodt and the Company through the website maintained by the SEC at http://www.sec.gov. Copies of the documents filed with the SEC by Mallinckrodt will be available free of charge on Mallinckrodt's internet website at www.mallinckrodt.com or by contacting Mallinckrodt's Investor Relations Department at (314) 654-6650. Copies of the documents filed with the SEC by the Company will be available free of charge on the Company's internet website at www.questcor.com or by contacting the Company's Investor Relations Department at (714) 497-4899.

Participants in the Merger Solicitation

Mallinckrodt, the Company, their respective directors and certain of their executive officers and employees may be considered participants in the solicitation of proxies in connection with the proposed transaction. Information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of the Mallinckrodt and the Company shareholders in connection with the proposed merger and a description of their direct and indirect interests, by security holdings or otherwise, will be set forth in the joint proxy statement/prospectus when it is filed with the SEC. Information about the directors and executive officers of Mallinckrodt is set forth in its proxy statement for its 2014 annual meeting of stockholders, which was filed with the SEC on January 24, 2014. Information about the directors and executive officers of the Company is set forth in the amendment to its Annual Report on Form 10-K/A, which was filed with the SEC on April 30, 2014.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

99.1 Revisions, where applicable, to the 2013 Form 10-K include:

- Part I, Item 1. Business
- Part I, Item 1A. Risk Factors
- Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

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: July 10, 2014

QUESTCOR PHARMACEUTICALS, INC.

By /s/ Michael H. Mulroy
Michael H. Mulroy
Executive Vice President, Strategic Affairs and
General Counsel

EXHIBIT INDEX

Exhibit	Description
99.1	Revisions, where applicable, to the 2013 Form 10-K include: • Part I, Item 1. Business • Part I, Item 1A. Risk Factors • Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Item 1. Business

Business Overview

We are a biopharmaceutical company focused on the treatment of patients with serious, difficult-to-treat autoimmune and inflammatory disorders. We also supply specialty contract manufacturing services to the global pharmaceutical and biotechnology industry through our wholly-owned subsidiary, BioVectra Inc.

We have historically operated in one business segment. On January 18, 2013, we acquired all of the issued and outstanding shares of BioVectra Inc, a wholly-owned subsidiary through which we supply specialty contract manufacturing services to the global pharmaceutical and biotechnology industry. We now manage our operations through two operating segments that are defined by our separate companies - Questcor Pharmaceuticals, Inc. and BioVectra, Inc. Each segment is operated as an independent business under its own management team, and has responsibility for its commercial activities, operations, and research and development activities related to its products.

Except to the extent that differences among operating segments are material to an understanding of our business taken as a whole, the description of our business in this Annual Report on Form 10-K is presented on a consolidated basis.

For financial information relating to our reporting segments, see Note 1 to our consolidated financial statements included in Item 15 of Part IV " *Exhibits and Financial Statement Schedules* " of this Annual Report on Form 10-K., which are incorporated herein by reference.

Questcor Pharmaceutical Segment

Our primary product is H.P. Acthar ® Gel (repository corticotropin injection), or Acthar, an injectable drug that is approved by the U.S. Food and Drug Administration, or FDA, for the treatment of 19 indications. Of these 19 indications, for the year ended December 31, 2013, we generated substantially all of our pharmaceutical net sales from the use of Acthar in connection with the following indications:

- Nephrotic Syndrome (NS): Acthar is indicated "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." According to the National Kidney Foundation, nephrotic syndrome can result from several idiopathic type kidney disorders, including idiopathic membranous nephropathy, focal segmental glomerulosclerosis, IgA nephropathy and minimal change disease. Nephrotic syndrome can also occur due to lupus erythematosus. In this Form 10-K, the terms "nephrotic syndrome" and "NS" refer only to the proteinuria in nephrotic syndrome conditions that are covered by the Acthar label of approved indications.
- Rheumatology Related Conditions: Acthar is approved for the following rheumatology related conditions: (i) Collagen Diseases: Acthar is indicated "during an exacerbation or as maintenance therapy

in selected cases of systemic lupus erythematosus, systemic dermatomyositis (polymyositis)" and (ii) Rheumatic Disorders: Acthar is indicated as "adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis."

- Multiple Sclerosis (MS): Acthar is indicated "for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease."
- Infantile Spasms (IS): Acthar is indicated "as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age."

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.

We derive net sales of Acthar from our sales of vials to our distributor, which in turn sells Acthar primarily to specialty pharmacies. These specialty pharmacies place orders with our distributor 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 NS, rheumatology related conditions, MS exacerbations, IS, respiratory manifestations of symptomatic sarcoidosis and various other conditions.

Acthar is a low-volume, specialty pharmaceutical product. Physicians do not purchase Acthar from Questcor for resale to patients. Typically, patients purchase Acthar directly from specialty pharmacies after receiving a prescription and after arranging for third party reimbursement (government or commercial insurance)-most often after satisfying a prior authorization requirement imposed by their insurance carrier or a third-party administrator for a government healthcare program. Alternatively, eligible patients who are uninsured or under-insured, may receive Acthar through a Questcor sponsored patient assistance program. We do not generate any revenue or net sales from the vials provided through our sponsored patient assistance programs. See Business—Reimbursement.

Our total net sales were $798.9 million for the year ended December 31, 2013 as compared to $509.3 million and $218.2 million for the years ended December 31, 2012 and 2011, respectively. Over 95% of our net sales in each of these years were from Acthar. Our net income was $292.6 million for the year ended December 31, 2013 as compared to $197.7 million and $79.6 million for the years ended December 31, 2012 and 2011, respectively.

Healthcare provider understanding of Acthar is facilitated by our experienced team of sales representatives and managers. See Business - Sales and Marketing.

Our research and development program for Acthar is focused on: (i) the continued evaluation of the use of Acthar for certain on-label indications; (ii) the investigation of other potential uses of Acthar for indications not currently FDA approved; and (iii) the expansion of our understanding of how Acthar works in the human body (pharmacology), and ultimately, its mechanism(s) of action in the disease states for which it is currently used, or may be used in the future. We have also implemented a research and development program for Synacthen Depot. See Business - Research and Development.

Our primary corporate objectives entering 2014 are to continue to create shareholder value by:

- continuing the commercial growth of our existing business,
- pursuing our efforts to grow the body of evidence for Acthar, and
- assessing various strategic opportunities.

To assist with maximizing our strategic options, our Board has established two new committees: a Science Committee and a Strategic Advisory Committee. The committees will assist management and the Board in its ongoing assessment and development of potential strategies to supplement our strong sales growth, both organically through internal research and development activities and potentially through external strategic activity.

Acquisition of Synacthen and Synacthen Depot

On June 11, 2013, the Effective Date, we acquired from Novartis AG and Novartis Pharma AG, collectively Novartis, a license to develop, market, manufacture, distribute, sell and commercialize Synacthen and Synacthen Depot for all uses in humans in the United States. Subject to certain conditions and limitations in the License Agreement, the license is exclusive, perpetual and irrevocable. Synacthen Depot is a synthetic melanocortin agonist approved in various countries outside of the United States for certain autoimmune and inflammatory conditions. Since our acquisition of Synacthen and Synacthen Depot, we have implemented a new research and development program for Synacthen Depot and intend to seek FDA approval. Prior to our acquisition, Synacthen Depot has never been developed for approval for patients in the United States.

Subject to certain closing conditions, we also will acquire from Novartis a license and certain assets to develop, market, manufacture, distribute, sell and commercialize Synacthen and Synacthen Depot in certain countries outside the U.S. for all uses in humans. Subject to certain conditions and limitations, these rights and assets are exclusive, perpetual and irrevocable.

Under the terms of the transaction agreements, we paid Novartis an upfront consideration of $60.0 million. We will also be making annual cash payments of $25 million on each of the first, second and third anniversaries of the Effective Date, a potential additional annual cash payment on each anniversary subsequent to the third anniversary until we obtain the first approval of the FDA related to the products, or the FDA Approval, and a milestone payment upon our receipt of the FDA Approval. If we successfully obtain FDA Approval, we will pay an

annual royalty to Novartis based on a percentage of the net sales of the product in the U.S. market until the maximum payment is met. The first three annual payments aggregating to $75.0 million are secured by a letter of credit and classified as restricted cash on the Consolidated Balance Sheets. In no event will the total payments related to this transaction exceed $300 million.

See Item 1A *"Risk Factors:* Risks Associated with our Business" for a discussion of risks related to the Synacthen and Synacthen Depot acquisition.

BioVectra Segment

On January 18, 2013, we completed our acquisition of BioVectra Inc. As a result of this acquisition, we have greater control over the manufacturing and quality of the active pharmaceutical ingredient, or API, in Acthar.

We acquired 100% of the issued and outstanding shares of BioVectra for $50.3 million utilizing cash on hand. The former shareholders of BioVectra could receive additional cash consideration of up to C$50.0 million based on BioVectra's financial results over the next 3 years. Contingent consideration in conjunction with the acquisition of BioVectra of $30.4 million was recorded on our Consolidated Balance Sheet at the acquisition date. Any differences between our estimate and actual payments or subsequent adjustments will be recorded in operating expenses. Consequently, in 2013, BioVectra met its performance milestones for the year and earned an additional C$5.0 million in consideration. Additionally, financial projections for 2014 and 2015 improved resulting in an increase in the value of the contingent consideration, which was recorded during the fourth quarter as a reduction to operating income.

BioVectra is a supplier of contract manufacturing services to the global pharmaceutical and biotechnology industry. BioVectra manufactures API's, chemical intermediates, and bioprocessing reagents, and is our manufacturing partner for the API in our H.P. Acthar ® Gel (repository corticotropin injection). BioVectra is proficient in synthetic organic chemistry, natural extraction of bioactive compounds, PEGylation and conjugation chemistry, and fermentation of chemical and biologic molecules.

See Item 1A *"Risk Factors:* Risks Associated with our Business" for a discussion of risks related to BioVectra acquisition.

Sales and Marketing

Our sales forces seek to educate physicians about the potential benefit of Acthar for their patients. We have a Neurology Sales Force, a Nephrology Sales Force and a Rheumatology Sales Force, which, as of January 31, 2014, consists of 111, 68, and 69 sales personnel, respectively. Most recently, we initiated a pilot Pulmonology Sales Force to communicate to physicians that Acthar is a treatment option for the treatment of respiratory manifestations of symptomatic sarcoidosis.

See Item 1A "Risk Factors: Risks Associated with our Business" for a discussion of risks related to sales and marketing.

Customers and Distribution

In the U.S., our exclusive customer for Acthar is a specialty distributor, CuraScript Specialty Distributor. We sell Acthar at a discount from our list price to this specialty distributor, which then resells Acthar primarily to approximately 12 specialty pharmacy companies and to children's hospitals.

We recognize revenue when we have persuasive evidence that an arrangement, agreement or contract exists, when title for our product and risk of loss have passed to our customer, the price we charge for our product is fixed or is readily determinable, and we are reasonably assured of collecting the amounts owed under the resulting receivable. For Acthar, this occurs when the specialty distributor accepts a shipment of Acthar based on its order of Acthar. We do not require collateral from our customers for sales of our product.

See Item 1A "*Risk Factors:* Risks Associated with our Business" for a discussion of risks related to Risks Associated with Acthar.

Reimbursement

Sales of Acthar depend in significant part on the coverage and reimbursement policies of third party payers, including government payers such as Medicare and Medicaid, and private health insurers. All third party payers are sensitive to the cost of drugs, have taken efforts to control those costs, and presumably will continue to do so in the future. Acthar will likely continue to be subject to payer-driven restrictions.

We provide administrative reimbursement support through our Acthar Support and Access Program, an insurance reimbursement support program that provides administrative support to help patients work with their insurance companies.

See Item 1A "*Risk Factors:* Risks Associated with Government Regulations and Health Care Reform" for a discussion of risks related to reimbursement.

Competition

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. There are products and treatments currently on the market that compete with Acthar. In addition, a number of companies are pursuing the development of pharmaceuticals and products that target the same diseases and conditions for which Acthar is currently approved to treat or which we may seek to add to the label of approved indications for Acthar. There are also products and treatments in other parts of the world that could be introduced into the United States following FDA approval.

Many of our competitors are larger than we are and have substantially greater financial, marketing and technical resources than we have. Other smaller companies may also prove to be significant competitors, sometimes through collaborative arrangements with large and established companies. If any of our present or future competitors develop new products that are superior to Acthar, our financial performance may be materially and adversely affected.

With the increase in our net sales, we likely will attract additional competition.

See Item 1A *"Risk Factors:* Risks Associated with our Business" for a discussion of additional risks related to competition.

Manufacturing

Acthar is derived from the extraction and purification of porcine pituitary glands through complicated processes, and is difficult to manufacture. Acthar bulk concentrate, the active pharmaceutical ingredient, or API, used in Acthar, is processed in several stages to produce a purified raw material for formulation. We produce our own API at our BioVectra subsidiary. We have a supply agreement with Cangene bioPharma Inc., or Cangene, to manufacture commercial quantities of Acthar finished product. Cangene is our sole source supplier for Acthar finished product. The processes used to manufacture and test Acthar are complex and subject to FDA inspection and approval. Acthar has a shelf life of 18 months from the date of manufacture.

During the year ended December 31, 2011, we entered into an agreement with a third party vendor to provide potency and toxicity testing on Acthar prior to releasing the product for commercial distribution. Beginning on January 1, 2012, the agreement provides for a maximum number of tests to be performed each year. Tests performed in excess of the maximum are to be paid on a per test basis. We have been in compliance with the terms of our agreement with this third party vendor.

Our internal manufacturing facilities for API or our finished goods contract manufacturers may not be able to continue to meet our requirements for quality, quantity and timeliness. Our internal manufacturing facilities or contract manufacturers may not be able to meet all of the FDA's current good manufacturing practice, or cGMP, requirements.

Our dependence upon others for the manufacture of our finished products may adversely affect the future profit margin on the sale of those products and our ability to develop and deliver products on a timely and competitive basis. We do not have substitute suppliers for our products although we strive to plan appropriately and maintain safety stocks of product to cover unforeseen events at manufacturing sites.

See Item 1A *"Risk Factors:* Risks Associated with our Business" for a discussion of additional risks related to manufacturing.

Research and Development

Our research and development program for Acthar is focused on: (i) the continued evaluation of the use of Acthar for certain on-label indications; (ii) the investigation of other potential uses of Acthar for indications not currently FDA approved; and (iii) the expansion of our understanding of how Acthar works in the human body (pharmacology), and ultimately, its mechanism(s) of action in the disease states for which it is currently used, or may be used in the future. We conduct research internally and also through contracts with third parties.

We are currently conducting on-label Phase 4 clinical trials in Nephrotic Syndrome and Systemic Lupus Erythematosus. We are currently conducting Phase 2 clinical trials in Diabetic Nephropathy, Amyotrophic Lateral Sclerosis and Acute Respiratory Distress Syndrome to explore the possibility of pursuing FDA approval for indications not currently on the Acthar label. We continue to conduct non-clinical and clinical pharmacology studies to expand our understanding of Acthar and its mechanism of action(s).

We also provide financial grants to support independent academic research such as investigator initiated studies. In 2013, we provided $3.2 million in financial grants to support investigator initiated studies.

We have also initiated a research and development program for Synacthen Depot. Novartis has the right to terminate the license allowing us to develop, market, manufacture, distribute, sell and commercialize Synacthen and Synacthen Depot in the United States under certain circumstances, including if we fail within time periods set forth in the License Agreement to achieve certain development milestones related to (i) conducting a pre-IND meeting with the United States Food and Drug Administration, or FDA, with respect to Synacthen or Synacthen Depot, (ii) commencing a clinical trial with respect to Synacthen or Synacthen Depot and (iii) submitting a new drug application, or NDA, for Synacthen or Synacthen Depot for filing with the FDA.

We anticipate that these research and development efforts will result in a significant increase in research and development expense in 2014 and future years.

During the years ended December 31, 2013, 2012 and 2011, we spent $59.7 million, $34.3 million and $16.8 million, respectively, on research and development activities.

The expenditures that will be necessary to execute our development plans are subject to numerous uncertainties, which may affect our research and development expenditures and capital resources. For instance, the duration and the cost of clinical trials may vary significantly depending on a variety of factors including a trial's protocol, the number of patients in the trial, the duration of patient follow-up, the number of clinical sites in the trial, and the length of time required to enroll suitable patients or subjects. Even if earlier results are positive, we may obtain different results in later stages of development, including failure to show the desired safety or efficacy, which could impact our development expenditures for a particular indication, affect FDA approval of the indication in the label, and/or affect our sales of Acthar for existing commercialized indications. Although we spend a considerable amount of time planning our development activities, we may be required to deviate from our plan based on new circumstances or events or our assessment from time to time of a particular indication's market potential, other product opportunities and our corporate priorities. Any deviation from our plan may require us to incur higher or lower levels of expenditures or accelerate or delay the timing of our development spending. Furthermore, as we obtain results from trials and review the path toward regulatory approval, we may elect to discontinue development of certain indications or product candidates, in order to focus our resources on more promising indications or candidates. As a result, we are unable to reliably estimate the amount or range of the cost and timing to complete our product development programs and each future product development program.

See Item 1A *"Risk Factors:* Risks Associated with our Business" for a discussion of additional risks related to research and development.

Compliance

We have an active compliance program led by our Chief Compliance Officer who reports directly to our Chief Executive Officer and to the Compliance Committee of our Board of Directors. Our compliance program is based on the Office of Inspector General's guidance relating to the following elements of an effective compliance program: (i) written policies and procedures, (ii) compliance officer and compliance committee, (iii) effective training and communication, (iv) effective lines of communication, (v) monitoring and auditing, (vi) enforcement and disciplinary guidelines, and (vii) corrective action process.

Patents and Proprietary Rights

The FDA first approved the use of Acthar in 1952, and Acthar is no longer subject to patent protection. Acthar does have orphan drug exclusivity for its infantile spasm indication that extends until October 15, 2017 for that indication only.

For Acthar, our success depends partially upon our ability to maintain confidentiality and operate without infringing upon the proprietary rights of third parties. We rely primarily on a combination of copyright, trademark and trade secret laws, confidentiality procedures, and contractual provisions to protect our intellectual property.

Our efforts to protect our intellectual property may not be adequate. Our competitors may independently develop similar technology or duplicate our products or services. Unauthorized parties may infringe upon or misappropriate our products, services, trade secrets or other proprietary information. In addition, the laws of some foreign countries do not protect intellectual property rights as well as the laws of the United States. In the future, litigation may be necessary to enforce our intellectual property rights or to determine the validity and scope of the proprietary rights of others. Any such litigation could be time consuming, costly and face an uncertain outcome.

We could be subject to intellectual property infringement claims as we expand our position in our currently targeted therapeutic areas and enter new therapeutic areas. Defending against these claims, even if the claims are without merit, could be expensive and may divert our attention from our operations. If we become liable to third parties for infringing upon their intellectual property rights, we could be required to pay substantial damage awards and be forced to develop non-infringing technology, obtain a license or cease using the applications that contain the infringing technology or content. We may be unable to develop non-infringing technology or content or obtain a license on commercially reasonable terms, or at all.

See Item 1A *"Risk Factors:* Risks Associated with our Business" for a discussion of additional risks related to patents and proprietary rights.

Government Regulation

Our pharmaceutical products are subject to extensive government regulation in the United States. FDA regulations govern, among other things, the research, development, testing, manufacture, quality control, labeling, storage, record-keeping, approval, sale, distribution, advertising and promotion of our products.

The FDA testing and approval process for new indications for previously approved drugs requires substantial time, effort and money. Any application we submit to the FDA may not be timely approved, if at all.

Under the Food, Drug, and Cosmetic Act, or FDCA, FDA approval is required before any new drug, or any previously approved drug with a new indication, can be marketed in the United States. As a general matter, the FDA must approve an NDA before a new drug product may be marketed in the United States, and a supplemental new drug application, or sNDA, before a previously approved drug with a new indication can be marketed in the United States. NDAs and sNDAs often require extensive studies and submission of a large amount of data by the applicant.

The FDA may withdraw product approval for non-compliance with regulatory requirements or if safety or efficacy problems occur after the product reaches the market. The FDA also has the power to require changes in labeling or to prevent further marketing of a product based on the results of post-marketing programs.

The facilities, procedures, and operations of our internal manufacturing facilities and contract manufacturers must be determined to be adequate by the FDA before an NDA or sNDA is approved. Additionally, manufacturing facilities are subject to inspections by the FDA for compliance with cGMP, licensing specifications, and other FDA regulations on an on-going basis. Vendors that supply to us finished products or components used to manufacture, package and label products are subject to similar regulations and periodic inspections.

Following such inspections, the FDA may issue notices on Form 483 and issue Warning Letters that could cause us to modify certain activities identified during the inspection. The FDA generally issues a Form 483 notice at the conclusion of an FDA inspection and lists conditions the FDA investigators believe may violate cGMP or other FDA regulations. FDA guidelines specify that a Warning Letter be issued only for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

In addition, the FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceuticals, including but not limited to, standards and regulations for direct-to-physician promotion, direct-to-consumer advertising, payments to physicians, communications about off-label uses, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Our sales and marketing activities are monitored by our compliance team, which is headed by our Chief Compliance Officer. Our Chief Compliance Officer reports to our Chief Executive Officer and the Compliance Committee of our Board of Directors. Our Chief Compliance Officer is also supported by our General Counsel and other internal and external personnel.

Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products and promotional materials, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs or sNDAs, injunctions, disqualification from participation in government reimbursement programs and criminal prosecution. Any of these actions or events could have a material adverse effect on us both financially and reputationally.

In addition to regulation by the FDA, the Drug Enforcement Administration, or DEA, imposes various registration, recordkeeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products

under the Controlled Substances Act. States also impose similar requirements for handling controlled substances. A principal factor in determining the particular requirements, if any, applicable to a product is the actual or potential abuse profile. Controlled substances are subject to DEA and state regulations relating to manufacturing, storage, distribution and physician prescription procedures, and the DEA regulates the amount of the scheduled substance that would be available for clinical trials and commercial distribution.

We are also subject to federal, state, local and foreign environmental laws and regulations. We believe that our operations comply in all material respects with applicable environmental laws and regulations in each country where we have a business presence. The costs of compliance with these laws and regulations are high and are likely to increase in the future and any failure on our part to comply with these laws may subject us to significant liabilities and other penalties.

See Item 1A *"Risk Factors:* Risks Associated with Government Regulation and Health Care Reform" for a discussion of additional risks related to government regulation.

Human Resources

As of January 31, 2014, we had 703 full-time employees, 324 of whom are engaged in sales and commercialization activities.

Our continued success will depend in large part on our ability to attract and retain key employees. We believe that our relationship with our employees is good. None of our employees is represented by a collective bargaining agreement, nor have we experienced work stoppages.

General Information

We incorporated in California in September 1992 as Cypros Pharmaceutical Corporation. In November 1999, we changed our name to Questcor Pharmaceuticals, Inc. We are located at 1300 North Kellogg Drive, Suite D, Anaheim, California 92807, and our telephone number is (714) 786-4200.

We make the following reports available on our website, at *www.questcor.com* , free of charge as soon as practicable after filing with the U.S. Securities and Exchange Commission, or SEC:

- Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our proxy statements on Schedule 14A, and amendments to these reports and statements;
- Our policies related to corporate governance, including our Code of Conduct which apply to our directors, officers and employees (including our principal executive officer and principal financial and accounting officer) that we have adopted to meet the requirements set forth in the rules and regulations of the SEC and its corporate governance principles; and
- The charters of the Audit, Compensation, Nomination & Corporate Governance, Compliance, Science and Strategic Advisory Committees of our Board of Directors.

All such reports are also available free of charge via EDGAR through the SEC website *www.sec.gov* . In addition, the public may read and copy material filed by us with the SEC at the SEC's public reference room located at 100 F St., NE, Washington, D.C., 20549. Information regarding operation of the SEC's public reference room can be obtained by calling the SEC at 1-800-SEC-0330. The contents of our website are not incorporated by reference into this Annual Report.

Item 1A. Risk Factors

Investment in our stock involves a high degree of risk. Our business, operating results, growth prospects and financial condition are subject to various risks, many of which are not exclusively within our control, that may cause actual performance to differ materially from historical or projected future performance. We urge you to consider carefully the risks described below, together with the other information in this report and our other public filings, before making investment decisions regarding our stock. Each of these risk factors, as well as additional risks not presently known to us or that we currently deem immaterial, could adversely affect our business, operating results, growth prospects or financial condition, as well as the trading price of our common stock, in which case you may lose all or part of your investment.

Risks Associated with our Business

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. 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 Membraneous Nephropathy and Systemic Lupus Erythematosus. 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.

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:

- Small Number of Prescriptions. Acthar is approved to treat patients with rare diseases. Therefore, the number of prescriptions 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.

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 specialty distributor; the

Company does not have visibility into the mark-ups applied by specialty pharmacies). 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, case-by-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. 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.

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.

The manufacture of Acthar is a highly exacting and complex process and, if our internal manufacturing operations or any of our suppliers encounter problems manufacturing products, our business could suffer.

Acthar is derived from the extraction and purification of porcine pituitary glands through complicated processes and, as a result, Acthar is difficult to manufacture. Biological products such as Acthar require production processes that are significantly more complicated than those required for chemical pharmaceuticals, due in part to strict regulatory requirements. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, natural disasters, and environmental factors. In addition, we currently use single source and sole source suppliers for certain aspects of the manufacturing process of Acthar. For example, we currently obtain our finished Acthar product from a sole source supplier, Cangene. Reliance on those third party suppliers entails risks to which we would not be subject if we conducted those aspects of manufacturing ourselves, including reliance on those third parties for regulatory compliance and quality assurance.

If problems arise during the production of a batch of product, that batch of product may have to be discarded. Among other impacts to our business, lost batches could lead to increased costs, lost revenue, damage to our reputation, changes in physician practices with respect to the use of Acthar, time and expense spent investigating the cause of such problems and, depending on the cause, similar losses with respect to other batches of Acthar. If we do not discover problems before Acthar is released to the market, we also may incur recall and product liability costs. To the extent that our internal manufacturing facilities or one of our suppliers experiences significant manufacturing problems, these could have a material adverse effect on our revenues and profitability.

On January 18, 2013, we acquired all of the outstanding shares of BioVectra which, among other things, produces the API for Acthar. As a result of the acquisition of BioVectra, we currently use our own internal facilities to manufacture the API for Acthar. Our ability to adequately and timely manufacture and supply Acthar is dependent on the uninterrupted and efficient operation of our facilities, which may be impacted by many events. Furthermore, our ability to retain key BioVectra management and successfully integrate BioVectra could impact our

ability to manufacture or sell Acthar. In the event of a material disruption in the manufacturing capability of BioVectra for any reason, if we were unable to enter into a supply agreement with a third party manufacturer, or are unable to obtain FDA approval for a third party manufacturer, we may not be able to manufacture or sell Acthar, which would result in a loss of almost all of our revenues and damage to our business.

We have a supply agreement with Cangene to produce our finished vials of Acthar. Our supply agreement with this vendor is in effect until terminated by either party upon 12 months' notice. If the vendor terminates the agreement, it is obligated under the agreement to continue to provide manufacturing services for up to three years after the termination. If either party cancels the supply agreement, and we are unable to enter into a new supply agreement on substantially similar terms with a new manufacturer, or are unable to obtain FDA approval for a new manufacturer, we may not be able to manufacture or sell Acthar, which would result in a loss of almost all of our revenues and damage to our business.

Failure by our internal manufacturing facilities or our third-party suppliers or manufacturers to comply with regulatory requirements could adversely affect our ability to manufacture API in Acthar or our third-party suppliers' ability to supply finished vials of Acthar. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with the FDA's cGMP requirements. In complying with cGMP requirements, we, and our suppliers, must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that our products and product candidates meet applicable specifications and other requirements for product safety, efficacy and quality. Manufacturing facilities are subject to periodic unannounced inspection by the FDA and other regulatory authorities, including state authorities. The failure of our internal manufacturing facilities or our third-party suppliers to comply with applicable legal requirements could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or to take other legal or regulatory action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Any delay in supplying, or failure to supply, Acthar by our manufacturing facilities or any of our suppliers could result in our inability to meet the commercial demand for Acthar or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects.

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 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.

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. 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.

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 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.

We have no patent protection for Acthar, and existing and potentially competitive products to Acthar may reduce or eliminate our commercial opportunity.

The composition patent for Acthar has expired and we may have no patent-based market exclusivity with respect to any indication or condition we might target.

There are products and treatments currently on the market that compete with Acthar. In addition, the pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change, and a number of companies are pursuing the development of products that target the same diseases and conditions that we target. Some of the companies developing products have significantly greater financial resources and expertise in development, manufacturing, obtaining regulatory approvals and marketing than we do. Other smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. In the event we are successful in further developing markets for Acthar, our increasing the overall sales volume of Acthar may lead other companies to dedicate greater resources to attempt to develop and introduce generic or biosimilar versions of Acthar and other competitive therapies for the same diseases and conditions that we target. We cannot predict with accuracy the timing or impact of the introduction of additional competitive products or their possible effect on our net sales. If a competitor did apply to the FDA for a generic or biosimilar version of Acthar or any competitive product not based on ACTH (adrenocorticotropic hormone), we would not receive any notice from the FDA about the existence of the application. Further, the announcement of a filing with the FDA relating to a potentially competitive product could have an adverse effect on our business and share price, regardless of the ultimate outcome of such filing.

We rely on trade secrets and proprietary know-how for Acthar. We currently seek protection, in part, through confidentiality and proprietary information agreements. These agreements may not provide meaningful protection or adequate remedies for proprietary technology in the event of unauthorized use or disclosure of confidential and proprietary information. The parties may not comply with or may breach these agreements. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, competitors.

Our success will further depend, in part, on our ability to operate without infringing the proprietary rights of others. If our activities infringe on patents owned by others, we could incur substantial costs in defending ourselves

in suits brought against a licensor or us. In addition, such litigation or the threat of litigation could create substantial distractions for our management, which would decrease our ability to focus on increasing sales of Acthar. Should Acthar or its associated technologies be found to infringe on patents issued to third parties, the manufacture, use and sale of Acthar could be enjoined, and we could be required to pay substantial damages. In addition, we, in connection with the development and use of Acthar and its associated technologies, may be required to obtain licenses to patents or other proprietary rights of third parties, which may not be made available on terms acceptable to us or at all.

Our attempts to further develop other on-label therapeutic uses for our pharmaceutical products may be unsuccessful.

In connection with the FDA's October 2010 approval of our sNDA to add the treatment of IS to the label of approved indications for Acthar, the overall label for Acthar was modernized and there are now 19 approved indications, including the treatment of IS, the treatment of acute exacerbations of MS in adults, the use of Acthar 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, and the treatment of certain rheumatology related conditions including the rare and closely related neuromuscular disorders DM/PM. Commercializing Acthar to treat other on-label indications, such as for the treatment of respiratory manifestations of symptomatic sarcoidosis, will be time consuming, expensive and unpredictable. We may not be able to, either by ourselves or in collaboration with others, successfully commercialize Acthar for the treatment of new, on-label therapeutic uses.

Once developed, a number of factors may negatively affect the market acceptance of additional therapeutic uses for our pharmaceutical products, including, among others:

- the price of our products relative to other therapies for the same or similar treatments;
- limited published data of the efficacy of our products for such additional therapeutic uses;
- the perception by patients, physicians and other members of the health care community of the safety and efficacy of our products for their prescribed treatments;
- the availability of third-party reimbursement for our products; and
- the effectiveness of our sales and marketing efforts.

If the additional therapeutic uses for our products are not accepted by the market, our ability to grow our business will be affected.

If our business partners do not fulfill their obligations with respect to any future collaboration agreements our revenues and our business will suffer.

We may decide to collaborate with third parties in the commercialization of new products or new on-label therapeutic uses for Acthar or our products, such collaboration may require us to commit substantial effort and expense in seeking out, evaluating and negotiating collaboration agreements, which expense may be incurred without achieving our desired results and which effort involves inherent risks, including uncertainties due to matters

that may affect the successful commercialization of such uses, as well as the possibility of contractual disagreements with regard to terms such as proprietary rights, license scope, net income and royalty calculation or termination rights. It may be necessary for us to enter into arrangements with other pharmaceutical companies in order to effectively market any new, on-label therapeutic uses for Acthar. We may not be successful in entering into such arrangements on terms favorable to us or at all.

The amount and timing of resources dedicated by our collaborators to their collaborations with us are not within our control. If any collaborator breaches or terminates its agreements with us or fails to conduct its collaborative activities in a timely manner, the commercialization of our product candidates could be slowed or blocked completely. In addition, our collaborative partners may change their strategic focus, pursue alternative technologies or develop alternative products as a means for developing treatments for the diseases targeted by these collaborative programs and these could compete with products we are developing.

Further, our collaborations may not be successful. Disputes may arise between us and our collaborators as to a variety of matters, including financing obligations under our agreements and ownership of intellectual property rights. These disputes may be both expensive and time-consuming and may result in delays in the development and commercialization of products. If any of the product candidates that we are commercializing with collaborators are delayed or blocked from entering the market or we experience increased costs as a result of our relationship with our collaborators, our financial performance could be adversely affected.

We depend substantially on third parties to assist us in our research and development; our efforts to increase our in-house capabilities to conduct research and development projects may be unsuccessful.

We heavily rely upon third-party vendors to plan, conduct and report on clinical trials for uses of Acthar and other products. Managing these third-party contract research organizations, or CROs, requires significant time and resources. In the event that any of our CROs has unforeseen compliance, quality assurance, or operational difficulties that negatively impact the quality of its work, our ability to evaluate and rely upon clinical results may also be negatively impacted. A CRO’s failure to appropriately conduct a clinical study could also result in FDA rejecting the data from that study. In addition, any one of these vendors could determine that its own research and development requirements or those of other parties take precedence over the research and development they provide to us. We could experience a development gap if one or more of our clinical trial vendors does not properly execute a clinical trial or chose to prioritize other projects over our development projects. This prioritization could cause a gap in our research and development timelines until we achieve further advancement of our own capabilities. Any gap could impact our ability to develop and commercialize other therapeutic uses for Acthar or our other products.

Switching or adding new CROs involves additional cost and requires management time and focus. If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. We are actively growing our ability to conduct our own clinical trial research and development projects. In the event that we fail to manage these in-house capabilities, we may negatively impact our ability to successfully conduct clinical trials for uses of Acthar and other products.

A clinical trial failure could adversely affect our ability to develop data to support the use of Acthar in the treatment of on-label indications or file for or gain regulatory approvals for new indications for Acthar or other products on a timely basis.

If pre-clinical trials do not produce successful results or if clinical trials do not demonstrate safety and efficacy in humans, we will not be able to obtain approval for new products or to add to the label of approved indications for Acthar or our other products.

The regulatory process, which may include extensive pre-clinical trials and clinical trials to establish the safety and efficacy of a new product or the expansion of a label for an existing product in a new therapeutic area, can lead to uncertain outcomes, can span many years, and requires the expenditure of substantial time and resources to conduct and to ensure compliance with complex regulations. Should we fail to comply with applicable regulations, possible regulatory actions could include warning letters, fines, damages, injunctions, civil penalties, recalls, seizures of our products and criminal prosecution. These actions could result in, among other things, substantial modifications to our business practices and operations; refunds, recalls or a total or partial shutdown of production in one or more of our suppliers' facilities while our suppliers remedy the alleged violation; the inability to obtain future pre-market clearances or approvals; restrictions on the labeling, promotion and use of Acthar; and withdrawals or suspensions of our products from the market. Any of these events could disrupt our business and have a material adverse effect on our revenues and financial condition.

In addition, data obtained from pre-clinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory approval or clearance. Also, we may encounter delays or rejections based upon changes in regulatory policy during the development period and the period of review of any application for regulatory approval or clearance for Acthar or our other products.

Our success in obtaining approval for new products and in adding to the label for approved indications for Acthar or our other products will depend on the success of the pre-clinical and clinical trials conducted by us and our clinical trial vendors. It can take several years to complete the pre-clinical and clinical trials of a new therapeutic use, and a failure of one or more of these pre-clinical or clinical trials can occur at any stage of testing. We believe that the development of new therapeutic uses for our products involves significant risks at each stage of testing. If pre-clinical or clinical trial difficulties and failures arise, new therapeutic uses for our products may never be approved for sale or become commercially viable.

In addition, the possibility exists that:

- the results from early pre-clinical or clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;
- there may be delay or failure in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience delay or failure in recruiting and enrolling suitable patients to participate in a trial;

- clinical sites and investigators may deviate from trial protocol or fail to conduct the trial in accordance with regulatory requirements, or drop out of a trial;
- feedback from FDA, the institutional review board, or data safety monitoring boards, or results from earlier stage or concurrent pre-clinical and clinical studies, may require modification to the study protocol;
- a proposed new use for Acthar may not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use, even if approved;
- we, institutional review boards, or regulators, including the FDA, may hold, suspend or terminate our pre-clinical or clinical research or the pre-clinical or clinical trials of Acthar for various reasons, including noncompliance with regulatory requirements or if, in our or their opinion, the participating subjects are being exposed to unacceptable health risks;
- the cost of our pre-clinical or clinical trials may be greater than we currently anticipate; and
- the difficulties and risks associated with pre-clinical and clinical trials may result in the failure to receive regulatory approval, and could impact our ability to continue to test or to sell our products in new or existing therapeutic uses or the inability to commercialize our products for any of these therapeutic uses.

The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product's clinical development and may vary among jurisdictions. It is possible that Acthar or our other products will never obtain regulatory approval for new therapeutic uses.

There are many reasons why we may fail to receive a regulatory approval from the FDA, including:

- failure to demonstrate to FDA's satisfaction that our products are safe and effective for their proposed indications;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials may be insufficient to support the submission and filing of an NDA or supplement or to obtain regulatory approval; and
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA may require more information, including additional preclinical or clinical data to support approval of our products for new therapeutic uses, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve our products for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, if the FDA determines that there are undesirable side effects or safety issues, the FDA may require the establishment of Risk Evaluation Mitigation Strategies that may, for instance, restrict distribution and impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects for our products in new therapeutic areas.

In addition to regulations in the U.S., if we expand our operations to the European Union, or EU, we may be subject to a variety of EU, EU Member States, and other foreign regulations governing clinical trials. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

If we are unable to obtain approval to add new indications for our products, or if we are unable to support the commercialization of other currently labeled indications with additional data, our sales and marketing efforts and market acceptance and the commercial potential of Acthar and our other products may be negatively affected.

We are dependent on third parties to distribute our pharmaceutical products who may not fulfill their obligations.

We currently have no in-house distribution channels for Acthar and we are dependent on a third-party specialty distributor, CuraScript Specialty Distributor, to distribute Acthar. We rely on this distributor for all of our proceeds from sales of Acthar in the United States. The outsourcing of our distribution function is complex, and we may experience difficulties that could reduce, delay or stop shipments of Acthar. If we encounter such distribution problems, and we are unable to quickly enter into a similar agreement with another specialty distributor on substantially similar terms, Acthar distribution could become disrupted, resulting in lost revenues, provider dissatisfaction, and/or patient dissatisfaction.

We may be unable to identify, acquire, close or integrate acquisition targets successfully.

Part of our business strategy includes evaluating potential acquisitions and other business combinations to help create shareholder value. Acquisitions or similar arrangements may be complex, time consuming and expensive. We may not consummate some negotiations for acquisitions or other arrangements, which could result in significant diversion of management and other employee time, as well as substantial out-of-pocket costs. In addition, there are a number of risks and uncertainties relating to our closing of transactions.

If an acquisition or other potential business combination is consummated, the integration of the acquired business, product or other assets into our company may be complex and time-consuming and, if such businesses, products or assets are not successfully integrated, we may not achieve the anticipated benefits.

Furthermore, these acquisitions and other arrangements, even if successfully integrated, may fail to further our business strategy as anticipated or expose us to additional liabilities associated with an acquired business, product, technology or other asset or arrangement. Any one of these challenges or risks could impair our ability to realize any benefit from our acquisition or arrangement after we have expended resources on them.

If we fail to realize the anticipated benefits from our acquisition of BioVectra our business and financial condition may be adversely affected.

We may fail to realize the anticipated benefits from our acquisition of BioVectra for a variety of reasons, including the following:

- the difficulties of overseeing manufacturing operations in a foreign country where we have no or limited direct prior experience;
- failure to successfully manage relationships with suppliers and customers;
- difficulties in integrating and harmonizing business systems;
- the loss of key employees; and
- failure to properly protect against foreign currency exchange rate fluctuations.

If we are not able to successfully manage these issues, the anticipated benefits and efficiencies of the BioVectra acquisition may not be realized fully or at all, or may take longer to realize than expected, and our revenue and gross margins and our results of operations may be adversely affected.

The acquisition of Synacthen and Synacthen Depot could have an adverse impact on future operations if we are unable to successfully develop Synacthen Depot for commercial sale in the US and/or are unable to successfully transition or grow the international business.

On June 11, 2013 we acquired from Novartis certain rights to Synacthen and Synacthen Depot. The License Agreement we entered into with Novartis provides for an exclusive, perpetual and irrevocable license to develop, market, manufacture, distribute, sell and commercialize Synacthen and Synacthen Depot. Since our acquisition of Synacthen and Synacthen Depot, we have implemented a new research and development program for Synacthen Depot and intend to seek FDA approval. Novartis has the right to terminate the license under certain circumstances, including if Questcor fails within time periods set forth in the License Agreement to achieve certain development milestones related to (i) conducting a pre-IND meeting with the FDA with respect to Synacthen or Synacthen Depot, (ii) commencing a clinical trial with respect to Synacthen or Synacthen Depot and (iii) submitting an NDA for Synacthen or Synacthen Depot for filing with the FDA. The timing and process for completing these regulatory milestones is difficult to predict and we may not be able to achieve any or all of these milestones on a timely basis. We plan to rely on third-parties to conduct research and clinical trials necessary to meet each of the milestones. Our ability to meet these milestones will depend on a number of factors, including our ability to oversee third-party research and clinical trials and our ability to successfully show the safety and efficacy of Synacthen or Synacthen Depot. If Novartis terminates the license as a result of our failure to meet these milestones, we will not be able to realize the gains in revenues and gross margins and our results of operations may be adversely affected.

Under an asset purchase agreement with Novartis, Novartis has the right to terminate the right to purchase assets and intellectual property related to Synacthen and Synacthen Depot on a country by country basis if we are unable to obtain the necessary regulatory approvals for such country or if we fail to make Synacthen Depot in such country for a period of time following the transfer of the applicable marketing authorization. If our right to sell Synacthen Depot in any or all of the countries we have contracted for are terminated, we will not be able to realize revenue in those countries, which may adversely affect our results of operations.

Our business and operations have experienced rapid growth. If we fail to effectively manage our growth, our business and operating results could be harmed.

We have experienced rapid growth, both from organic growth and our recent acquisition of BioVectra and certain rights to Synacthen and Synacthen Depot, in our headcount and operations that has placed, and will continue to place, significant demands on our management and operational and financial infrastructure. To effectively manage this growth, we will need to continue to improve our operational, financial and management controls and our reporting systems and procedures. These systems enhancements and improvements will require significant capital expenditures and management resources. Failure to implement these improvements could hurt our ability to manage our growth and our financial position.

We have begun to establish our international footprint and operations, and we may expand further in the future, which subjects us to additional business risks. We may not achieve the results that we or our shareholders expect.

As a result of the BioVectra and Synacthen Depot transactions, we expect to be conducting a portion of our business outside of the United States. Accordingly, we are now subject to risks and complexities that could materially and adversely affect our business, results of operations and financial condition, including, among other things:

- The increased complexity and costs inherent in managing international operations;
- The ability of our international subsidiaries to successfully implement their commercial objectives;
- Diverse regulatory, financial and legal requirements, and any changes to such requirements in one or more countries where we are located or do business;
- Country-specific tax laws and regulations;
- Financial risks such as longer sales and payment cycles and difficulty collecting accounts receivables;
- Political and economic instability;
- Complying with applicable international trade laws, including but not limited to U.S. and EU sanctions laws and regulations, U.S. anti-boycott laws and regulations, U.S. and EU export control laws and regulations; tariffs, export quotas, custom duties and other requirements; or other trade restrictions and any changes to them;

- Complying with applicable anti-corruption laws, including but not limited to the U.S. Foreign Corrupt Practices Act, or FCPA, which generally prohibit directly or indirectly giving, offering, or promising inducements to public officials to elicit an improper commercial advantage. Under the FCPA, this prohibition has been interpreted to apply to doctors and other medical professionals who work in state-run hospitals and state-run healthcare systems outside the U.S. Some of these laws also prohibit directly or indirectly giving, offering, or promising (and, in some cases, accepting or soliciting) inducements to (or from) private parties to elicit (or grant) an improper commercial advantage;
- Challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations;
- Changes in currency rates; and
- Regulations relating to data security and the unauthorized use of, or access to, commercial and personal information.

Failure to effectively manage these risks could have a material adverse effect on our business.

The loss of our key management personnel or failure to integrate new management personnel could have an adverse impact on future operations.

We are highly dependent on the services of the principal members of our senior management team, and the loss of one or more members of senior management could create significant disruption in our ability to operate our business. We do not carry key person life insurance for our senior management or other personnel. Additionally, the future potential growth and expansion of our business is placing increased demands on our management skills and resources. Recruiting and retaining management and operational personnel to perform sales and marketing, financial operations, clinical development, regulatory affairs, compliance, quality assurance, medical affairs and contract manufacturing in the future will also be critical to our success. We do not know if we will be able to attract and retain skilled and experienced management and operational personnel in the future on acceptable terms given the intense competition among numerous pharmaceutical and biotechnology companies for such personnel. If we are unable to hire necessary skilled personnel in the future, or we are unable to successfully integrate new management personnel into their roles, our business could be harmed.

Our financial results can be negatively impacted by economic downturns.

Downturns in the general economic environment present us with several potential challenges. In challenging economies and periods of increased unemployment, a greater percentage of our unit volume may be subject to reimbursement under Medicaid and other government programs. This shift in payer mix can negatively impact our financial results because of the resulting decrease in our net sales. In addition, third-party payers such as private insurance companies may be less willing to satisfy their reimbursement obligations in a timely manner, or at all.

As a result of downturns in the economy, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborators. If a significant third-party contractor, supplier or collaborator is unable to satisfy its commitments to us, our business could be adversely affected.

Downturns in the capital markets may have a negative impact on the market values of the investments in our investment portfolio. We cannot predict future market conditions or market liquidity and the markets for these securities may deteriorate or the institutions that hold these investments may not be able to meet their debt obligations at the time we may need to liquidate such investments or until such time as the investments mature.

If product liability or other lawsuits are successfully brought against us, we may incur substantial liabilities and costs and may be required to limit commercialization of Acthar.

The development, manufacture, testing, marketing and sale of pharmaceutical products entail significant risk of product liability claims or recalls. Side effects of, or manufacturing defects in, the products sold by us could result in exacerbation of a patient's condition, serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. Acthar has boxed warnings in its label.

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of Acthar could materially adversely affect our business by rendering us unable to sell Acthar for some time, causing us to incur significant recall costs and by adversely affecting our reputation. A recall could also result in product liability claims.

Product liability claims may be brought by individuals seeking relief for themselves, or by groups seeking to represent a class. While we have not had to defend against any product liability claims to date, as sales of our products increase, we believe it is likely product liability claims will be made against us. We cannot predict the frequency, outcome or cost to defend any such claims. Under a 2009 United States Supreme Court ruling, FDA approval of a drug does not prevent the filing of product liability claims in state courts, potentially making it more costly and time consuming to defend against such claims.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, if at all. We currently have product liability insurance for claims up to $10 million. Partly as a result of product liability lawsuits related to pharmaceutical products, product liability and other types of insurance have become more difficult and costly for pharmaceutical companies to obtain. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products or, in the case of BioVectra, the liabilities we might incur in connection with their manufacture of product for other companies. In addition, we may not continue to be able to obtain insurance on satisfactory terms or in adequate amounts.

In addition to product liability insurance coverage, we have other insurance coverage, including but not limited to directors' and officers' liability insurance. Directors' and officers' liability insurance is also expensive, can be difficult to obtain and may not be available in the future on acceptable terms, if at all. We currently have directors' and officers' liability insurance for claims up to $45 million. This insurance may not cover all the future liabilities we may incur in connection with lawsuits related to the Company or our directors and officers.

A successful claim or claims brought against us in excess of available insurance coverage could subject us to significant liabilities and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Such claims could also harm our reputation and the reputation of our products, adversely affecting our ability to market our products successfully. In addition, defending a lawsuit can be expensive and can divert the attention of key employees from operating our business.

Business interruptions could limit our ability to operate our business.

Our operations, including those of our suppliers, are vulnerable to damage or interruption from computer viruses, human error, natural disasters, telecommunications failures, intentional acts of vandalism and similar events. We have not established a formal disaster recovery plan, and our back-up operations and our business interruption insurance may not be adequate to compensate us for losses that occur. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we or our distribution partners and clinical trial partners may collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees, in our outside data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, destroyed or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, including state laws and rules and regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and regulatory penalties, disrupt our operations, and damage our reputation, and cause a loss of confidence in our products and services, which could adversely affect our business.

In addition to regulations in the U.S., if we expand our operations to the European Union, or EU, we may be subject to a variety of EU, EU Member States, and other foreign regulations. The collection and use of personal health data in the EU is governed by the provisions of the Data Protection Directive. This Directive imposes a number of requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the EU to the United States. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States

may result in fines and other administrative penalties. The draft EU Data Protection Regulation currently going through the adoption process is expected to introduce new data protection requirements in the EU and substantial fines for breaches of the data protection rules. If the draft Data Protection Regulation is adopted in its current form, to the extent we expand our operations to the EU, it may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules. This may be onerous and increase our cost of doing business if we expand our operations to the EU.

Risks Associated with Government Regulation and Health Care Reform

We are involved in an ongoing government investigation by the United States Department of Justice involving our promotional practices and related matters, the results of which may have a material adverse effect on our sales, financial condition and results of operations.

In September 2012, we received a subpoena from the United States Attorney's Office for the Eastern District of Pennsylvania (or USAO), requesting documents pertaining to an investigation of our promotional practices. We have been informed by the USAO for the Eastern District of Pennsylvania that the USAO for the Southern District of New York and the SEC are also participating in the investigation to review our promotional practices and related matters. We are cooperating with the USAO and the SEC with regard to this investigation. Responding to this investigation has been and is expected to continue to be expensive and time-consuming.

If some of our existing business practices are challenged as unlawful, we may have to change those practices, which could have a material adverse effect on our business, financial condition and results of operations. If, as a result of this investigation, we are found to have violated one or more applicable laws, we could be subject to a variety of fines, penalties, and related administrative sanctions, and our business, financial condition and results of operations could be materially adversely affected.

We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.

We are subject to significant ongoing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, the manufacture, quality control, labeling, packaging, safety surveillance, adverse event reporting, storage, advertising, promotion and recordkeeping for our products are subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems or potential safety risks associated with any of our products, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us. If we, our products and product candidates, or the manufacturing facilities for our products and product candidates fail to comply with applicable regulatory requirements, a regulatory agency, including the FDA, may send enforcement letters, mandate labeling changes, suspend or withdraw regulatory approval, suspend any ongoing clinical trials, require new clinical trials, impose a risk evaluation and mitigation strategy, refuse to approve pending applications or supplements filed by us, suspend or impose restrictions on manufacturing operations, request a recall

of, seize or detain a product, seek criminal prosecution or an injunction, or impose civil or criminal penalties or monetary fines. In such instances, we could experience a significant drop in the sales of the affected products, our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits.

The FDA and other governmental authorities also actively enforce regulations prohibiting off-label promotion, and the government has levied large civil and criminal fines against companies for alleged improper promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution or deferred prosecution agreements that impose significant reporting and other burdens on the affected companies.

We are also subject to regulation by regional, national, state and local agencies, including but not limited to the FDA, Centers for Medicare and Medicaid Services, Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies. The Federal Food, Drug, and Cosmetic Act, Social Security Act, Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, clinical research, approval, production, labeling, sale, distribution, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government health care programs. Our manufacturing partners are subject to many of the same requirements.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any health care item or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements that pharmaceutical companies have with prescribers, purchasers and formulary managers. Further, the Healthcare Reform Act, among other things, clarified that a person or entity no longer needs to have actual knowledge of the anti-kickback statute or specific intent to violate it. In addition, the Healthcare Reform Act as amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Although there are a number of statutory exemptions and regulatory safe harbors under the federal anti-kickback statute protecting certain common manufacturer business arrangements and activities from prosecution, the exemptions and safe harbors are drawn narrowly and an arrangement must meet all of the conditions specified in order to be fully protected from scrutiny under the federal anti-kickback statute. We seek to comply with the exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability and may be subject to scrutiny. Violations of the federal anti-kickback statute can result in civil and criminal fines and penalties and related administrative sanctions, including exclusion from federal health care programs.

The Federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds, or knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid. Many pharmaceutical and other health care companies have been investigated and have reached substantial financial settlements with the federal government under the Federal False Claims Act for a variety of alleged marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which may be used by states to set drug payment rates under government health care programs. Companies have been prosecuted for causing false claims to be submitted because of the marketing of their products for unapproved uses. Pharmaceutical and other health care companies are also subject to other federal false claim laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

Many states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, which apply regardless of the payer. Several states now require pharmaceutical companies to report their expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to certain individual health care providers in those states. Some of these states also prohibit certain marketing related activities, including the provision of gifts, meals, and other items to certain health care providers. In addition, California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes.

Compliance with various federal and state laws is difficult and time consuming, and companies that violate them may face substantial penalties. The potential sanctions include significant civil, criminal and administrative penalties, damages and fines and exclusion from participation in federal health care programs. Because of the breadth of these laws and the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge under one or more of these laws. Such a challenge, irrespective of the underlying merits of the challenge or the ultimate outcome of the matter, could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to the pending investigation by the Department of Justice, we could become subject to further government investigations and related subpoenas. Such subpoenas are often associated with previously filed qui tam actions, or lawsuits filed under seal under the Federal False Claims Act. Qui tam actions are brought by private plaintiffs suing on behalf of the federal government for alleged violations of the Federal False Claims Act. The time and expense associated with responding to such subpoenas, and any related qui tam or other actions, may be extensive, and we cannot predict the results of our review of the responsive documents and underlying facts or the results of such actions. Responding to government investigations, defending any claims raised, and any resulting fines, restitution, damages and penalties, settlement payments or administrative actions, as well as any related actions brought by shareholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

The number and complexity of both federal and state laws continues to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the Healthcare Reform Act includes a number of provisions aimed at strengthening the government's ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, amendments to the False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations and, beginning in March 2014 for payments made on or after August 1, 2013, public reporting of payments by pharmaceutical manufacturers to physicians and teaching hospitals nationwide. While it is too early to predict what effect these changes will have on our business, we anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of further government investigations and enforcement actions. Responding to a government investigation or enforcement action would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we or any of our partners fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our or our partners' ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

In addition to regulations in the U.S., if we expand our operations to the European Union, or EU, we may be subject to a variety of EU, EU Member States, and other foreign regulations governing clinical trials and commercial sales and distribution of our investigational medicinal products and our authorized medicinal products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Failure to comply with the EU Member State laws implementing the Community Code on medicinal products, and EU rules governing the promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, with the EU Member State laws that apply to the promotion of medicinal products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements can result in enforcement action by the EU Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

Changes in the health care law and regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may adversely affect our business.

The number and complexity of both federal and state laws continue to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, in March 2010, the President signed the Healthcare Reform Act. The Healthcare Reform Act includes a number of provisions aimed at strengthening the government's ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, amendments to the Social Security Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations. Additionally, Healthcare Reform Act implemented the Physician Payment Sunshine Act which requires extensive tracking of payments or transfers of value to physicians and teaching hospitals, maintenance of a payments database, and public reporting of the payment data. The Centers for Medicare and Medicaid Services, or CMS, recently issued a final rule implementing the Physician Payment Sunshine provisions and clarified the scope of the reporting obligations. The final rule provided that manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program must begin tracking payment or transfers of value on August 1, 2013 and must report payment data to CMS by March 31, 2014 and annually thereafter. While it is too early to predict what effect these changes will have on our business, we anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions. Responding to a government investigation or enforcement action would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The Healthcare Reform Act substantially changes the way health care is financed by both governmental and private insurers, and could have a material adverse effect on our future business, cash flows, financial condition and results of operations. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B program, and fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. The Healthcare Reform Act made significant changes to Medicaid Drug Rebate Program. Effective March 23, 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. This expanded eligibility affected our rebate liability for that utilization.

The Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014 (and set to increase in ensuing years), based on the dollar value of its branded prescription drug sales to certain programs identified in the law.

Additional provisions of the Healthcare Reform Act, some of which became effective in 2011, may negatively affect our revenues in the future. For example, as part of the Healthcare Reform Act's provisions closing a coverage gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole.

The Healthcare Reform Act also expanded the Public Health Service's 340B drug pricing discount program. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The Healthcare Reform Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act.

The Healthcare Reform Act also obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program and to ensure the agreement that manufacturers must sign to participate in the 340B program obligates a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. HRSA is expected to issue a comprehensive proposed regulation in 2014 that will address many aspects of the 340B program. When that regulation is finalized, it could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Many of the Healthcare Reform Act's most significant reforms do not take effect until 2014. In 2012, the Centers for Medicare and Medicare Services, or CMS, the federal agency that administers the Medicare and Medicaid programs, issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2014.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. We expect any Medicaid expansion to impact the number of adults in Medicaid more than children because many states have already set their eligibility criteria for children at or above the level designated in the Healthcare Reform Act. An increase in the proportion of patients who receive Acthar and who are covered by Medicaid could adversely affect our net sales.

Presently, uncertainty exists as many of the specific determinations necessary to implement the Healthcare Reform Act have yet to be decided and communicated to industry participants. Further, many of the Healthcare Reform Act' most significant reforms do not take effect until 2014 and thereafter, and the details of these reforms will be shaped significantly by regulations that have yet to be proposed. We have made several estimates with regard to important assumptions relevant to determining the financial impact of the Healthcare Reform Act on our business due to the lack of availability of both certain information and complete understanding of how the process of applying the Healthcare Reform Act will be implemented.

Moreover, legislative changes to the Healthcare Reform Act remain possible, and the President may make additional refinements to the implementation of the Healthcare Reform Act that may have an additional, potential negative impact on our overall financial position, results of operations and cash flows. At this time, we cannot predict the full impact of the Healthcare Reform Act, or the timing and impact of any future rules or regulations promulgated to implement the Healthcare Reform Act.

Medicaid eligible patients and government entities may account for a greater proportion of our Acthar unit sales resulting in reduced pharmaceutical net sales.

Our pharmaceutical net sales may be adversely affected by laws and regulations that reduce reimbursement rates. Administrative or judicial interpretations of such laws and regulations could impact reimbursement for our products or increase the amount of rebates paid to certain government entities. The sources and amounts of our revenues are determined by a number of factors, including payer reimbursement for our products. Changes in the payer mix among private pay, Medicaid, and government programs usage may significantly affect our profitability.

A portion of the estimated end-user vial demand for Acthar is for patients covered under Medicaid and other government-related programs. As required by Federal regulations, under the Medicaid Drug Rebate Program, we provide rebates related to Acthar dispensed to Medicaid patients. The Healthcare Reform Act made changes to the Medicaid Drug Rebate Program, including increasing the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products such as Acthar. In addition, federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service's 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. Under the 340B program, covered entities are permitted to purchase Acthar at the 340B ceiling price. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's issuance of final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results or operations. As a result of the enactment of the Healthcare Reform Act and fiscal pressures placed upon federal and state governments to reduce current budget deficits, it is possible that a greater proportion of Acthar sales could be subject to Medicaid rebates and chargebacks, reducing our net sales. Additionally, changes to Medicaid, Medicare or other regulations, or the application of such regulations to our products, resulting in higher rebates and chargebacks, could reduce our pharmaceutical net sales further.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and certain federal grantees, we participate in the Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veteran's Health Care Act of 1992. Under this program, we are obligated to make our product available for procurement on an FSS contract and charge a price to four federal agencies - VA, Department of Defense, Public Health Service, and Coast Guard - that is no higher than the statutory Federal Ceiling Price, or FCP. The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. We also participate in the Tricare Retail Pharmacy program, established by Section 703 of the National Defense Authorization Act for Fiscal Year 2008 and related regulations, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between Annual Non-FAMP and FCP.

Significant judgment is inherent in the selection of assumptions and the interpretation of historical experience as well as the identification of external and internal factors affecting the determination of our reserves for Medicaid rebates and other government program rebates and chargebacks. We believe that the assumptions used to determine these sales reserves are reasonable considering known facts and circumstances. However, our Medicaid rebates and other government program rebates and chargebacks could materially differ from our reserve amounts because of unanticipated changes in prescription trends or patterns in the states' submissions of Medicaid claims, adjustments to the amount of product in the distribution channel, or if our estimates of the number of Medicaid patients with IS, MS, NS and rheumatology related conditions are incorrect. We have greater visibility on the future submission of Medicaid claims and the amount of product in the distribution channel for Acthar distributed to a specialty pharmacy owned by our specialty distributor than we have with respect to Acthar distributed through other specialty pharmacies. If actual Medicaid rebates, or other government program rebates and discounts are materially different from our estimates, we would account for such differences as a change in estimate in the period in which they become known. If actual future payments for such reserves exceed the estimates we made at the time of sale, our consolidated financial position, results of operations and cash flows may be negatively impacted.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We have certain price reporting obligations due to our participation in the Medicaid Drug Rebate program, under several state Medicaid supplemental rebate programs, related to other governmental pricing programs, and we report average sales price for the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. Those rebates are based on pricing data (including Average Manufacturer Price and Best Price data) reported by us on a monthly and quarterly basis to CMS.

Federal law requires that a company that participates in the Medicaid Drug Rebate program report average sales price, or ASP, information to CMS for certain categories of drugs that are paid under Part B of the Medicare program. Manufacturers calculate ASP based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS as to what should or should not be considered in computing ASP. CMS uses these submissions to determine payment rates for drugs under Medicare Part B.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. CMS or another government agency could disagree with our interpretation of applicable law and regulation and could challenge our rebate calculations. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price, average sales price, or best price information to the government, we may be liable for civil monetary penalties. Our failure to submit monthly/quarterly average manufacturer price, average sales price, and best price data on a timely basis could result in civil monetary penalties. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

In September 2010, CMS and the Office of the Inspector General indicated that they intend more aggressively to pursue companies who fail to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

We also participate in the Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Pursuant to the applicable law, knowing provision of false information in connection with a non-federal average manufacturer price filing under this program can subject a manufacturer to penalties of $100,000 for each item of false information.

In addition, pursuant to regulations issued by the DoD TRICARE Management Activity, or TMA, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs is listed on a Section 703 Agreement with TMA under which we have agreed to pay rebates on covered drug

prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may be negatively affected by unforeseen invoicing of historical Medicaid sales.

We provide a rebate related to Acthar dispensed to Medicaid eligible patients in instances where we are required to do so and establish a reserve for such rebate payments. We multiply the estimated rebate amount per unit for the period by the estimated number of rebate eligible units utilized during the period to calculate the estimated reserve for the period. This reserve is deducted from gross sales in the determination of net sales. Other than for Medicaid rebates associated with Medicaid Managed Care Organization (Medicaid MCO) utilization, the Medicaid rebates associated with end user demand for a period are mostly paid to the states by the end of the quarter following the quarter in which the rebate reserve is established. As a result, at the end of each quarter we must estimate the amount of Medicaid sales in that quarter to calculate the reserves and such estimates could prove to be inaccurate. Revisions in the Medicaid rebate estimates are charged to income in the period in which the information that gives rise to the revision becomes known. However, certain states may provide their requested rebates to us on a delayed basis, which to the extent not previously reserved for would negatively affect future financial performance in periods occurring after the period in which the original reserved Medicaid rebate accrual occurred. Effective March 23, 2010, the Healthcare Reform Act expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid MCOs as well. In connection with this expansion, we increased our reserves for Medicaid rebates. Our reserves for Medicaid MCO related rebates may not be adequate.

In addition to receiving requested rebates on a delayed basis, pharmaceutical and biologic companies may be subject to investigation by various governmental agencies concerning Medicaid rebates. Governmental agencies and their agents, such as the Medicare Administrative Contractors, fiscal intermediaries and carriers, as well as the Office of the Inspector General, the Federal Bureau of Investigations, CMS, and state Medicaid programs, may conduct audits of our operations. The cost of responding to and resolving these audits could have a material, adverse effect on our financial position, results of operations and liquidity. Although we have processes and controls in place, should we be found out of compliance with any of these laws, regulations or programs, our business, our financial position and our results of operations could be negatively impacted.

Risks Related to our Common Stock

Our stock price has a history of volatility, and an investment in our stock could decline in value.

The price of our common stock is subject to significant volatility. The closing price per share of our common stock ranged in value from $17.83 to $72.34 during the two-year period ended December 31, 2013. Any number of

events, both internal and external to us, may continue to affect our stock price. For example, our quarterly revenues or earnings or losses can fluctuate based on the buying patterns of our specialty distributor and our end users. In the event that patient demand for Acthar is less than our sales to our specialty distributor, excess Acthar inventories may result at our specialty distributor, which may impact future Acthar sales. Other potential events that could affect our stock price include, without limitation, our quarterly and yearly revenues and earnings or losses; announcements by us or our competitors regarding product development efforts, including the status of regulatory approval applications; the outcome of legal proceedings; the launch of competing products or the public notice of an FDA filing relating to a potential competitive product; and our ability to obtain product from our contract manufacturers, the publication of negative or neutral coverage by research analysts or others, and efforts to try to manipulate our stock price or interfere with our business operations by investors or others that engage in the manipulation of stock prices.

As of January 31, 2014, NASDAQ reported a short interest of approximately 20.3 million shares in our common stock, and it is possible that the NASDAQ short interest reporting system does not fully capture total short interest. It is generally in the short seller's interests for the price of a stock to decline. We are aware that other companies have alleged that short sellers have taken various actions aimed at attempting to cause harm to a company's business or reducing the stock price of such companies in order to generate profit on their short positions. These actions have been alleged to include arranging for the publication of negative opinions, mischaracterization of facts regarding companies and their business prospects, or taking more direct action to try to cause harm to a company's business. As this potentially relates to us, our stock price exhibited significant volatility at various times during 2013 following various publications and other communications relating to us. There is risk that similar actions could continue to occur in 2014 and therefore continue to create significant volatility in our stock price.

Our future policy concerning the payment of dividends is uncertain, which could adversely affect the price of our stock.

We currently pay a quarterly dividend on our common stock. We may not have the financial ability to fund this quarterly dividend in perpetuity or to pay it at the current rate. Further, our Board of Directors may decide not to declare a dividend at some future time for financial or non-financial reasons. Unfulfilled expectations regarding future dividends could adversely affect the price of our stock.

Our quarterly results may fluctuate significantly and could fall below the expectations of securities analysts and investors, resulting in a decline in our stock price.

In addition to the risk factors detailed elsewhere in this Annual Report on Form 10-K, our quarterly operating results and share price may fluctuate significantly because of several factors, including:

- public concern as to the safety of drugs developed by us or others;
- availability of Acthar;
- patient safety concerns;

- announced inquiries by governmental agencies or updates regarding previously announced inquiries;
- unfavorable outcomes related to the government investigations or lawsuits brought against us or our directors and officers, including those currently in process;
- departure of key managers;
- negative opinions regarding company actions from proxy advisory firms;
- activities of certain investors who elect to short sell our stock;
- the announcement and timing of new product introductions by us or others;
- the timing of our regulatory submissions or approvals, or the failure to receive regulatory approvals;
- prescription trends and the level of orders from our specialty distributor within a given quarter and preceding quarters;
- availability and level of third party reimbursement;
- political developments or proposed legislation in the pharmaceutical or healthcare industry;
- economic or other external factors, disaster or crisis;
- changes in government regulations or policies or patent decisions;
- unforeseen financial or operational issues related to BioVectra or our other international operations;
- failure to meet market expectations or changes in opinions of analysts who follow our stock; or
- general market conditions.

If we were to be negatively impacted by any of these factors, it could cause a decrease in our stock price.

We have significant stock option overhang which could dilute your investment.

We have an overhang of common stock due to a low average exercise price of employee stock options. The future exercise of employee stock options could cause dilution, which may negatively affect the market price of our shares.

We have certain anti-takeover provisions in place.

Certain provisions of our Amended and Restated Articles of Incorporation and the California General Corporation Law could discourage a third-party from acquiring, or make it more difficult for a third-party to acquire, control of our company without approval of our Board of Directors. These provisions could also limit the price that certain investors might be willing to pay in the future for shares of our common stock. Certain provisions allow the Board of Directors to authorize the issuance of preferred stock with rights superior to those of the common stock. We are also subject to Section 1101(e) of the California General Corporation Law, which, among other things, limits the ability of a majority shareholder holding more than 50% but less than 90% of the outstanding shares of a California corporation from consummating a cash-out merger.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Annual Report on Form 10-K contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995 and concern matters that involve risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. Discussions containing forward-looking statements may be found in the material set forth under "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other sections of this Annual Report on Form 10-K. Words such as "may," "will," "should," "could," expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" or similar words are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Although we believe that our opinions and expectations reflected in the forward-looking statements are reasonable as of the date of this Annual Report on Form 10-K, we cannot guarantee future results, levels of activity, performance or achievements, and our actual results may differ substantially from the views and expectations set forth in this Annual Report on Form 10-K. We expressly disclaim any intent or obligation to update any forward-looking statements after the date hereof to conform such statements to actual results or to changes in our opinions or expectations. Readers are urged to carefully review and consider the various disclosures made by us, which attempt to advise interested parties of the risks, uncertainties, and other factors that affect our business, set forth in detail in Item 1A of Part I, under the heading "Risk Factors."

The following discussion and analysis should be read in conjunction with our consolidated financial statements and the related notes to those statements contained elsewhere in this Annual Report on Form 10-K.

Overview

Questcor is a biopharmaceutical company focused on the treatment of patients with serious, difficult-to-treat autoimmune and inflammatory disorders. Our primary product is H.P. Acthar ® Gel (repository corticotropin injection), or Acthar, an injectable drug that is approved by the FDA for the treatment of 19 indications. Of these 19 FDA approved indications, we currently generate substantially all of our net sales from the following indications:

- Nephrotic Syndrome (NS): Acthar is indicated "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." According to the National Kidney Foundation, nephrotic syndrome can result from several idiopathic type kidney disorders, including idiopathic membranous nephropathy, focal segmental glomerulosclerosis, IgA nephropathy and minimal change disease. Nephrotic syndrome can also occur due to lupus erythematosus. In this Annual Report on Form 10-K, the terms "nephrotic syndrome" and "NS" refer only to the proteinuria in nephrotic syndrome conditions that are covered by the Acthar label of approved indications.
- Rheumatology Related Conditions: Acthar is approved for the following rheumatology related conditions: (i) Collagen Diseases: Acthar is indicated "during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus, systemic dermatomyositis (polymyositis)" and (ii)

Rheumatic Disorders: Acthar is indicated as “adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), and Ankylosing spondylitis.”

- Multiple Sclerosis (MS): Acthar is indicated “for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.”
- Infantile Spasms (IS): Acthar is indicated “as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.”

We continue to explore additional markets for other on-label indications. For example, in 2013 we initiated a pilot commercialization effort for Acthar for the treatment of respiratory manifestations of symptomatic sarcoidosis. In addition, we are exploring the possibility of pursuing FDA approval for indications not currently on the Acthar label that are related to the treatment of other serious, difficult-to-treat autoimmune and inflammatory disorders having high unmet medical need.

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 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.

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 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.

Results of Operations

Years Ended December 31, 2013, 2012 and 2011

Net Sales. Net sales, which we derive primarily from our sales of Acthar, were $798.9 million in 2013, compared to $509.3 million in 2012 and $218.2 million in 2011. The following table sets forth our net sales for the years ended December 31, 2013, 2012 and 2011, respectively (in thousands):

	Years Ended December 31,		
	2013	2012	2011
Total pharmaceutical gross sales	$825,710	$582,097	$268,827
Sales reserves	64,363	72,805	50,658
Total pharmaceutical net sales	761,347	509,292	218,169
Total contract manufacturing net sales	37,582	—	—
Total net sales	$798,929	$509,292	$218,169

2013 compared to 2012: Net sales for the year ended December 31, 2013 were derived from pharmaceutical net sales and contract manufacturing net sales, while net sales for the year ended December 31, 2012 were derived solely from pharmaceutical net sales. Pharmaceutical net sales are comprised primarily of sales of Acthar, while contract manufacturing net sales are comprised of sales from BioVectra. Net sales of Acthar increased by approximately 49.6% to $761.3 million for the year ended December 31, 2013 from $508.9 million in 2012. This growth resulted primarily from increased vial demand from our specialty distributor for Acthar. We shipped 28,112 vials for the year ended December 31, 2013 as compared to 20,741 vials shipped for the year ended December 31, 2012. While we do not receive complete information regarding prescriptions by therapeutic area, we believe

increased demand resulted from our entry into the rheumatology field in the second half of 2012 and the expansion of our Rheumatology Sales Force in early 2013. Increased demand was also driven by the expanded usage of Acthar by nephrologists in the treatment of NS and neurologists in the treatment of MS. Net sales attributable to IS were positively impacted by the reduction in the Medicaid rebate amount for Acthar.

In addition to the increase in vial demand, the increase in pharmaceutical net sales was also attributable to the reduction in our sales related reserves. Our net sales of Acthar are impacted by the amount of our Medicaid and other sales reserves, which are deducted from pharmaceutical sales in the calculation of net sales. For the year ended December 31, 2013, this provision was impacted by two factors. For the year ended December 31, 2013, the Medicaid rebate amount for Acthar was lower than for the corresponding period in 2012, due to the reduction in the rebate amount that became effective in the first quarter of 2013. Second, partially offsetting the reduction in the Medicaid rebate amount, we received correspondence from CMS that indicates that Questcor should have maintained the existing baseline AMP as used by the prior owner of Acthar before Questcor acquired the drug in 2001. We have no indication that CMS' assertion is without merit and have, therefore, accrued an estimated liability for 2002 to 2009, the prior years affected by this item. This item does not impact periods following 2009. Specifically, we accrued an estimated liability for rebates totaling $11.5 million because the amount is estimable and it is probable that we will pay such amount. For the year ended December 31, 2013, we recorded a provision of 7.8% of our pharmaceutical sales for sales-related reserves, a decrease from the 12.5% in the year ended December 31, 2012.

We believe that approximately two-thirds of our growth in net sales from 2012 to 2013 was due to increased vial shipments, with the remainder of our net sales growth being due to the increase in the percentage of our product sales that are not subject to Medicaid rebates as described above, as well as increased product pricing. However, it is difficult to ascribe the sources of net sales growth to these individual factors as the factors might not be independent.

Net sales for BioVectra were $37.6 million representing 4.7% of total net sales. Because we acquired BioVectra on January 18, 2013, there were no comparable sales in the same period 2012.

Acthar orders may be affected by several factors, including inventory levels at specialty and hospital pharmacies, greater use of patient assistance programs, the overall pattern of usage by the health care community, including Medicaid and government-supported entities, the use of alternative therapies, and the reimbursement policies of insurance companies.

Our specialty distributor ships Acthar to specialty pharmacies and hospitals to meet end user demand. We track our own Acthar shipments daily, but those shipments vary compared to end user demand due to changes in inventory levels at specialty pharmacies and hospitals. As a result of the variation in order patterns, in channel inventory levels may be positively or negatively affected. We believe that distribution channel inventory was within the normal historic range as of December 31, 2013.

2012 compared to 2011: Net sales of Acthar increased by approximately 133.8% to $508.9 million for the year ended December 31, 2012 from $217.7 million for the year ended December 31, 2011. The increase in net sales was

due to an increase in the number of Acthar vials shipped from 10,710 vials shipped in 2011, up to 20,741 vials shipped in 2012. While we do not receive complete information regarding prescriptions by therapeutic area, we believe increased demand from our specialty distributor was driven by strong prescription growth in each of our NS and MS therapeutic areas.

Our net sales were also impacted by the amount of our sales reserves, which are deducted from revenue in the calculation of net sales. For the year ended December 31, 2012, we recorded a provision of 12.5% of our gross revenue for sales-related reserves, a decrease from the 18.8% in the year ended December 31, 2011.

We believe that approximately three-quarters of our growth in net sales from 2011 to 2012 was due to increased vial shipments, with the remainder of our net sales growth being due to the increase in the percentage of our product sales that are not subject to Medicaid rebates as described above, as well as increased product pricing.

Cost of Sales and Gross Profit

	Years Ended December 31,		
	2013	**2012**	**2011**
Pharmaceutical cost of sales	$ 43,270	$ 28,555	$ 12,459
Contract manufacturing cost of sales	31,095	—	—
Total cost of sales	$ 74,365	$ 28,555	$ 12,459
Pharmaceutical gross profit	$718,077	$480,737	$205,710
Contract manufacturing gross profit	6,487	—	—
Total gross profit	$724,564	$480,737	$205,710
Pharmaceutical gross margin	94%	94%	94%
Contract manufacturing gross margin	17%	—%	—%
Total gross margin	91%	94%	94%

Cost of sales was $74.4 million for the year ended December 31, 2013, as compared to $28.6 million for 2012 and $12.5 million for 2011. Our gross profit and margin was $724.6 million and 91%, respectively, in 2013, as compared to $480.7 million and 94%, respectively, in 2012 and $205.7 million and 94%, respectively, in 2011.

Cost of sales for the year ended December 31, 2013 primarily included costs associated with the sale of Acthar ($43.3 million or 58% of the total costs) and costs associated with our manufacturing activity at BioVectra ($31.1 million or 42% of the total costs). We include in cost of sales direct material costs, manufacturing labor, indirect manufacturing costs including plant supplies, packaging, warehousing and distribution, royalties, product liability insurance, quality control (which primarily includes product stability and potency testing), quality assurance, depreciation of manufacturing equipment and facilities and reserves for excess or obsolete inventory.

The increase in gross profit dollars is due to continued growth in vials sold for all of our indications. The increase in cost of sales was primarily due to the following: (1) the inclusion of BioVectra manufacturing costs, (2) an increase in Acthar net sales, (3) an increase in costs associated with the distribution of Acthar, including our hub reimbursement support center, and (4) an increase in royalties on Acthar net sales.

The decrease in the overall gross margin quarter over quarter is due to the inclusion of BioVectra, a manufacturing company, which has a lower gross margin on sales than our sales of Acthar, in our consolidated results.

We continue to expect our cost of sales, in absolute dollars, to increase in future periods due to the inclusion of BioVectra, increased costs associated with our hub reimbursement support center, outside product potency testing, product stability testing and, in the event of increased net sales, higher royalty payments. The manufacturing process for pharmaceutical products, including Acthar, and other pharmaceutical ingredients, is complex and problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, natural disasters, and environmental factors.

Selling and Marketing. Selling and marketing expenses were $152.9 million for the year ended December 31, 2013, as compared to $114.1 million in 2012 and $56.7 million in 2011. The increase of $38.8 million in 2013 as compared to 2012 is due primarily to increases in headcount-related costs and costs associated with our expanded sales and marketing efforts. We include in sales and marketing expenses headcount-related costs, including share-based compensation costs, promotional costs and physician program costs. We have expanded our sales force and expect selling and marketing expenses to increase in future periods.

The increase in selling and marketing expenses of $57.4 million in 2012 as compared to 2011 was also due primarily to increases in headcount-related costs and costs associated with our expanded sales and marketing effort.

General and Administrative. General and administrative expenses were $56.4 million for the year ended December 31, 2013, as compared to $33.6 million in 2012 and $17.7 million in 2011. We include in general and administrative expenses headcount-related costs, including share-based compensation expense, legal and accounting expenses. The increase of $22.8 million in 2013 as compared to 2012, as well as the increase of $15.9 million in 2012 as compared to 2011, is due primarily to increased headcount and headcount-related costs to support our growth, and increased legal and compliance costs.

Research and Development. Research and development expenses were $59.7 million in 2013, as compared to $34.3 million in 2012 and $16.8 million in 2011. The increase of $25.4 million in research and development expenses in 2013 as compared to 2012 was primarily due to increases in headcount and headcount-related costs, including share-based compensation costs, to continue and expand our various research and development programs. The increase of $17.5 million in research and development expenses in 2012 as compared to 2011 was primarily due to increases in headcount and headcount-related costs to support our efforts to explore the use of Acthar as a therapeutic alternative for the treatment of NS and costs incurred associated with clinical studies.

Costs included in research and development also include costs associated with providing financial grants to support medical research projects to better understand the therapeutic benefit of Acthar in current and new therapeutic applications, product development efforts and regulatory compliance activities.

We manage and evaluate our research and development expenditures generally by the type of costs incurred. We generally classify and separate research and development expenditures into amounts related to medical affairs, regulatory, product development and manufacturing costs. Such categories include the following types of costs:

- Regulatory Costs – Regulatory costs, which include compliance and all FDA interactions.
- Product Development Costs – Product development costs, which include contract research organization costs and study monitoring costs.
- Medical Affairs Costs – Medical affairs costs, which include activities related to medical information in support of Acthar and its related indications, as well as costs associated with providing financial grants to support third-party research and development efforts.
- Manufacturing Costs – Manufacturing costs, which include costs related to production scale-up and validation, raw material qualification and stability studies.

For the year ended December 31, 2013, approximately 4% of our research and development expenditures were for regulatory costs, 49% was spent on product development costs, 36% of our research and development expenditures were for medical affairs costs, and approximately 11% was spent on manufacturing costs.

For the year ended December 31, 2012, approximately 8% of our research and development expenditures were for regulatory costs, 39% was spent on product development costs, 42% of our research and development expenditures were for medical affairs costs, and approximately 11% was spent on manufacturing costs.

For the year ended December 31, 2011, approximately 12% of our research and development expenditures were for regulatory costs, 37% was spent on product development costs, 36% of our research and development expenditures were for medical affairs costs, and approximately 15% was spent on manufacturing costs.

We continue to invest in Acthar through the expansion of our product development efforts and expect our research and development expense to continue to increase.

The expenditures that will be necessary to execute our development plans are subject to numerous uncertainties, which may affect our research and development expenditures and capital resources. For instance, the duration and the cost of clinical trials may vary significantly depending on a variety of factors including a trial's protocol, the number of patients in the trial, the duration of patient follow-up, the number of clinical sites in the trial, and the length of time required to enroll suitable patient subjects. Even if earlier results are positive, we may obtain different results in later stages of development, including failure to show the desired safety or efficacy, which could impact our development expenditures for a particular indication. Although we spend a considerable amount of time planning our development activities, we may be required to deviate from our plan based on new circumstances or events or our assessment from time to time of a particular indication's market potential, other product opportunities and our corporate priorities. Any deviation from our plan may require us to incur additional expenditures or accelerate or delay the timing of our development spending. Furthermore, as we obtain results from trials and review the path toward regulatory approval, we may elect to discontinue development of certain indications or

product candidates, in order to focus our resources on more promising indications or candidates. As a result, the amount or ranges of cost and timing to complete our product development programs and each future product development program is not estimable.

With our June 2013 acquisition of rights to Synacthen Depot, we have initiated a research and development effort for Synacthen Depot aimed at obtaining FDA and additional international approvals of Synacthen Depot for one or more indications. This will be a multi-year effort, require a significant investment of time and resources including financial resources, and will be subject to numerous risks and uncertainties.

Share-based compensation costs. Total share-based compensation costs for the years ended December 31, 2013, 2012 and 2011 were $28.8 million, $15.8 million and $7.3 million, respectively.

Our equity incentive award plan, which includes stock options, restricted share awards and restricted stock units, is broad-based and Questcor full-time employee and certain Questcor part-time employees are eligible to receive an equity grant. The increase in our share-based compensation is due to the increase in Questcor employees to 470 on December 31, 2013 from 365 employees on December 31, 2012 and 198 on December 31, 2011.

For the year ended December 31, 2013, we granted stock options to employees and non-employee directors to purchase approximately 426,896 shares of our common stock at a weighted average exercise price of $35.66 per share, which was equal to the weighted average of the fair market value of our common stock on the date of each grant. The total share-based compensation costs related to options for the years ended December 31, 2013, 2012 and 2011 were $12.7 million, $13.1 million and $6.7 million, respectively.

In addition to stock options, we also grant restricted stock awards to certain employees. For the year ended December 31, 2013, we issued 829,899 restricted stock awards (including performance-based awards), as compared to 777,524 and 31,762 issued for the years ended December 31, 2012 and 2011, respectively. During the first and second quarter of 2013, we issued 207,250 shares of performance-based restricted stock awards. These performance-based restricted stock awards include a one-time performance achievement and vest according to the degree at which the performance milestone is achieved. At December 31, 2013, we determined achievement of the milestone was reasonably probable and estimable at a level equal to one-third the value and, therefore, recorded an appropriate amount of stock-based compensation expense associated with such grants. The total share-based compensation costs related to restricted stock awards for the years ended December 31, 2013, 2012 and 2011 were $14.6 million, $1.8 million and $163,000, respectively.

For the year ended December 31, 2013, we granted 10,515 restricted stock units to certain of our employees. We did not issue any restricted stock units during the years ended December 31, 2012 and 2011. The total share-based compensation costs related to restricted stock units for the year ended December 31, 2013 was $9,000.

Lastly, we issued shares of our common stock through our 2003 Employee Stock Purchase Plan, or ESPP, which provides our employees the opportunity to purchase our common stock through accumulated payroll deductions. During the years ended December 31, 2013, 2012 and 2011, 137,472, 92,030 and 90,650 shares, respectively, had been issued to participants. The total share-based compensation costs related to our ESPP for the years ended December 31, 2013, 2012 and 2011 were $1.4 million, $1.0 million and $0.5 million, respectively.

The following table sets forth our share-based compensation costs for the years ended December 31, 2013, 2012 and 2011, respectively (in thousands):

	Years Ended December 31,		
	2013	2012	2011
Selling and marketing	$10,897	$ 5,360	$4,236
General and administrative	12,302	7,467	1,884
Research and development	5,554	2,965	1,206
Total share-based compensation expense	$28,753	$15,792	$7,326

Total Interest and Other (Expense) Income and Change in Foreign Currency Translation Loss. Total interest and other (expense) income for the year ended December 31, 2013 was $(0.3) million, as compared to $0.7 million for 2012 and $0.6 million for 2011. The decrease in total interest and other (expense) income of $1.0 million in 2013 as compared to 2012 was due to the foreign currency transaction loss recorded as a result of the BioVectra acquisition. The increase in total interest and other (expense) income of $0.1 million in 2012 as compared to 2011 was the result of the recording of an increase in the average cash balances on hand for 2012 as compared to 2011 resulting in higher interest income.

Income tax expense. Income tax expense for the years ended December 31, 2013, 2012 and 2011 was $146.9 million, $99.6 million and $34.2 million, respectively, and our effective tax rate for financial reporting purposes was approximately 33.4%, 33.5% and 30.0%, respectively. The change in our effective income tax rate in 2013 as compared to 2012 is primarily due to the absence of research and development tax credits in 2012. The change in the effective tax rate in 2012 as compared to 2011 is due to an increase in nondeductible expense, the absence of research and development tax credits in 2012, and the one-time tax credit recorded in 2011 for the costs incurred in obtaining the orphan drug designation.

Liquidity and Capital Resources

Cash and cash equivalents, short-term investments and working capital as of December 31, 2013 and 2012, respectively, were as follows (in thousands):

Financial Assets:

	Years Ended December 31,	
	2013	2012
Cash and cash equivalents	$ 175,840	$ 80,608
Short-term investments	69,166	74,705
Cash, cash equivalents and short-term investments	$ 245,006	$ 155,313

Select measures of liquidity and capital resources:

	Years Ended December 31,	
	2013	2012
Current assets	$ 396,776	$ 237,276
Current liabilities	161,172	90,399
Working Capital	$ 235,604	$ 146,877
Current Ratio	2.46	2.62

Until required for use in our business or returned to shareholders through our dividend, share repurchase program or other method, we invest our cash reserves in money market funds and high quality commercial, corporate and U.S. government and agency bonds in accordance with our investment policy. The objective of our investment policy is to preserve capital, provide liquidity consistent with forecasted cash flow requirements, maintain appropriate diversification and generate returns relative to these investment objectives and prevailing market conditions.

The increase in cash, cash equivalents and short-term investments from December 31, 2013 to December 31, 2012 was primarily due to the increase in our net sales and the related cash generated from operations, offset by the acquisitions of BioVectra and Synacthen Depot and the repurchase of 960,000 shares of our common stock through our approved stock repurchase plan for $53.1 million. The increase in our working capital was primarily due to increases in our overall cash position, inventory (due primarily to the acquisition of BioVectra), and accounts receivable due to the growth in our sales, offset by increases in the current portion of our contingent liabilities associated with the acquisitions of BioVectra and Synacthen Depot and accrued royalties. We expect to maintain increased amounts of inventory as compared to historical averages as a result of the acquisition of BioVectra.

Our collection terms on our accounts receivable relating to sales of Acthar to our specialty distributor are net 30 days. This specialty distributor represents approximately 92% of our accounts receivable and 95% of our net sales.

We expect continued growth in our research and development and selling and marketing expenses. However, we anticipate that cash generated from operations and our existing cash, cash equivalents and short-term investments should provide us adequate resources to fund our operations as currently planned for the foreseeable future.

During the period from October 1, 2013 through December 31, 2013, we repurchased the following shares of our common stock:

Period [1]	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares That May Yet be Purchased Under the Plans or Programs
October 1 - October 31, 2013	—	$ —	—	6,252,793
November 1 - November 30, 2013	360,914	$ 56.60	360,914	5,891,879
December 1 - December 31, 2013	599,086	$ 54.46	599,086	5,292,793
Total	960,000	$ 55.26	960,000	

(1) In February 2008, our Board of Directors approved a stock repurchase plan that provides for the repurchase of up to 7 million shares of our common stock. Stock repurchases under this program may be made through either open market or privately negotiated transactions in accordance with all applicable laws, rules and regulations. On May 29, 2009, our Board of Directors increased the stock repurchase program authorization by an additional 6.5 million shares; on May 9, 2012, our Board of Directors increased the stock repurchase program authorization by an additional 5 million shares; and on September 28, 2012, our Board of Directors increased the stock repurchase program authorization to 7 million shares, including the 3.2 million shares that were remaining under the prior authorization.

Cash Flows

Change in cash and cash equivalents:

	Years Ended December 31,		
	2013	2012	2011
Net cash flows provided by operating activities	$ 337,778	$ 219,037	$ 85,599
Net cash flows (used in) / provided by investing activities	(177,317)	44,642	(51,479)
Net cash flows (used in) / provided by financing activities	(64,151)	(271,540)	12,841
Impact of exchange rate on cash flows	(1,078)	—	—
Net change in cash and cash equivalents	$ 95,232	$ (7,861)	$ 46,961

The increase in net cash and cash equivalents as of December 31, 2013 from December 31, 2012 is primarily due to the increased net income achieved in 2013 versus the net income achieved in the same period in 2012, offset by the acquisitions of BioVectra and Synacthen Depot, the repurchase of our common stock and dividends paid. The decrease in net cash and cash equivalents as of December 31, 2012 from December 31, 2011 is primarily due to the repurchase of our common stock and dividends paid, offset by the increased net income achieved in 2012 versus the net income achieved in the same period in 2011.

Operating Activities

The components of cash flows from operating activities, as reported on our Consolidated Statements of Cash Flows, are as follows:

- Our reported net income, adjusted for non-cash items, including share-based compensation expense, deferred income taxes, amortization of investments, depreciation and amortization, loss on disposal and impairment of property, equipment and intangibles, imputed interest and changes in fair value for contingent consideration and other compensation expense was $334.8 million, $217.3 million and $84.6 million for the years ended December 31, 2013, 2012 and 2011, respectively.
- Net cash inflow due to changes in operating assets and liabilities was $3.0 million for the year ended December 31, 2013, which primarily relates to the following: an increase in accrued royalties of $25.4 million and an increase in other accrued liabilities of $3.3 million, offset by a decrease in income taxes payable of $3.7 million and an increase in accounts receivable of $19.2 million, which relates to an increase in sales.
- Net cash inflow due to changes in operating assets and liabilities was $1.7 million for the year ended December 31, 2012, which primarily relates to an increase in accounts payable of $7.6 million, an increase in accrued compensation $9.7 million, an increase in sales related reserves of $3.3 million, which relates to an increase in Acthar gross sales, and an increase in accrued royalties of $5.5 million, offset by an increase in accounts receivable of $33.6 million.
- Net cash inflow due to changes in operating assets and liabilities was $1.0 million for the year ended December 31, 2011, which primarily relates to an increase in accrued compensation of $7.4 million, an increase in sales related reserves of $12.6 million, which relates to an increase in Acthar gross sales, offset by an increase in accounts receivable of $16.7 million.

Investing Activities

Cash flows used in investing activities for the year ended December 31, 2013 included the acquisitions of BioVectra and Synacthen Depot, as well as securing a portion of the future payments for Synacthen Depot in the form of a letter of credit representing three annual payments totaling $75.0 million. The remaining components of cash flows from investing activities for the years ended December 31, 2013, 2012 and 2011 consisted of the following:

- Purchases of property and equipment of $3.5 million for the year ended December 31, 2013, $1.1 million for the year ended December 31, 2012 and $1.8 million for the year ended December 31, 2011; and
- Purchases of short-term investments of $120.6 million for the year ended December 31, 2013, $145.4 million for the year ended December 31, 2012 and $162.3 million for the year ended December 31, 2011; offset by
- Maturities of short-term investments of $125.7 million for the year ended December 31, 2013, $191.1 million for the year ended December 31, 2012 and $112.6 million for the year ended December 31, 2011.

Financing Activities

Net cash flows from financing activities for the year ended December 31, 2013, 2012 and 2011 reflected the following:

- The income tax benefit realized on our share-based compensation plans of $22.8 million for the year ended December 31, 2013, $7.5 million for the year ended December 31, 2012 and $17.7 million for the year ended December 31, 2011; and
- The issuance of common stock related to both our Employee Stock Purchase Plan and the exercise of stock options for $15.9 million for the year ended December 31, 2013, $6.3 million for the year ended December 31, 2012 and $6.6 million for the year ended December 31, 2011; offset by
- The repurchase of shares of our common stock of $53.1 million to repurchase 960,000 shares of our common stock under our stock repurchase plan for the year ended December 31, 2013, $261.8 million to repurchase 6,759,861 shares of our common stock under our stock repurchase plan for the year ended December 31, 2012, and $11.5 million to repurchase 884,300 shares of our common stock under our stock repurchase plan for the year ended December 31, 2011; and
- Dividends paid during the years ended December 31, 2013 and 2012 of $48.1 million and $23.5 million, respectively. No dividends were paid during the year ended December 31, 2011.

On January 18, 2013, we acquired 100% of the issued and outstanding shares of BioVectra for $50.8 million plus up to an additional C$50.0 million in cash tied to the future performance of BioVectra.

We review our level of liquidity and anticipated cash needs for the business on an ongoing basis, and consider whether to return additional capital to our shareholders as well as alternative methods to return capital. Historically, our primary method of returning capital to shareholders has been open market share repurchases and dividend payments. Since the beginning of 2008, we have repurchased a total of 17.0 million shares of our common stock under our stock repurchase plan for $363.0 million through December 31, 2013, at an average price of $21.40 per share. Additionally, we have repurchased 6.2 million shares of our common stock outside of our stock repurchase plan for a total of $30.3 million through December 31, 2013 at an average price of $4.93 per share for a total repurchase value of $393.3 million. As of December 31, 2013, there are 5.3 million shares authorized remaining under our stock repurchase plan.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2013. This table does not include potential milestone payments, future sales-based royalty obligations and assumes non-termination of agreements (in thousands):

	Payments Due by Period				
	Total	1 Year or Less	1 to 3 Years	3 to 5 Years	After 5 Years
			(In $000's)		
Minimum payments remaining under operating leases(1)	$ 13,654	$ 5,651	$ 6,296	$1,376	$ 331
Novartis (2)	75,000	25,000	50,000	0	0
BioVectra Shareholders (3)	37,462	4,238	33,224	0	0
Long-term debt (4)	15,663	1,665	5,721	2,806	5,471
Potency Testing (5)	6,000	2,000	4,000	0	0
Total contractual cash obligations	$147,779	$38,554	$99,241	$4,182	$5,802

Total contractual cash obligations include the following:

(1) As of December 31, 2013 we leased space in buildings with lease terms expiring in 2014, 2017 and 2018. We leased land for our BioVectra operations with a lease term expiring in 2051, subject to 10 year revaluation clauses based upon comparable land values at the date of revaluation. We have also entered into various office equipment leases and automobile leases, the terms of which are typically three years. Annual rent expense for all of our facilities, equipment and automobile leases for the year ended December 31, 2013 was approximately $4.0 million.

We lease space primarily in the following locations:

- We lease 30,000 square feet of laboratory and office space in Hayward, California under a master lease that expires in May 2018. This facility is occupied by our Commercial Development, Sales and Marketing, Medical Affairs, Contract Manufacturing, Quality Control and Quality Assurance departments.
- We lease 15,600 square feet of office space in Ellicott City, Maryland under a lease agreement that expires in October 2017. This facility is occupied by our Product Development and Regulatory Affairs departments.
- We lease 7,900 square feet of office space in Anaheim, California under a lease agreement that expires in October 2014. This facility is occupied by our Executive, Finance and Administration departments, and serves as our corporate headquarters.

(2) Under the terms of the transaction agreements, we paid Novartis an upfront consideration of $60 million. We will also be making annual cash payments of $25 million on each of the first, second and third anniversaries of the Effective Date, a potential additional annual cash payment on each anniversary subsequent to the third anniversary until we obtain the first approval of the FDA related to Synacthen or Synacthen Depot, or the FDA Approval, and a milestone payment upon our receipt of the FDA Approval. If we successfully obtain the FDA Approval, we will pay an annual royalty to Novartis based on a percentage of the net sales

of the product in the U.S. market until the maximum payment is met. The first three annual payments aggregating to $75 million are secured by a letter of credit. In no event will the total payments related to this transaction exceed $300 million. As of December 31, 2013, we recorded an asset (because it was determined that the intangible asset has alternative future use) related to the acquisition of Synacthen Depot of $191.5 million and a corresponding liability of $140.1 million. The asset and liability (which was determined to be a derivative) were originally valued using a weighted discounted probability model. The asset is considered to be definite-lived and is amortized over its useful life to research and development expense. The liability is reviewed each reporting period for any changes in the probability assumptions and for changes due to the passage of time. Differences between payments included above and the consolidated financial statements relate to the balance sheet including contingent payments within the probability model.

(3) On January 18, 2013, we completed our acquisition of BioVectra Inc. We acquired 100% of the issued and outstanding shares of BioVectra for $50.3 million utilizing cash on hand. The former shareholders of BioVectra could receive additional cash consideration of up to C$50.0 million based on BioVectra's financial results over the next three years. As of December 31, 2013, the estimated value of the contingent consideration of $37.5 million has been recorded as a liability in our condensed consolidated balance sheets ($4.2 million has been recorded as the current portion of the contingent consideration). In 2013, BioVectra met its performance milestone for the year and earned an additional C$5.0 million in consideration.

(4) Our subsidiary, BioVectra, has (1) a 2.85% term loan, payable monthly and is due April 2016. The loan is secured with BioVectra accounts receivable and inventory, and (2) a supply agreement with a customer to supply a pharmaceutical product for a period of 10 years ending in June 2023. Per the supply agreement, BioVectra financed and constructed a facility for the manufacture of the pharmaceutical product to be supplied under the agreement. BioVectra entered into a term loan agreement to finance C$14.8 million of the construction costs of the facility. The term loan has an interest rate of 4%, is due in full by February 2022 and is secured by certain of our BioVectra assets. Under the supply agreement, the customer agreed to reimburse BioVectra (such reimbursement is recorded to net sales) for the quarterly financing payments of C$450,743 during the term of the loan.

(5) During the year ended December 31, 2011, we entered into an agreement with a third party vendor to provide potency and toxicity testing on Acthar prior to releasing the product for commercial distribution. Beginning on January 1, 2012, the agreement provides for a maximum number of tests to be performed each year. Tests performed in excess of the maximum are to be paid on a per test basis. We have been in compliance with the terms of our agreement with this third party vendor.

Critical Accounting Policies and Estimates

We base our management's discussion and analysis of financial condition and results of operations, as well as disclosures included elsewhere in this Annual Report on Form 10-K, upon our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles, or GAAP. We describe our significant accounting policies in the notes to the audited consolidated financial statements contained elsewhere

in this Annual Report on Form 10-K. We include within these policies our "critical accounting policies." Critical accounting policies are those policies that are most important to the preparation of our consolidated financial statements and require management's most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Changes in estimates and assumptions based upon actual results may have a material impact on our results of operations and/or financial condition.

We believe that the critical accounting policies that most impact the consolidated financial statements are described below.

Revenue Recognition

We recognize revenue in accordance with Accounting Standards Codification 605, "Revenue Recognition-Products," or ASC 605. Pursuant to ASC 605, we recognize revenue when we have persuasive evidence that an arrangement, agreement or contract exists, when each of the following three criteria are satisfied: (i) title for our product and risk of loss have passed to our customer, (ii) the price we charge for our product is fixed or is readily determinable, and (iii) we are reasonably assured of collecting the amounts owed under the resulting receivable. We do not require collateral from our customers.

International sales of our products are immaterial.

Net Sales

We record net sales after establishing reserves for the following:

i. Medicaid rebates;

ii. TRICARE retail program rebates;

iii. Medicare Part D Coverage Gap Discount Program rebates;

iv. Chargebacks due to other government programs;

v. Questcor-sponsored co-pay assistance programs;

vi. Exchanges, which have historically been immaterial; and

vii. Other deductions such as payment discounts.

We currently provide our products to Medicaid participants under an agreement with CMS. Under this agreement, states are eligible to receive rebates from us for Medicaid patients in accordance with CMS regulations. States have historically provided us with rebate invoices for their Medicaid Fee for Service reimbursements between 60 and 90 days after the end of the calendar quarter in which our products were provided. Certain states are taking longer to submit complete rebate invoices for the Medicaid Managed Care utilization that became rebate eligible on March 23, 2010, as a result of the enactment of the Health Care Reform Acts.

Significant judgment is inherent in the selection of assumptions and the interpretation of historical experience as well as the identification of external and internal factors affecting the determination of our reserves for Medicaid

rebates and other government program rebates and chargebacks. We believe that the assumptions used to determine these sales reserves are reasonable considering known facts and circumstances. However, our Medicaid rebates and other government program rebates and chargebacks could materially differ from our reserve amounts because of unanticipated changes in prescription trends or patterns in the states' submissions of Medicaid claims, adjustments to the amount of product in the distribution channel, or if our estimates of the number of Medicaid patients with IS, MS, NS and rheumatology related-conditions are incorrect. We have greater visibility on the future submission of Medicaid claims and the amount of product in the distribution channel for Acthar distributed to certain specialty pharmacies than we have with respect to Acthar distributed through other specialty pharmacies. If actual Medicaid rebates, or other government program rebates and chargebacks are materially different from our estimates, we would account for such differences as a change in estimate in the period in which they become known. If actual future payments for such reserves exceed the estimates we made at the time of sale, our consolidated financial position, results of operations and cash flows may be negatively impacted.

The following table summarizes the activity in the account for sales-related reserves for Medicaid rebates (in thousands):

	Years Ended December 31,		
	2013	2012	2011
Balance at January 1	$ 33,921	$ 29,874	$ 17,384
Actual Medicaid rebate payments for sales made in prior year	(22,891)	(18,449)	(9,104)
Actual Medicaid rebate payments for sales made in current year	(19,333)	(35,709)	(24,887)
Current Medicaid rebate provision for sales made in prior year	11,500	1,153	8
Current Medicaid rebate provision for sales made in current year	27,784	57,052	46,473
Balance at December 31	$ 30,981	$ 33,921	$ 29,874

Total Sales-related Reserves

At December 31, 2013 and 2012, respectively, sales-related reserves included in the accompanying Consolidated Balance Sheets were as follows (in thousands):

	December 31,	
	2013	2012
Medicaid rebates	$30,981	$33,921
Other rebates, chargebacks and discounts	4,389	3,455
Total	$35,370	$37,376

Product Exchanges

Acthar has a shelf life of 18 months from the date of manufacture. We authorize Acthar exchanges for expiring and expired product in accordance with our stated return policy, which allows the specialty distributor we work for to return product within one month of its expiration date and for a period up to three months after such product has reached its expiration date. Product exchanges have been insignificant since we began utilizing the services of a specialty distributor to distribute Acthar.

Inventories

We state inventories, net of allowances, at the lower of cost or market value. For our Acthar product, cost is determined by the first-in, first-out method. For our production materials and supplies, work-in-process and finished goods at our contract manufacturer, cost is determined on an average cost basis.

We review inventory periodically for slow-moving or obsolete status. We adjust our inventory if we do not expect to recover the cost of inventory. We would record a reserve to adjust inventory to its net realizable value when any of the following occur: (i) a product is close to expiration and we do not expect it to be sold, (ii) a product has reached its expiration date or (iii) we do not expect a product to be saleable. In determining the reserves for these products, we consider factors such as the amount of inventory on hand and its remaining shelf life, and current and expected market conditions, including management forecasts and levels of competition. We have evaluated the current level of inventory considering historical trends and other factors, and based on our evaluation, have recorded adjustments to reflect inventory at its net realizable value. These adjustments are estimates, which could vary significantly from actual results if future economic conditions, customer demand, competition or other relevant factors differ from expectations. These estimates require us to assess the future demand for our products in order to categorize the status of such inventory items as slow-moving, obsolete or in excess-of-need. These future estimates are subject to the ongoing accuracy of our forecasts of market conditions, industry trends, competition and other factors. Differences between our estimated reserves and actual inventory adjustments have been immaterial, and we account for such adjustments in the current period as a change in estimate.

Share-based Compensation

We recognize compensation expense for all share-based awards made to employees and directors. The fair value of share-based awards is estimated at grant date using an option pricing model and the portion that is ultimately expected to vest is recognized as compensation cost over either (1) the requisite service period or (2) the performance period.

Since share-based compensation is recognized only for those awards that are ultimately expected to vest, we have applied an estimated forfeiture rate to unvested awards for the purpose of calculating compensation cost. These estimates will be revised, if necessary, in future periods if actual forfeitures differ from estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

We use the Black-Scholes option-pricing model to estimate the fair value of share-based awards. The determination of fair value using the Black-Scholes option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividends and projected employee stock option behaviors. We estimate the expected term based on the contractual term of the awards and employees' exercise and expected post-vesting termination behavior.

We use the intrinsic method to account for restricted stock awards. The restricted stock awards are valued based on the closing stock price on the date of grant and amortized ratably over the life of the award.

Additionally, we are required to disclose in our consolidated statements of cash flows the income tax effects resulting from share-based payment arrangements. We adopted the simplified method to calculate the beginning balance of the additional paid-in capital, or APIC, pool of excess tax benefits, and to determine the subsequent effect on the APIC pool and consolidated statements of cash flows of the tax effects of employee share-based compensation awards.

At December 31, 2013, there was $25.8 million of total unrecognized compensation cost related to unvested restricted stock awards and restricted stock units and $20.4 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a remaining weighted average vesting period of approximately 2.2 years.

Income Taxes

We account for income taxes under the provisions of Accounting Standards Codification, 740 “Income Taxes,” or ASC 740. We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

As part of the process of preparing our consolidated financial statements, we are required to estimate income taxes in each of the jurisdictions in which we operate. This process involves estimating our tax exposure under the most current tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets.

Utilization of our net operating loss and research and development credit carryforwards may still be subject to substantial annual limitations due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions for ownership changes after December 31, 2011. Such annual limitations could result in the expiration of the net operating loss and research and development credit carryforwards available as of December 31, 2011 before utilization.

Income tax expense for the years ended December 31, 2013, 2012 and 2011 was $146.9 million, $99.6 million and $34.2 million, respectively, and our effective tax rate for financial reporting purposes was approximately 33.4%, 33.5% and 30.0%, respectively. The change in our effective income tax rate in 2013 as compared to 2012 is primarily due to the absence of research and development tax credits in 2012. The change in the effective tax rate in 2012 as compared to 2011 is due to an increase in nondeductible expense, the absence of research and development tax credits in 2012, and the one-time tax credit recorded in 2011 for the costs incurred in obtaining the orphan drug designation.

As of December 31, 2013, we have recorded a liability for unrecognized tax benefits of $1.3 million related to various federal and state income tax matters. Our policy is to recognize interest and penalties accrued on any

unrecognized tax benefits as a component of tax expense. As of December 31, 2013 and 2012, our accrual for interest and penalties on any unrecognized tax benefits was $78,000 and $106,000, respectively. We expect unrecognized tax benefits to decrease by approximately $0.5 million over the next 12 months as a result of the settlement of an IRS examination.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that are adopted by us as of the specified effective date. We did not adopt any new accounting pronouncements during the year ended December 31, 2013 that had a material effect on our financial position or results of operations.