CORNERSTONE THERAPEUTICS INC
Form 10-K
March 14, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2012

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 000-50767

CORNERSTONE THERAPEUTICS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3523569**
(State or Other Jurisdiction of Incorporation or Organization)	*(IRS Employer Identification No.)*
1255 Crescent Green Drive, Suite 250	**27518**

Cary, North Carolina
(Address of Principal Executive Offices) *(Zip Code)*

Registrant s telephone number, including area code:

(919) 678-6611

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.001 par value per share	**The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act:

None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No þ

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨	Non-accelerated filer þ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No þ

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant as of June 30, 2012 was approximately $55,969,487 based on a price per share of $6.33, the last reported sale price of the registrant s common stock on the NASDAQ Stock Market on that date.

As of March 7, 2013 the registrant had 26,719,163 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant s proxy statement for the registrant s 2013 annual meeting of stockholders are incorporated by reference into Part III of this report.

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CORNERSTONE THERAPEUTICS INC.

ANNUAL REPORT

ON FORM 10-K

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PART I

Cautionary Statement Regarding Forward-Looking Statements

This annual report on Form 10-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding the progress and timing of our product development programs and related trials; our future opportunities; our strategy, future operations, anticipated financial position, future revenues and projected costs; our management s prospects, plans and objectives; and any other statements about management s future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use words such as anticipate, believe, could, estimate, expect, intend, may, plan, project, should, target, will, wo convey uncertainty of future events or outcomes to identify these forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including our critical accounting estimates ; our ability to develop and maintain the necessary sales, marketing, supply chain, distribution and manufacturing capabilities to commercialize our products; our ability to replace the revenues from products we no longer market; the adverse impact of returns of previously sold inventory; patient, physician and third-party payer acceptance of our products as safe and effective therapeutic products; our heavy dependence on the commercial success of a relatively small number of currently marketed products; our ability to maintain regulatory approvals to market and sell our products; our ability to obtain FDA approval to manufacture, market and sell our products and product candidates, including our lixivaptan compound, LIXAR® (formerly referred to as CRTX 080), and RETAVASE®; our ability to successfully and effectively launch our Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product (formerly referred to as CRTX 067); our ability to enter into additional strategic licensing, product acquisition, collaboration or co-promotion transactions on favorable terms, if at all; our ability to manage and control unknown liabilities in connection with any acquisitions; our ability to successfully manage growth or integrate acquired businesses and operations; our ability to maintain compliance with NASDAQ listing requirements; adverse side effects experienced by patients taking our products; difficulties relating to clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to our product candidates and whether such results will be indicative of results obtained in later clinical trials; our ability to develop and commercialize our product candidates before our competitors develop and commercialize competing products; our ability to satisfy FDA and other regulatory requirements; our substantial indebtedness and debt covenants; and our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates. These and other risks are described in greater detail below in Item 1A. Risk Factors. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, any forward-looking statements in this annual report on Form 10-K represent our views only as of the date of this annual report on Form 10-K and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise, except as may be required by law. Our forward-looking statements do not reflect the potential impact of any acquisitions, mergers, dispositions, business development transactions, joint ventures or investments we may enter into or make.

ITEM 1. ***BUSINESS***

Overview

We are a specialty pharmaceutical company focused on commercializing products for the hospital and adjacent specialty markets. Unless specifically noted otherwise, as used herein, the terms we, us and our refer to Cornerstone Therapeutics Inc. We are actively seeking to expand our portfolio of products for these markets through the acquisition of companies and products and through internal development.

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Our strategy is to:

- Focus our commercial and development efforts in the hospital and adjacent specialty markets within the U.S. pharmaceutical marketplace;
- Acquire companies, marketed or registration-stage products, and late-stage development products that fit within our focus areas; and
- Market approved generic products through our wholly owned subsidiary, Aristos Pharmaceuticals, Inc., or Aristos.

In June 2012, we acquired EKR Holdings, Inc. and its wholly owned subsidiary, EKR Therapeutics, Inc., or collectively EKR, a specialty pharmaceutical company focused on serving the acute-care hospital setting. As part of the transaction, we acquired the product rights to EKR s cardiovascular products, CARDENE® I.V. and RETAVASE. We realized significant cost synergies through the elimination of duplicative administrative functions during the integration of EKR into our existing operations. Our combined sales force has significantly expanded our reach in the U.S. hospital market and expanded our commercial infrastructure, including our national accounts team. This expansion enables us to enter into contracts more efficiently upon launch of new hospital products and react more quickly to changes in the hospital market.

Our currently marketed and approved products include:

- CARDENE I.V., an FDA-approved premixed injection indicated for the short-term treatment of hypertension when oral therapy is not feasible or not desirable, for which we acquired the worldwide rights in June 2012;
- CUROSURF®, an FDA-approved natural lung surfactant indicated for the treatment of Respiratory Distress Syndrome, or RDS, in premature infants, for which we acquired the U.S. rights in August 2009;
- ZYFLO®, the only FDA-approved leukotriene synthesis inhibitor indicated for prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older, for which we acquired worldwide rights in December 2003 and March 2004;
- BETHKIS®, an inhaled tobramycin-based product indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa, or PA, approved by the FDA in October 2012. We acquired the U.S. rights in November 2012 and are targeting commercialization of the product in 2013; and
- Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension, or HP/CP ER Suspension, an FDA approved antitussive/antihistamine combination product that is a generic equivalent for the product currently sold under the Tussionex® Pennkinetic®,or Tussionex, brand name in the United States. We are targeting commercialization of the product in 2013.

In addition to our commercial products, we are focused on advancing the following development-stage products to commercialization:

- RETAVASE, a recombinant plasminogen activator that was approved by the FDA in 1996 for the use in the management of acute myocardial infarction, or AMI, in adults for the improvement of ventricular function following AMI, the reduction of incidence of congestive heart failure, and the reduction of mortality associated with AMI; and
- LIXAR, an investigational, orally-active, vasopressin receptor 2 antagonist targeting the treatment of hyponatremia.

Our management team has broad experience in the acquisition, commercialization, development, and integration of pharmaceutical companies and products. We intend to leverage our management expertise and our expanded sales infrastructure as we focus on the following priorities during 2013:

Acquiring products and companies in the hospital and adjacent specialty markets;

Growing revenue from our existing product portfolio;

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Launching BETHKIS, which we licensed from Chiesi Farmaceutici S.p.A., or Chiesi, in November 2012;

Launching HP/CP ER Suspension, which we expect to be distributed by Aristos; and

Progressing toward FDA approval of a new active pharmaceutical ingredient, or API, supplier and certain manufacturing process changes to allow for re-launch of RETAVASE.

Products

CARDENE I.V.

Overview. CARDENE I.V. (nicardipine hydrochloride) is a premixed injection indicated for the short-term treatment of hypertension when oral therapy is not feasible or not desirable. It is a calcium ion influx inhibitor (slow channel blocker or calcium channel blocker) that was approved by the FDA in 1992. Ready-to-use CARDENE I.V., or CARDENE RTU, is currently the only marketed FDA-approved premixed formulation of nicardipine hydrochloride and is designed to be immediately available for healthcare providers to provide rapid intervention and to minimize the risk of medication errors.

Market Opportunity. According to NSP (National Sales Perspectives), or NSP, from IMS Health, a third-party provider of pharmaceutical spending data, the nicardipine market generated approximately $78 million, $83 million and $98 million in sales in 2012, 2011 and 2010, respectively and is on a slight downward trend. The downward trend in sales is primarily caused by the financial impact of the increasing market share of generic nicardipine.

Proprietary Rights. We have a number of U.S. and foreign patents and patent applications related to CARDENE RTU. The U.S. patents for CARDENE RTU are related to method of treatment and composition. These patents expire in April and December 2027, respectively. Additionally, we have the registered trademark for CARDENE I.V. in the United States and in certain foreign countries.

CUROSURF

Overview. CUROSURF (poractant alfa) is a porcine-derived natural lung surfactant indicated for the treatment of RDS in premature infants. It is a world-leading treatment that was approved by the FDA in 1999 and launched in the United States in 2000. CUROSURF is currently available in 1.5mL and 3.0mL vials in over 60 countries, including the United States and most of Europe, and has been administered to over 1.5 million infants since 1992. RDS can lead to serious complications and is one of the most common causes of neonatal mortality. We licensed the U.S. product rights for CUROSURF from Chiesi during the third quarter of 2009 and began promoting and selling CUROSURF in September 2009.

Market Opportunity. Approximately 50,000 or one out of every 10 premature infants require surfactant treatment in the United States each year. Surfactants are typically dispensed in over 2,000 hospital neonatal intensive care units annually. According to NSP, the surfactant market generated approximately $66 million, $70 million and $75 million in sales in 2012, 2011 and 2010, respectively and is on a slight downward trend. The downward trend is primarily caused by a shift in treatment protocols toward an emphasis on later treatment or rescue surfactant use after less invasive ventilation techniques have failed. We believe Surfactant use will stabilize in the coming years as the shift in treatment protocols becomes complete.

Proprietary Rights. We have an exclusive license from Chiesi under its CUROSURF know-how and the CUROSURF trademark to import, store, handle, promote, market, offer to sell and sell CUROSURF for RDS in the United States and its territories and possessions.

ZYFLO

Overview. ZYFLO CR® (zileuton) and ZYFLO, collectively ZYFLO , are leukotriene synthesis inhibitor drugs indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. ZYFLO was approved by the FDA in 1996 as an immediate-release, four-times-a-day tablet and was first launched in the United States in 1997. We began selling ZYFLO in the United States in October 2005. The FDA approved our new drug application, or NDA, for ZYFLO CR in May 2007, and we launched ZYFLO CR in

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October 2007. We believe ZYFLO CR offers a more convenient regimen for patients, which we believe may increase patient drug compliance because of its twice-daily, two tablets per dose dosing regimen, as compared to ZYFLO s four-times daily dosing regimen.

Market Opportunity. Asthma is a chronic respiratory disease characterized by the narrowing of the lung airways, making breathing difficult. An asthma attack leaves the victim short of breath as the airways become constricted and inflamed. The National Center for Health Statistics estimated that in 2011, approximately 8.5% of the U.S. population, or approximately 26.0 million people, had asthma and approximately 4.2% of the U.S. population, or 13.2 million people, had asthma attacks. According to NSP, the leukotriene agents market generated approximately $3.7 billion, $4.8 billion and $4.3 billion in sales in 2012, 2011 and 2010, respectively.

Proprietary Rights. We licensed from Abbott exclusive worldwide rights to ZYFLO and other formulations of zileuton for multiple diseases and conditions. The U.S. patent covering the composition of matter of zileuton that we licensed from Abbott expired in December 2010. The U.S. patent for ZYFLO CR expires in September 2013 and relates only to the controlled-release technology. We could experience generic competition after the patent expires.

BETHKIS

Overview. BETHKIS (tobramycin) is an inhaled tobramycin-based product indicated for the management of cystic fibrosis patients with PA. The FDA approved the NDA for BETHKIS in October 2012, and we are targeting launching this product in 2013 in the United States. We licensed the U.S. product rights for BETHKIS from Chiesi in November 2012.

Market Opportunity. According to NSP, nebulized tobramycin products generated approximately $413 million, $366 million and $292 million in sales in 2012, 2011 and 2010, respectively.

Proprietary Rights. We have an exclusive license for the U.S. market from Chiesi under its BETHKIS patent, which expires in September 2022, and other patents and pending patent applications. These patents and patent applications are related to formulation and method of treatment. We have also licensed the BETHKIS trademark to market and sell BETHKIS in the United States and its territories and possessions.

HP/CP ER Suspension

Overview. HP/CP ER Suspension is an antitussive/antihistamine combination product that is a generic equivalent for the product currently sold under the Tussionex brand name. HP/CP ER Suspension is indicated for the relief of cough and upper respiratory symptoms associated with an allergy or a cold in adults and children six years of age and older. The FDA approved HP/CP ER Suspension in June 2012 and manufacturing scale-up and launch activities have been underway since approval. We are targeting launch prior to the start of the fall 2013 cough/cold season.

Market Opportunity. Cough can adversely affect quality of life, leading patients to seek medical attention. According to NPA (National Prescription Audit Family of Services), or NPA, from IMS Health, a third-party provider of prescription data, in 2012 there were approximately 35 million prescriptions generated for antitussive products in the United States. Over 7.5 million of these prescriptions were for products similar to HP/CP ER Suspension.

Proprietary Rights. We have licensed the rights to Neos Therapeutics, L.P. s, or Neos, Dynamic Time Release Suspension®, or DTRS®, technology and Coating Place, Inc. s, or Coating Place, drug resin complex technology. These licensed technologies allowed us to formulate our suspension product such that a portion of its API is immediately activated followed by a sustained timed release of the remaining API over a 12-hour period. Neos s DTRS technology and Coating Place s drug resin complex technology are covered under U.S. patents that will expire in 2025.

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Product Development Pipeline

We are committed to the expansion of our product portfolio with particular focus in the hospital pharmaceutical product sector. Our development pipeline consists of product candidates that are strategically aligned with our current products and customer focus. The following table sets forth additional information regarding our product candidates:

Therapeutic Class	Product/Project Name	Developmental Stage	Regulatory Status
Thrombolytic	RETAVASE	Under FDA Review	Complete Response Letter received in December 2012. FDA response compilation in process.
Vasopressin-2 Receptor Antagonist	LIXAR	Under FDA Review	Complete Response Letter received in October 2012. End of Review Meeting requested in February 2013.

During 2012, 2011 and 2010, our research and development expenses were $4.3 million, $1.6 million and $4.5 million, respectively. Our development priorities may change from time to time. For example, during 2012, we ceased work on our anti-asthma product candidate CRTX 073 as a result of realigning our product development pipeline with our focus on hospital and adjacent specialty markets.

RETAVASE

Overview. RETAVASE (retaplase) is a recombinant plasminogen activator that the FDA approved in 1996 for use in the management of AMI in adults, the improvement of ventricular function following AMI, the reduction of incidence of congestive heart failure and the reduction of mortality associated with AMI. RETAVASE is not currently available for sale in the United States.

Status. In connection with our June 2012 acquisition of EKR, we acquired the U.S. product rights to RETAVASE during the second quarter of 2012. We continue to work toward regulatory approval of the Supplemental Biologics Application, or sBLA, for RETAVASE. The sBLA is intended to qualify SCIL Proteins Productions in Germany, or SCIL, as a new supplier of retaplase, the API for RETAVASE, and to modify the finished goods manufacturing process.

Market Opportunity. According to NSP, the injectable thrombolytic market generated approximately $593 million, $510 million and $446 million in sales in 2012, 2011 and 2010, respectively, and is on an upward trend. The upward trend is primarily due to price increases of the products in this market.

Proprietary Rights. RETAVASE is covered by three patents we own, the last of which expires in March 2015.

LIXAR

Overview. LIXAR (lixivaptan) is the investigational, orally-active, vasopressin receptor 2 antagonist lixivaptan targeting the treatment of hyponatremia. Hyponatremia is a metabolic condition that occurs when there is not enough sodium (salt) in the blood. On December 30, 2011, we acquired Cardiokine, Inc., or Cardiokine, a specialty pharmaceutical company focused on developing hospital products for cardiovascular indications. Prior to the acquisition, Cardiokine completed a series of phase III clinical trials for LIXAR, and filed an NDA with the FDA on December 29, 2011.

Status. On October 31, 2012, we received a Complete Response Letter, or CRL, from the FDA following its review of the NDA for LIXAR for the treatment of symptomatic hypervolemic and euvolemic hyponatremia associated with heart failure and syndrome of inappropriate antidiuretic hormone, or SIADH. The FDA has requested that we complete additional clinical studies to further evaluate the efficacy and safety of lixivaptan in both heart failure patients and SIADH patients. We are requesting an End-of-Review meeting with the FDA s Division of Cardiovascular and Renal Drug Products to better understand the contents of the CRL and the nature and scope of the additional clinical trials requested by the agency. Following that meeting, we will determine appropriate next steps for LIXAR, which may result in abandonment of the development program.

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Market Opportunity. Hyponatremia is the most common electrolyte disorder among hospitalized patients, affecting up to six million people in the United States, and is often diagnosed in patients with congestive heart failure, or CHF. In the United States alone, there are five million heart failure patients, and each year approximately one-fourth of them develop hyponatremia. Other causes of hyponatremia include burns, diuretic medications, kidney disease, liver cirrhosis and SIADH. According to NSP, the hyponatremia market generated approximately $99 million, $63 million and $33 million in sales in 2012, 2011 and 2010, respectively, and is on an upward trend.

Proprietary Rights. We have exclusively licensed from Pfizer Inc. its worldwide patent portfolio covering LIXAR, which includes two issued U.S. patents with claims to the composition of matter and uses of the API, lixivaptan, and one issued patent for the formulation of the lixivaptan product candidate. The U.S. lixivaptan product candidate patents extend through September 2020. We have issued patents with claims to the composition of matter and uses of the API, lixivaptan, in Europe and Japan that extend through July 2013 and July 2014, respectively. Additionally, we own LIXAR, the U.S. registered trademark for our lixivaptan product candidate, and have registered trademarks for LIXAR in other foreign countries.

Sales and Distribution

Sales and Marketing

We have built a commercial organization comprised of professionals in a variety of disciplines, including hospital sales specialists, regional business managers, trade/national account managers, marketing managers, sales trainers, sales administration/operations and analytics personnel.

Our sales organization consists of field-based hospital sales specialists who promote and educate doctors and other healthcare professionals on the use of CUROSURF and CARDENE I.V. in hospitals within the neonatal intensive care units and various hospital departments that treat uncontrolled hypertension, respectively. These hospital sales specialists call on neonatologists, neonatal nurses, respiratory therapists, emergency department physicians and a variety of other physician specialists and hospital-based paraprofessionals, along with hospital pharmacists and administrators. Field-based regional business managers oversee the activities of our hospital sales specialists. Our trade and national accounts managers work to establish and maintain contracts with wholesalers, retail pharmacy chains, group purchasing organizations, hospital systems and integrated delivery networks, certain large individual hospital accounts and specialty pharmacies. They also work with commercial and government payers to assure market access and achieve reimbursement coverage for our products. Our national accounts team provides us with the capability to contract efficiently upon launch of new hospital products and react quickly to changes in the hospital market.

Our marketing team works to develop and implement strategies and tactics to support our products and the healthcare professionals who administer our products, including promotional materials, speaker programs, patient co-payment assistance, health care provider education, information to further support patient compliance and participation at national medical conventions.

Trade and Distribution

Our customers consist of drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the United States. We primarily sell products directly to drug wholesalers, which in turn distribute the products to retail drug stores, hospitals, mass merchandisers and grocery store pharmacies. Our top three customers, which represented 93% of gross product sales in 2012, are all drug wholesalers and are listed below:

Customer	2012	2011
Cardinal Health	33%	39%
McKesson Corporation	32%	34%
AmerisourceBergen Corporation	28%	21%

Consistent with industry practice, we maintain a returns policy that allows our customers to return products within a specified period prior and subsequent to the expiration date. Occasionally, we may also provide additional discounts to some customers to ensure adequate distribution of our products.

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Our trade distribution group actively markets our products to authorized distributors through regular sales calls. This group has many years of experience working with various industry distribution channels. We believe that our trade distribution group enhances our commercial performance by ensuring product stocking in major channels across the country, continually following up with accounts and monitoring of product performance, developing successful product launch strategies and partnering with customers on other value-added programs.

We rely on Cardinal Health, Specialty Pharmaceutical Services, or Cardinal SPS, a third-party logistics provider, for the distribution of our products to drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies. Cardinal SPS ships our products from its warehouse in LaVergne, Tennessee to our customers throughout the United States and its territories as orders are placed through our customer service center.

Manufacturing

We currently outsource the manufacturing of all of our commercially available products and the formulation development of our product candidates for use in clinical trials to third parties. We intend to continue to rely on third parties for our manufacturing requirements. We provide regular product forecasts to assist our third-party manufacturers with efficient production planning.

We place orders pursuant to supply agreements or purchase order arrangements with third-party manufacturers and packagers for each of our marketed products. Depending on the finished product presentation, some of our manufacturers also package the product. In other cases, the manufacturer supplies the bulk form of the product and we package the product through a separate third party. Information about our manufacturing and packaging agreements related to our marketed products is summarized in the following table.

Product	Manufacturer/Packager
CARDENE I.V.	
API (nicardipine)	Lusochimica
RTU bags (nicardipine hydrochloride)	Baxter Healthcare Corporation
CUROSURF	Chiesi
ZYFLO/ZYFLO CR	
API (zileuton)	Shasun Pharma Solutions Ltd. (or Shasun)
ZYFLO tablets	Patheon Pharmaceuticals Inc. (or Patheon)
ZYFLO CR tablet cores	Jagotec AG (or Jagotec)
ZYFLO CR tablet coating and packaging	Patheon

We and our manufacturers and packagers are subject to the FDA s current Good Manufacturing Practice, or cGMP, requirements and other applicable laws and regulations administered by the FDA, the Drug Enforcement Administration, or DEA, and other regulatory authorities, including requirements related to controlled substances. Risks related to our arrangements with our manufacturers and packagers are described in greater detail below in Item 1A. Risk Factors.

While none of our products has alternative manufacturers qualified due to exclusivity provisions in the respective licensing agreements or based on other commercial considerations, we believe there are other suppliers that could serve as replacements for the current manufacturers if the need arose. However, qualifying such a replacement manufacturer with the FDA could take a significant amount of time, and, as a result, we would not be able to guarantee an uninterrupted supply of the affected product to our customers.

Baxter Healthcare Corporation CARDENE I.V. Development and Manufacturing Agreement

Baxter Healthcare Corporation manufactures all of our CARDENE RTU bags pursuant to a development and manufacturing agreement dated November 6, 2009, as amended. We assumed this contract and related obligations from EKR in June 2012. We are obligated to purchase a minimum number of bags or pay a penalty for the shortfall in each of the calendar years during the term of the agreement, which extends until December 31, 2019, unless earlier terminated.

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Chiesi CUROSURF and BETHKIS License and Distribution Agreements

These agreements are described below under the caption License and Collaboration Agreements in this Item 1 of this annual report on Form 10-K.

Shasun Agreement for Manufacturing and Supply of Zileuton API

Shasun manufactures all of our commercial supplies of the zileuton API pursuant to an agreement dated February 8, 2005, as amended. The API purchased from Shasun currently has a shelf life of 36 months. The agreement will expire on the earlier of the date on which we have purchased a specified amount of the API for zileuton or December 31, 2013. The agreement automatically extends for successive one-year terms unless Shasun provides us with 18-months prior written notice of cancellation. We have not received written notice of cancellation.

Jagotec Manufacture and Supply Agreement for ZYFLO CR

Jagotec, a subsidiary of SkyePharma PLC, manufactures all of our bulk, uncoated tablets of ZYFLO CR pursuant to a manufacture and supply agreement dated August 20, 2007, as amended. We agreed to purchase from Jagotec a minimum of 20 million ZYFLO CR tablet cores in each of the four 12-month periods starting May 30, 2008. The agreement s initial term extended to May 22, 2012, and automatically continues thereafter unless we provide Jagotec with 24-months prior written notice of termination or Jagotec provides us with 36-months prior written notice of termination. We have not given or received written notice of cancellation.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our products, product candidates, technology and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to acquire the rights to products that are covered by U.S. and foreign patents or patent applications, trade secrets and know-how and offer the opportunity for continuing technological innovation.

Patents

Our patents and patent applications include patents and patent applications of which we are the owner or exclusive licensee with claims directed to composition of matter, formulations of our products and product candidates and methods of use of our products and product candidates to treat particular indications.

The following tables show our U.S. patents relating to our products and product candidates as of March 7, 2013:

Patents for Products

Number	Issued Patents	Product(s)	Expiration
6,183,778*	Tablets with controlled-rate release of active substances	ZYFLO CR	09/21/2013
6,987,094**	Optimized formulation of tobramycin for aerosolization	BETHKIS	09/24/2022
7,659,290	Pre-Mixed, Ready-To-Use Pharmaceutical Compositions	CARDENE I.V.	04/18/2027
7,659,291	Methods of treatment with pre-mixed, ready-to-use pharmaceutical compositions	CARDENE I.V.	04/18/2027
7,612,102	Pre-Mixed, Ready-To-Use Pharmaceutical Compositions	CARDENE I.V.	12/26/2027

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Patents for Product Candidates

Number	Issued Patents	Product(s)	Expiration
5,516,774	Vasopressin antagonists and oxytocin antagonists	LIXAR	07/29/2013
5,624,923	Vasopressin antagonists and oxytocin antagonists	LIXAR	07/29/2013
5,500,411	Method for Treating Thromboembolic Conditions by Inhibiting Reocclusion via the Use of Multiple Bolus Administration of Thrombolytically Active Proteins	RETAVASE	06/30/2014
5,648,250	Tissue Plasminogen Activator	RETAVASE	07/15/2014
5,840,533	Tissue Plasminogen Activator	RETAVASE	03/29/2015
6,352,718	Vasopressin antagonist formulation and process	LIXAR	09/25/2020

* Licensed from Abbott.

** Licensed from Chiesi.

All of the above patents were filed with and subsequently issued by the United States Patent and Trademark Office, or USPTO. Additionally we have filed patents, which have been subsequently issued, in foreign countries for CARDENE I.V. and LIXAR.

Other than LIXAR, patent protection is not available for composition of matter claims directed to the APIs of our current products and product candidates. As a result, we primarily rely on the protections afforded by our formulation and method of use patents, which may be more difficult to enforce than composition of matter patents.

The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. Our success depends, in part, on our ability to protect proprietary products, methods and technologies that we develop under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from using our inventions and proprietary information. If any parties should successfully claim that our proprietary products, methods and technologies infringe upon their intellectual property rights, we might be forced to pay damages, and a court could require us to stop the infringing activity. We do not know if our pending patent applications will result in issued patents. Our issued patents and those that we may obtain in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

For information about the patents and patent applications that we own or exclusively license that we consider to be most important to the protection of our products and product candidates, see Proprietary Rights under each of the products and product candidates described above under Products and Product Development Pipeline.

Trade Secrets

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, scientific advisors and consultants. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently

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discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how or inventions.

Trademarks

We use trademarks on many of our products, and believe that having distinctive marks is an important factor in marketing these products. We have U.S. and/or foreign trademark registrations and filings for certain of our corporate names, products (including CARDENE I.V., ZYFLO CR and ZYFLO) and product candidates (including RETAVASE and LIXAR). CUROSURF and BETHKIS are owned by Chiesi and are licensed to us for sales and marketing purposes in the United States. Other trademarks or service marks appearing in this annual report are the property of their respective holders. We no longer use the AlleRx®, Factive® and Spectracef® trademarks. AlleRx, Factive and Spectracef are registered trademarks of Bausch & Lomb Inc., LG Life Sciences, Ltd. and Meiji Seika Kaisha, Ltd., respectively.

License and Collaboration Agreements

We have entered into a number of license agreements under which we have licensed intellectual property and other rights needed to develop our products or under which we have licensed intellectual property and other rights to third parties, including the license and collaboration agreements summarized below.

Chiesi CUROSURF License and Distribution Agreement

Overview. On May 6, 2009, we entered into a license and distribution agreement with Chiesi pursuant to which we obtained an exclusive, 10-year license to the U.S. commercial rights to Chiesi s CUROSURF product and a two-year right of first offer on all drugs Chiesi intends to market in the United States, which has lapsed without renewal. On December 14, 2012, we entered into an amendment to the agreement, which extended the initial term of the original agreement a further five years to a total of 15 years starting from September 1, 2009.

Fees, Milestones and Royalties. Under the amended license and distribution agreement, we pay Chiesi for product at the stated supply prices as set forth in the agreement.

Exclusive Supplier. Under the amended license and distribution agreement, Chiesi is our exclusive supplier of CUROSURF.

Term and Termination. Our license agreement with Chiesi is for a 15-year initial term and thereafter will be automatically renewed for successive one-year renewal terms, unless earlier terminated by either party upon six months prior written notice.

Abbott Zileuton License Agreements

Overview. In December 2003, we acquired an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell controlled-release and injectable formulations of zileuton for all clinical indications, except for the treatment of children under age seven and use in cardiovascular and vascular devices. This license included an exclusive sublicense of Abbott s rights in proprietary controlled-release technology originally licensed to Abbott by Jagotec. The agreement was amended in January 2010 to expand the patent rights to additional zileuton products. In March 2004, we acquired from Abbott the U.S. trademark ZYFLO and an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell the immediate-release formulation of zileuton for all clinical indications.

Fees and Royalty Payments. In consideration for the December 2003 license, we paid Abbott an initial license fee and agreed to make aggregate milestone payments of up to $13.0 million to Abbott upon the achievement of various development and commercialization milestones, including the specified minimum net sales of licensed products. We have made all of the required milestone payments under the December 2003 license agreement. In addition, under each of the December 2003 and March 2004 license agreements, as amended, we agreed to pay royalties to Abbott based on the net sales of licensed products by us, our affiliates and our sublicensees. Our obligation to pay royalties continues on a country-by-country basis for a period of

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10 years from the first commercial sale of a licensed product in each country. Upon the expiration of our obligation to pay royalties for licensed products in a given country, the license will become perpetual, irrevocable and fully paid up with respect to licensed products in that country. If we decide to sublicense rights under the license, we must first enter into good faith negotiations with Abbott for the commercialization rights to the licensed product.

Term and Termination. Except for a termination right provided to a party in connection with a breach by the other party, the term of the December 2003 license agreement is perpetual, although we have the right to terminate the license at any time upon 60-days notice to Abbott and payment of a termination fee. Except for a termination right provided to a party in connection with a breach by the other party or a force majeure event that prevents the performance of a party for six months or more, the term of the March 2004 license agreement also is perpetual.

Jagotec Consent to Abbott Sublicense of Zileuton

In December 2003, we entered into an agreement with Jagotec under which Jagotec consented to Abbott s sublicense to us of rights to make, use and sell ZYFLO CR covered by Jagotec s patent rights and know-how. In addition to an upfront fee, we agreed to make aggregate milestone payments to Jagotec of up to $6.6 million upon the achievement of various development and commercialization milestones. We have made all of the required milestone payments. In addition, we agreed to pay royalties to Jagotec based on the net sales of the product by us and our affiliates. We also agreed to pay royalties to Jagotec under the license agreement between Jagotec and Abbott based on the net sales of the product by us and our affiliates. In addition, we agreed to pay Jagotec fees if we sublicense our rights under the licensed patent rights and know-how. Except for a termination right provided to a party in connection with a breach by the other party, the term of this agreement is perpetual.

Chiesi BETHKIS License and Distribution Agreement

Overview. On November 6, 2012, we entered into a license and distribution agreement with Chiesi pursuant to which we obtained an exclusive license to the U.S. commercial rights to Chiesi s BETHKIS product.

Fees, Milestones and Royalties. Under the license and distribution agreement, we made an initial payment to Chiesi of $1.0 million and will make a milestone payment of $2.5 million upon the first commercial sale of the product in the United States. We are also required to pay certain costs related to a Phase IV clinical trial with respect to the product and quarterly royalties based on a percentage of net sales.

Term and Termination. Our license agreement with Chiesi will remain in force for an initial term until the last date on which the sale of BETHKIS in the United States would infringe a valid claim of any of the patents that are licensed under the agreement. Thereafter, the agreement will automatically renew for an additional period of five years, during which time it may be terminated by either party with effect on December 31 of any year, by giving at least 12 months prior written notice. The agreement will automatically terminate if we fail to make the first commercial sale of the product in the United States within nine months (by August 2013) after obtaining FDA approval of a label for the product that includes a registered trademark for BETHKIS, subject to extension for certain specified product supply failures outside of our control.

Competition

The pharmaceutical industry and hospital market in which we principally compete are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Our current products compete, and any product candidates that we successfully develop and commercialize will compete, with a wide range of products for the same therapeutic indications and new therapies that may become available in the future.

Upon loss of regulatory marketing exclusivity or patent protection or as a result of design-around strategies that allow for generic product introduction prior to the expiration of key product patents, we are potentially subject to competition from generic versions of our branded products. Generics are typically priced at lower

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levels than branded products and may substantially erode prescription demand and sales of our branded products. Our generic products are subject to competition from equivalent products introduced by other pharmaceutical companies. Such competition may adversely impact the sales volume and pricing of these products and our ability to profitably market these products.

Some or all of our product candidates, if approved, may face competition from other branded and generic drugs approved for the same therapeutic indications, approved drugs used off label for such indications and novel drugs in clinical development. Our ability to successfully market and sell the products in our pipeline will depend on the extent to which our newly formulated product candidates have the benefit of patent protection or some other form of regulatory marketing exclusivity or are meaningfully differentiated from these existing drugs or new competitive formulations of these drugs offered by third parties.

Our products compete, and our product candidates (if approved) will compete, principally with the following products or with new drugs that may be developed for the same indication:

CARDENE I.V. Generic formulations of intravenous hydralazine, sodium nitroprusside, Prometheus Lab s Trandate® (labetalol) and The Medicine Company s Cleviprex® (clevidipine butyrate).

CUROSURF Abbott s Survanta®, ONY s Infasurf® and Discovery Laboratories Inc. s Surfaxin®.

ZYFLO CR IgE blockers, such as Genentech USA, Inc. s and Novartis Pharmaceutical Corporation s Xolair®; bronchodilatory drugs, such as Teva Respiratory LLC s ProAir® HFA (albuterol sulfate) Inhalation Aerosol and Schering Corporation s, or Schering, Proventil® HFA (albuterol sulfate) Inhalation Aerosol; Leukotriene Receptor Agonists, such as Merck Sharp and Dohme Corporation s Singulair® (montelukast sodium); inhaled corticosteroids, such as GlaxoSmithKline s, or GSK, Flovent® Diskus® (fluticasone propionate inhalation powder); and combination products, such as GSK s Advair Diskus® (fluticasone propionate and salmeterol inhalation powder) and AstraZeneca LP s Symbicort® (budesonide/formoterol fumarate dehydrate) Inhalation Solution.

BETHKIS Novartis Pharmaceuticals Corporation s Tobi® (tobramycin inhalation solution) and Gilead Sciences, Inc. s Cayston® (aztreonam for inhalation solution).

HP/CP ER Suspension or any cough/cold product candidate various narcotic and non-narcotic antitussives, such as UCB, Inc. s, or UCB, Tussionex (hydrocodone polistirex and chlorpheniramine polistirex), generic formulations of Tussionex marketed by UCB and Par Pharmaceuticals Companies, Inc., or Par Pharmaceuticals, generic formulations of promethazine hydrochloride and codeine phosphate oral syrup, King Pharmaceuticals Research and Development, Inc. s Tussigon® (hydrocodone and homatropine), Hi-tech Pharmacal Co, Inc. s TussiCaps® (hydrocodone polistirex and chlorpheniramine polistirex), and Wyeth LLC s Tessalon® (benzonatate), over-the-counter antitussives, such as Reckitt Benckiser Inc. s Delsym® (dextromethorphan polistirex) and MSD Consumer Care Inc. s Coricidin HBP® Cough & Cold (chlorpheniramine and dextromethorphan).

RETAVASE Genentech USA, Inc. s Activase® (alteplase, recombinant) and Genentech Inc. s TNKase® (tenecteplase).

LIXAR or any hyponatremia product candidate Otsuka Pharmaceutical Co., Ltd s Samsca® (tolvaptan) and Astellas Pharma Inc. s Vaprisol® (conivaptan).

Regulatory Matters

Government authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of our products. In the United States, the FDA regulates drugs and biologics under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations under the Public Health Service Act, or

PHSA. Failure to comply with applicable regulatory requirements may subject us and our products to administrative or judicial sanctions, which may impede the approval process of our products, hinder our development activities and manufacturing processes and, in some cases, result in, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

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FDA Regulation of Drug Product

Before a new drug may be marketed in the United States, it must be approved by the FDA. Depending on the drug for which approval is sought, FDA marketing approval can be issued either as approval of an NDA or an abbreviated new drug application, or ANDA.

New Drug Applications. The steps required for approval of an NDA include:

- pre-clinical laboratory tests, animal studies and formulation studies;
- submission to the FDA of an investigational new drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an the FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP; and
- FDA review and approval of the NDA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulations, as well as animal studies. The results of these pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the clinical trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND may not result in FDA authorization to commence clinical trials. Once an IND is in effect, each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed. The FDA may stop the trial from continuing if it concludes that there are safety issues or potential violations of law. The trial cannot resume until the FDA determines the issues are resolved.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified physician-investigators and healthcare personnel. Clinical trials are conducted under protocols detailing, for example, the parameters to be used in monitoring patient safety and the safety and effectiveness criteria, or endpoints, to be evaluated. Clinical trials are typically conducted in three defined phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent institutional review board, or IRB, before it can begin. Phase I usually involves the initial administration of the investigational drug to people to evaluate its safety, dosage, tolerance and pharmacodynamics, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population afflicted with the disease or condition for which the drug is being developed, to evaluate dosage tolerance and appropriate dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate the effectiveness of the drug for specific indications. Phase III trials further evaluate effectiveness and test further for safety by administering the drug in its final form in an expanded patient population. Any Phase I, Phase II or Phase III clinical trials we initiate may not be completed successfully within any specified period of time, if at all. Further, we, third parties assisting in our product development efforts or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or are obtaining no medical benefit from the product being studied.

Assuming successful completion of the required clinical testing, the results of the pre-clinical trials and the clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. Before approving an application, the FDA usually will inspect the facility or facilities at which the product is manufactured, and will not approve the product unless cGMP compliance is satisfactory.

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If the FDA determines the NDA is acceptable and there are no competitor patents or market exclusivity periods that might otherwise delay approval, it will approve the application. If the FDA determines the NDA is not acceptable, it will issue a CRL outlining the deficiencies in the NDA and often requesting additional data and information. Even if the sponsor provides the requested or other information or data, the FDA may ultimately decide that the NDA does not satisfy the regulatory criteria for approval.

Supplemental New Drug Applications. If we plan line extensions of certain of our products with approved NDAs, such as new formulations including extended release formulations, new labeling claims and new indications, before we may market these products, we must submit for FDA review a supplemental new drug application, or sNDA, and receive FDA approval. The sNDA must include any additional testing, data and information necessary to demonstrate that the changed product is safe, effective and properly manufactured. Approved sNDAs are also required for certain other product changes, such as significant changes to the manufacturing process or changes in the manufacturing site.

The testing and approval process for NDAs and sNDAs requires substantial time, effort and financial resources, and any approval may not be granted on a timely basis or at all.

In certain circumstances, product candidates may be eligible for submission of applications for approval that require less information than the NDAs discussed above. There are two such pathways to approval: ANDAs and 505(b)(2) NDAs.

Abbreviated New Drug Applications. The FDA may approve an ANDA if the product is the same in important respects as a listed drug, or a drug with FDA approval, or the FDA has declared it suitable for an ANDA submission. ANDAs for such drugs, often called generic drugs, must generally contain the same manufacturing and composition information as NDAs, but applicants do not need to submit pre-clinical data, and usually do not need to submit clinical safety and effectiveness data. Instead, they must demonstrate, among other things, that the product has the same active ingredient as the listed drug, is bioequivalent to the listed drug and is properly manufactured. Drugs are bioequivalent if the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug. Conducting bioequivalence studies is generally less time-consuming and costly than conducting pre-clinical and clinical trials necessary to support an NDA.

The FDCA provides that ANDA reviews and/or approvals will be delayed in various circumstances. For example, the holder of the NDA for the listed drug may be entitled to a period of market exclusivity, during which the FDA will not approve, and may not even review, the ANDA. If the listed drug is claimed to be covered by an unexpired patent that the NDA holder has listed with the FDA, the ANDA applicant may certify in a so-called paragraph IV certification that the patent is invalid, unenforceable or not infringed by the product that is the subject of the ANDA. If the holder of the NDA sues the ANDA applicant within 45 days of being notified of the paragraph IV certification, the FDA will not approve the ANDA until the earlier of a court decision favorable to the ANDA applicant or the expiration of 30 months. Also, in circumstances in which the listed drug is claimed to be covered by an unexpired patent and the patent s validity, enforceability or applicability to the generic drug has been challenged by more than one generic applicant, ANDA approvals of later generic drugs may be delayed until the first applicant has received a 180-day period of market exclusivity. The regulations governing marketing exclusivity and patent protection are complex, and it is often unclear how they will be applied in particular circumstances until the FDA acts on one or more ANDA applications.

Section 505(b)(2) New Drug Applications. Some product candidates may be eligible for approval under the Section 505(b)(2) approval process. Section 505(b)(2) applications may be submitted for drugs that represent a modification of a listed drug, such as a new indication or a new dosage form, for which an ANDA is not available. Section 505(b)(2) applications may rely on the FDA s previous determinations of safety and effectiveness for the listed drug as well as information provided by the 505(b)(2) applicant to support the modification of the listed drug. Preparing Section 505(b)(2) applications is generally less costly and time-consuming than preparing an NDA based entirely on new data and information. Like ANDAs, approval of Section 505(b)(2) applications may be delayed because of market exclusivity awarded to the listed drug or because patent rights are being adjudicated.

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In addition to the FDA s responsibilities with respect to drug approvals, both before and after approval of drugs for which approved NDAs and ANDAs have been obtained or will be sought, and in connection with marketed drugs that do not have approved NDAs or ANDAs, we and our manufacturers and other partners are required to comply with many FDA requirements. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising, promotion and sampling. Also, quality control and manufacturing procedures must conform to cGMP, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, sponsors, marketers and third-party manufacturers must continue to expend time, effort and money in all areas of regulatory compliance, including production and quality control, to comply with these requirements. Also, discovery of problems such as safety problems may result in changes in product approval delays, labeling, restrictions on the product manufacturer and NDA/ANDA holder, imposition of risk evaluation and mitigation strategies and/or removal of the product from the market.

We recently purchased the rights to market RETAVASE in the United States. The FDA regulates RETAVASE as a biologic and approved its Biologics License Application, or BLA, in 1998. Biological drugs are made from large molecules, and the processes, involving living cells, are more complex than those used to make small molecule, or conventional, drugs. The FDA regulates the manufacture and sale of biologics very similarly to the way it regulates drug products. While the PHSA is the primary legislation that governs the licensure of biological products, the basic principles of ensuring a safe, effective and quality product that apply to conventional drugs under the FDCA, also apply to biological drugs. Manufacturers of biologics may also be subject to state regulation.

The RETAVASE BLA included information about the applicant (in this case, the predecessor owner of RETAVASE at the time of the BLA), product and manufacturing information, pre-clinical studies, clinical studies, and labeling. We must comply with production, labeling, promotion, cGMPs, adverse event reporting, establishment registration, product listing and testing requirements applicable to our biological products. There are also specific requirements relating to lot releases, samples and protocols, which must be followed. Failure to comply with these requirements, both before and after product approval, may subject us or our partners, contract manufacturers and suppliers to administrative or judicial sanctions, including FDA refusal to approve applications, warning letters, product seizures, total or partial suspension of production or distribution, fines, injunctions or criminal prosecution. Furthermore, we may be required to take corrective actions, including recall of our product, if we become aware that such product might be unfit for use.

We aim to develop new potential uses for RETAVASE. We believe that we will be required to obtain an IND to conduct clinical trials and to submit an sBLA to market the product for any such new uses. The types of clinical trials that the FDA might require with respect to an sBLA for a biologic are similar to those the FDA might require for drug products, although the FDA will also give particular attention to such biologic s production and batch testing. The FDA may require a pre-approval inspection of our company or of our third-party partners before granting marketing authorization.

In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, which contain cost-containment measures and health care reforms to be implemented over the next decade, were signed into law. We refer to the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 as Health Care Reform. Health Care Reform empowered the FDA to develop an approval process for biological drugs that are not exact copies of drugs approved under a BLA, but are similar enough to work the same way. Health Care Reform provides that the FDA can approve a generic biologic, called a biosimilar, when the biosimilar is interchangeable with the brand name biologic for clinical purposes. The FDA is developing this program. Biosimilars are unlikely to be available in the United States for at least two years, although a number of biosimilars have been approved in Europe with no evidence of adverse consequences. As a result, it is possible that RETAVASE may face competition from biosimilars in the future.

Under the Prescription Drug User Fee Act, as amended, the fees payable to the FDA for reviewing an NDA, sNDA, BLA, or sBLA, as well as annual fees for commercial manufacturing establishments and for approved products, can be substantial. Each application submitted to the FDA for approval is typically reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If

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the FDA determines the application to be complete, the FDA will allow the application filing, thus triggering a full review of the application. The FDA may refuse to file any application that it deems incomplete or not properly reviewable at the time of submission. Further, the outcome of the review, even if generally favorable, may not be an actual approval but an action letter that describes additional work that must be done before the application can be approved. The FDA may deny approval of an application if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can delay the approval process.

Foreign Regulation

Approval of a product by comparable regulatory authorities may be necessary in foreign countries prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. The approval procedure varies among countries and can involve requirements for additional testing. The time required may differ from that required for FDA approval. Although there are some procedures for unified filings for some European countries, such as the sponsorship of the country which first granted marketing approval, in general each country has its own procedures and requirements, many of which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from foreign regulatory authorities after the relevant applications are filed. Additionally, each foreign country could modify its regulations, rules, or directives, which might affect our ability to sell and distribute our products in that country.

Regulation of Controlled Substances

We, our contract manufacturers and packagers, and our products and product candidates (in particular, HP/CP ER Suspension) are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we and our contract manufacturer and packager for HP/CP ER Suspension must adhere to a number of requirements, including registration, recordkeeping and reporting requirements; security controls; and, assuming regulatory approval is received, labeling and packaging requirements and certain restrictions on prescription refills.

In addition, a DEA quota system controls and limits the availability and production of certain controlled substances, including hydrocodone, which are or may be used in our products or product candidates. The DEA annually establishes aggregate quotas for how much of each controlled substance may be produced based on the DEA s estimate of the quantity needed to meet legitimate scientific and medical needs. The limited aggregate amounts of this substance that the DEA allows to be produced in the United States each year are allocated among individual companies, which must submit applications annually to the DEA for individual production and procurement quotas. A manufacturer or packager must receive an annual quota from the DEA in order to produce or procure any controlled substance product or product candidate. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, and it has substantial discretion over whether to make such adjustments. Our contract manufacturers and packagers quotas may not be sufficient for us to complete clinical trials of our product candidates. Any delay or refusal by the DEA in establishing our contract manufacturers or packagers quotas for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.

The DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure by us or our contract manufacturers or packagers to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Individual states also regulate controlled substances, and we and our contract manufacturers and packagers are subject to state regulation on distribution of these products.

Hazardous Materials

We rely on third parties to assist us in developing and manufacturing all of our products and do not directly handle, store or transport hazardous materials or waste products. We rely on third parties to comply with all

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applicable federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We do not expect the cost of complying with these laws and regulations to be material to us.

Iran Threat Reduction and Syria Human Rights Act of 2012

Section 219 of the Iran Threat Reduction and Syria Human Rights Act of 2012 added Section 13(r) to the Exchange Act. Section 13(r) requires an issuer to disclose in its annual or quarterly reports, as applicable, whether it or any of its affiliates knowingly engaged in certain activities, transactions or dealings relating to Iran or with designated natural persons or entities involved in terrorism or the proliferation of weapons of mass destruction. Disclosure is required even where the activities, transactions or dealings are conducted outside the U.S. by non-U.S. affiliates in compliance with applicable law, and whether or not the activities are sanctionable under U.S. law.

Chiesi, which owns a majority of our common stock, is considered to be an affiliate of ours under Section 13(r) of the Exchange Act. During 2012, Chiesi was a party to a distribution agreement with an Iranian distributor. Pursuant to the distribution agreement, the distributor has the right to sell and sold CUROSURF to hospitals in Iran, which may include hospitals owned by the Government of Iran. We believe Chiesi s gross revenue attributable to such sales during 2012 was approximately $2.8 million, while net profit generated from such sales was approximately $1.3 million.

We are committed to fully complying with all U.S. economic sanctions. However, because Chiesi owns a majority of our common stock, we have no ability to control whether it will sell CUROSURF or other products to distributors that may sell such products to hospitals in Iran. As a result, we cannot disclose with certainty whether Chiesi intends to continue distributing CUROSURF to Iranian hospitals.

As of the date of this annual report on Form 10-K, we are not aware of any other activity, transaction or dealing by us or any of our affiliates during the year ended December 31, 2012, that requires disclosure in this Annual Report under Section 13(r) of the Exchange Act. For affiliates that we do not control and that are our affiliates solely due to their common control by Chiesi, we have relied upon Chiesi for information regarding their activities, transactions and dealings.

Pharmaceutical Pricing and Reimbursement

Our ability to commercialize our products successfully depends in significant part on the availability of adequate coverage and reimbursement to patients from third-party payers, including governmental payers such as the Medicare and Medicaid programs, managed care organizations, or MCOs, and private health insurers.

We participate in a number of governmental programs that require us to provide rebates or discounts or otherwise limit reimbursement for our products. Under the Medicare Part D prescription drug benefit, which took effect in January 2006, Medicare beneficiaries can obtain prescription drug coverage from private plans that are permitted to limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class and to negotiate the prices to be paid for those drugs. Some Medicare Part D plans cover some or all of our products, but the amount and level of coverage vary from plan to plan. In addition, effective January 1, 2011, we were required to begin offering a 50% discount off of the plans negotiated prices on certain of our products to Medicare Part D beneficiaries during their coverage gap period. Our products may be excluded from private plans formularies and may be subject to significant price competition that depresses the prices we are able to charge. We believe that it is likely that private insurers will pattern their coverage and reimbursement policies on Medicare coverage and reimbursement policies with respect to prescription drug benefits.

In addition, we participate in the Medicaid Drug Rebate Program, or MDRP, with the Centers for Medicare and Medicaid Services in order for our products to be reimbursable under government health care programs. The MDRP requires us to pay rebates to the state Medicaid programs based on either a specified percentage of the average manufacturer price or the difference between the average manufacturer price and the best price. In addition, in order to participate in the MDRP, we are required to enter into a similar agreement with the U.S. Department of Veterans Affairs. Furthermore, some states currently require (and more states may begin to

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require) manufacturers to enter into supplemental rebate agreements, and we have entered into such agreements with some states.

We also participate in the Public Health Service s 340B Drug Pricing Program and some of our products are purchased under the program. As a participant in the program, we are required to charge a discounted price for our products to certain types of covered entities, such as qualified disproportionate share hospitals.

All of our products are generally covered by managed care and private insurance plans. Coverage by such plans for ZYFLO is similar to other products within the same class of drugs, but the status or tier of our products within each plan varies. A product s placement within a plan s status or tier structure can affect the out-of-pocket expense to the plan s beneficiaries. For example, the position of ZYFLO CR as a branded product often requires a higher patient copayment, which may make it more difficult to expand the current market share for this product.

Third-party payers are increasingly challenging the prices charged for medicines and examining their cost-effectiveness, in addition to their safety and efficacy. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for CARDENE I.V. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Even with these studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payers may decide not to provide coverage and reimbursement for our products, in whole or in part. Even if third-party payers approve coverage and reimbursement for our products, the resulting payment rates may not be sufficient for us to sell our products at a profit.

Moreover, political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental changes with respect to pricing and reimbursement. The provisions of Health Care Reform that are likely to impact our pricing and reimbursement for our products include the requirement to provide a 50% discount off negotiated prices to applicable brand-name drugs for Medicare Part D beneficiaries during their coverage gap period; an increase in the Medicaid rebates that we must pay to state Medicaid programs under the MDRP; the inclusion of Medicaid MCO enrollees in the calculation of rebates owed under the MDRP; the revised definition of average manufacturer price for rebate reporting purposes; and an increase in the number of entities eligible for discounted pricing under the 340B Drug Pricing Program. In addition, proposed regulations implementing the calculation and reporting requirements for average manufacturer price and best price were published in the Federal Register on February 2, 2012; we cannot predict whether and in what form these regulations will be made final, and what effect these regulations may have on our pricing and reimbursement. Furthermore, Health Care Reform includes initiatives to study and implement payment reforms and cost-containment measures, the results of which could reduce reimbursement for our products and reduce our profits.

One feature of Health Care Reform is the establishment of state-based Health Insurance Exchanges, or HIEs, to facilitate and improve the availability of health insurance to individual and small group purchasers. Although the increased availability of insurance might improve patients access to our products, we cannot predict its precise impact. Under the proposed rules relating to HIEs, insurance plans must meet requirements for Qualified Health Plans, including a requirement that they offer certain specified minimum Essential Health Benefits, or EHB. With respect to prescription drugs, the proposed EHB regulations would allow states to define the minimum drug coverage requirements for particular formulary categories by reference to the drug formulary of a benchmark plan within the state. Although we cannot predict the ultimate adoption or effect of these proposed regulations, it is possible that the regulations may result in the selection of benchmark plans with limited drug coverage or Qualified Health Plans adopting formularies or benefit designs that limit the coverage or reimbursement for our products.

We anticipate that Congress, state legislatures and the private sector will continue to consider and may adopt further health care policies intended to curb rising health care costs. These cost-containment measures could include, for example:

- controls on government-funded reimbursement for drugs;

- controls on payments to health care providers that affect demand for drug products;

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challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;

weakening of restrictions on imports of drugs; and

expansion of the use of managed care systems in which health care providers contract to provide comprehensive health care for a fixed cost per person.

We may also face competition for our products from lower-priced products from foreign countries that have placed price controls on pharmaceutical products. Although not implemented by Health Care Reform, potential future federal legislation may expand consumers ability to import lower-priced versions of competing products from Canada and other countries. The importation of foreign products that compete with our own products could negatively impact our business and prospects.

We are unable to predict how all or portions of Health Care Reform will be implemented, what additional legislation, regulations or policies, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost-containment measures, including those listed above, or other health care system reforms that are adopted could impair our ability to set prices that cover our costs, constrain our ability to generate revenue from government-funded or private third-party payers, limit the revenue and profitability of our potential customers, suppliers and collaborators and impede our access to capital needed to operate and grow. Any of these circumstances could significantly limit our ability to operate profitably.

Fraud and Abuse Regulation

A number of federal and state laws and related regulations, loosely referred to as fraud and abuse laws, are used to prosecute health care providers, suppliers, physicians and others that fraudulently or wrongfully obtain reimbursement for health care products or services from government health programs, such as Medicare and Medicaid, or private insurers. These laws are extremely complicated, apply broadly and may constrain our business and the financial arrangements through which we market, sell and distribute our products. Examples of these laws and regulations include:

Federal Anti-Kickback Law. The anti-kickback law contained in the federal Social Security Act is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay, or to solicit or receive, remuneration in order to induce the purchase, order, lease or recommending of items or services, or the referral of patients for services, that are reimbursed under a federal health care program, including Medicare and Medicaid. The term remuneration has been interpreted broadly and includes both direct and indirect compensation and other items and services of value. Both the party offering or paying remuneration and the recipient may be found to have violated the statute. Courts have interpreted the anti-kickback law to cover any arrangement where one purpose of the remuneration is to induce purchases or referrals, regardless of whether there are also legitimate purposes for the arrangement. There are narrow exemptions and regulatory safe harbors, but many legitimate transactions fall outside of the scope of any exemption or safe harbor, although that does not necessarily mean the arrangement will be subject to penalties under the anti-kickback statute. Penalties for federal anti-kickback violations are severe, including up to five years imprisonment, individual and corporate criminal fines, exclusion from participation in federal health care programs and civil monetary penalties in the form of treble damages plus $50,000 for each violation of the statute. Health Care Reform amended the intent requirement of the federal anti-kickback statute so that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. Violations of the federal anti-kickback statute may now also be treated as a false or fraudulent claim for purposes of the federal false claims act or a violation of the criminal health care fraud law.

Federal False Claims Law. The federal false claims act imposes liability on any person who knowingly submits, or causes another person or entity to submit, a false or fraudulent claim for payment of government funds or knowingly makes a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Penalties include three times the government s damages plus civil penalties of $5,500 to $11,000 per false claim. In addition, the federal false claims act permits a person

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with knowledge of fraud, referred to as a *qui tam* plaintiff or whistleblower, to file a lawsuit on behalf of the government against the person or entity that committed the fraud. If the government determines to intervene in the lawsuit and the government prevails, the *qui tam* plaintiff is rewarded with a percentage of the recovery.

Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and Health Information Technology for Economic and Clinical Health Act, or HITECH. The HIPAA statute imposes criminal liability for knowingly and willfully executing a scheme to defraud any health care benefit program. It also prohibits knowingly and willfully falsifying, concealing or covering up any material fact or making any materially false or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Furthermore, HIPAA and HITECH impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

Other Federal Criminal and Civil Health Care Laws. The Social Security Act contains numerous penalties for fraud and abuse in the health care industry, such as imposition of a civil monetary penalty, a monetary assessment, exclusion from participation in federal health care programs or a combination of these penalties.

State Laws. Various states have enacted laws and regulations comparable to the federal fraud and abuse laws and regulations. These state laws and regulations may apply to items or services reimbursed by any third-party payer, including private payers, commercial insurers and other payers. Moreover, these laws and regulations vary significantly from state to state and, in some cases, are broader than the federal laws and regulations. These differences increase the costs of compliance and the risk that the same arrangements may be subject to different compliance standards in different states.

In addition, there is a trend of increased federal and state regulation of payments made to physicians, including the tracking and reporting of gifts, compensation and other remuneration to physicians. Health Care Reform includes examples of this trend. Beginning in 2012, pharmaceutical manufacturers and distributors must provide the U.S. Department of Health and Human Services with an annual report of the drug samples requested by and provided to health care practitioners. Beginning in 2013, pharmaceutical manufacturers will be required to track, and ultimately report, information to the U.S. Department of Health and Human Services related to payments and other transfers of value to physicians during the preceding calendar year, which information will later be made publicly available. Pharmaceutical manufacturers will also be required to report and disclose physician ownership and investment interests in such manufacturers. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for knowing failures) for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Various states currently require or have proposed legislation that would require pharmaceutical companies to report expenses related to marketing and promotion of pharmaceutical products and gifts and payments to physicians within the states.

Employees

As of March 7, 2013, we had 105 full-time employees, 62 of whom were engaged in marketing and sales; 8 of whom were engaged in research, development and regulatory affairs; and 35 of whom were engaged in management, administration and finance. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages. We believe that relations with our employees are good.

Seasonality of Business

Our results of operations have not been materially impacted by seasonality.

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Available Information

We maintain a web site with the address www.crtx.com. We are not including the information contained on our web site as part of, or incorporating it by reference into, this annual report. We make available, free of charge, on or through our web site our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as practicable after such material is electronically filed with or furnished to the U.S. Securities and Exchange Commission, or SEC.

In addition, a copy of any exhibit to this annual report on Form 10-K will be furnished free of charge upon written request by one of our stockholders directed as follows: Attn: Executive Vice President, General Counsel and Secretary, Cornerstone Therapeutics Inc., 1255 Crescent Green Drive, Suite 250, Cary, NC 27518.

Our filings may also be read and copied at the SEC s Public Reference Room at 100 F. Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC.

ITEM 1A. *RISK FACTORS*

You should carefully consider the following risk factors, in addition to other information included in this annual report on Form 10-K and the other reports that we file with the SEC, in evaluating us and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected.

Risks Relating to Commercialization and Product Acquisitions

We use third parties to manufacture all of our products and product candidates. This may increase the risk that we will not have sufficient quantities of our products or product candidates at an acceptable cost, which could delay, impair or prevent the clinical development and commercialization of our product candidates or our ability to meet commercial demands for our products.

We have no manufacturing facilities and rely on third parties to purchase raw materials for, manufacture, package and supply all of our products. Some of the agreements we have entered into are exclusive agreements in which the manufacturer is a single-source supplier, preventing us from using alternative sources. Similarly, many of our agreements may require us to make volume commitments or agree to long-term pricing arrangements that may affect our margins or constrain our ability to position our products optimally in the market. If we choose to cancel or are unable to meet our volume commitments, we may be subject to penalties or increased costs to manufacture our products. For a description of the manufacturing and packaging agreements related to our more important products, please see Item 1. Business Manufacturing.

If any of the third-party manufacturers with whom we contract fails to perform its obligations, we may be adversely affected in a number of ways, including the following:

- We may not be able to meet commercial demands for our products;
- We may be required to cease distribution or issue recalls;
- We may not be able to initiate or continue clinical trials of product candidates that are under development; and
- We may be delayed in submitting applications for regulatory approvals for product candidates.

We may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. If we were required to change manufacturers, we would be required to obtain FDA approval of an sNDA covering the new manufacturing site. In addition, we would be required to conduct additional clinical bioequivalence trials to demonstrate that the products manufactured by the new manufacturer are

equivalent to the products manufactured by the current manufacturer, which could take 12 to 18 months or possibly longer.

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The technical transfer of manufacturing capabilities can be difficult. Any delays associated with the approval of a new manufacturer could adversely affect the production schedule or increase our production costs and could ultimately lead to a shortage of supply in the market.

We also rely on third-party manufacturers that, in some instances, have encountered difficulties obtaining raw materials needed to manufacture our product candidates as a result of DEA regulations. Although these difficulties have not had a material adverse impact on us, such problems could have a material adverse impact on us in the future. In addition, supply interruptions or delays could occur that require us or our manufacturers to obtain substitute materials or products, which would require additional regulatory approvals. Changes in our raw material suppliers could result in delays in production, higher raw material costs and loss of sales and customers because regulatory authorities must generally approve raw material sources for pharmaceutical products. Any significant supply interruption could have a material adverse effect on our business, financial condition and results of operation.

In addition, we import the API, tablet cores and/or finished product for all of our products from third parties that manufacture such items outside the United States, and we expect to do so in the future. This may give rise to difficulties in obtaining API, tablet cores or finished product in a timely manner as a result of, among other things, regulatory agency import inspections, incomplete or inaccurate import documentation or defective packaging. For example, in January 2009, the FDA released draft guidance on Good Importer Practices, which, if adopted, will impose additional requirements on us with respect to oversight of our third-party manufacturers outside the United States. The FDA has stated that it will inspect 100% of API, tablet cores and finished product that is imported into the United States. If the FDA requires additional documentation from third-party manufacturers relating to the safety or intended use of the API or finished product, the importation of the API or finished product could be delayed. While in transit from outside the United States or while stored with our third-party logistics provider, Cardinal SPS, our API, tablet cores or finished product could be lost or suffer damage, which would render such items unusable. We have attempted to take appropriate risk mitigation steps and to obtain transit or casualty insurance. However, depending upon when the loss or damage occurs, we may have limited recourse for recovery against our manufacturers or insurers. As a result, our financial performance could be impacted by any such loss or damage.

The commercial success of our currently marketed products and any additional products that we successfully develop or bring to market depends on the degree of market acceptance by physicians, patients, health care payers and others in the medical community.

Any products that we bring to the market may not gain market acceptance by physicians, patients, health care providers, health care payers and others in the medical community. The degree of market acceptance of our products, including our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of the products side effects;
- the efficacy and potential advantages of the products over alternative treatments;
- the ability to offer the products for sale at competitive prices, including in relation to any generic or re-imported products or competing treatments;
- the relative convenience and ease of administration of the products;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the perception by physicians and other members of the health care community of the safety and efficacy of the products and competing products;
- the willingness of the hospitals and other health care providers to purchase, stock and utilize the products;

the availability and level of third-party reimbursement for sales of the products;

the continued availability of adequate supplies of the products to meet demand;

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- the strength of marketing and distribution support;
- any unfavorable publicity concerning us, our products or the markets for these products, such as information concerning product contamination or other safety issues in the markets for our products, whether or not directly involving our products;
- changes in government reimbursement of hospitals or health care providers that have the effect of prohibiting the purchase of or adversely affecting the market position of our products relative to competing products used to treat the same indications; and
- regulatory developments related to our marketing and promotional practices or the manufacture or continued use of our products.

If our products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not be able to return to profitability.

Our strategy of obtaining, through product acquisitions and in-licenses, rights to products and product candidates for our development pipeline and to proprietary drug delivery and formulation technologies for our life cycle management of current products may not be successful.

Because we do not have discovery and research capabilities, the growth of our business will depend in significant part on our ability to acquire or in-license additional products, product candidates or proprietary drug delivery and formulation technologies that we believe have significant commercial potential and are consistent with our commercial objectives. However, we may be unable to license or acquire suitable products, product candidates or technologies from third parties for a number of reasons.

The licensing and acquisition of pharmaceutical products, product candidates and related technologies is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire products, product candidates and drug delivery and formulation technologies, which may mean fewer suitable acquisition opportunities for us, as well as higher acquisition prices. Many of our competitors have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

Other factors that may prevent us from licensing or otherwise acquiring suitable products, product candidates or technologies include:

- We may be unable to license or acquire the relevant products, product candidates or technologies on terms that would allow us to make an appropriate return on investment;
- Companies that perceive us as a competitor may be unwilling to license or sell their product rights or technologies to us;
- We may be unable to identify suitable products, product candidates or technologies within our areas of expertise; and
- We may have inadequate cash resources or may be unable to obtain financing to acquire rights to suitable products, product candidates or technologies from third parties.

If we are not successful in identifying and acquiring rights to products, or if we are not successful in developing product candidates, we may not be able to increase our revenues in future periods, which could result in significant harm to our financial condition, results of operations and prospects.

We face competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of drugs is highly competitive. We face competition with respect to our currently marketed products, our current product candidates and any products that we may seek to develop or commercialize in the future. Our competitors include major

pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic

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institutions, government agencies and other private and public research organizations that seek patent protection and establish collaborative arrangements for development, manufacturing and commercialization. We face significant competition for our currently marketed products.

Some or all of our product candidates, if approved, may face competition from other branded and generic drugs or biosimilars approved for the same therapeutic indications, approved drugs used off label for such indications and novel drugs in clinical development. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop.

Our patents will not protect our products if competitors devise ways of making products that compete with our products without legally infringing our patents. The FDCA and FDA regulations and policies provide certain exclusivity incentives to manufacturers to create modified, non-infringing versions of a drug in order to facilitate the approval of 505(b)(2) NDAs or ANDAs for competitive products. These same types of exclusivity incentives encourage manufacturers to submit NDAs that rely, in part, on literature and clinical data not prepared for or by such manufacturers. Manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same API, dosage form, strength, route of administration and conditions of use or labeling as our product and that the generic product is absorbed in the body at the same rate and to the same extent as our product, a comparison known as bioequivalence. Such products would be significantly less costly than our products to bring to market and could lead to the existence of multiple lower-priced competitive products, which would substantially limit our ability to obtain a return on the investments we have made in those products.

Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates. The FDCA provides a five-year period of exclusivity for a drug approved under the first NDA covering an API, and the drug approval for any of our product candidates may be blocked by such a period of marketing exclusivity. Similarly, the FDCA provides a three-year period of exclusivity for a drug approved under its first NDA (where there is some significant change to the product, such as a new indication or formulation of a drug) that includes a previously approved API and for which new studies essential to the approval of the application have been performed. These provisions may delay approval of our product candidates.

Even if we are not excluded from obtaining marketing approval for our product candidates, it may adversely affect the revenue potential of those product candidates if our competitors succeed in commercializing similar products more rapidly or effectively than we are able to. For instance, in October 2010, one of our competitors, Par Pharmaceuticals, with its licensing partner, Tris Pharma, Inc., launched an FDA-approved generic hydrocodone polistirex and chlorpheniramine polistirex extended-release oral suspension product, which, like HP/CP ER Suspension, is a generic version of UCB s, Tussionex. In addition, UCB launched its own generic version of Tussionex, through its generic subsidiary, Kremers Urban Pharmaceuticals Inc., which will make us the third entrant into the Tussionex generic market. The presence of competing products in the market may adversely affect both the price we can charge for our product and the portion of the market for that product that may be available to us, because product sales of pharmaceutical and/or therapeutic equivalents often follow a particular pattern over time based on regulatory and competitive factors. The first company to introduce an equivalent of a branded product is often able to capture a substantial share of the market. However, as other companies introduce competing equivalent products, the first entrant s market share, and the price of its equivalent product, will typically decline. The extent of the decline generally depends on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors.

For example, in the generic drug industry, when a company is the first to introduce a generic drug, the pricing of the generic drug is typically set based on a discount from the published price of the equivalent branded product. Other generic manufacturers or a manufacturer contracted to market an authorized generic to the brand may enter the market and, as a result, the price of the drug may decline significantly. In such event, we may in our discretion provide our customers a credit with respect to the customers remaining inventory for the difference between our new price and the price at which we originally sold the product to our customers. There are circumstances under which we may, as a matter of business strategy, not provide price adjustments to certain

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customers and, consequently, we may lose future sales to competitors. Our inability to introduce generic equivalents to our branded products or our withdrawal of existing products from the market due to increased competition would have a material adverse effect on our financial condition and results of operations.

The principal competitors to our products and potential competitors to our product candidates are more fully described under the caption Competition in Item 1 above.

Many of our competitors have significantly greater financial, technical and human resources than we have and superior expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products and thus may be better equipped than us to discover, develop, manufacture and commercialize products. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, registering patients for clinical trials and acquiring technologies. Many of our competitors have collaborative arrangements in our target markets with leading companies and research institutions. In many cases, products that compete with our currently marketed products and product candidates have already received regulatory approval or are in late-stage development, have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We will face competition based on the safety and effectiveness of our products, the timing, scope and market exclusivity of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products, or products with more effective patent protection, than our products. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely affect our competitive position, the likelihood that our product candidates will achieve initial market acceptance and our ability to generate meaningful revenues from our product candidates. Even if our product candidates achieve initial market acceptance, competitive products may render our products noncompetitive. If our product candidates are rendered noncompetitive, we may not be able to recover the expenses of developing and commercializing those product candidates.

If we are unable to identify and acquire products and/or companies, and if we cannot integrate them efficiently, our business and ability to realize the value of completed acquisitions, or ability to develop our product candidates and expand our product pipeline may be harmed.

Our plan to grow our existing product portfolio is based upon our ability to acquire or in-license products and to acquire companies that fit with our strategic focus. These acquisitions and licenses involve risks. For example:

- We may not be able to identify suitable companies to acquire or to acquire such companies on favorable terms. We compete with others in the pharmaceutical industry to acquire companies. We believe that this competition may increase and could result in decreased availability or increased prices for suitable acquisition candidates.
- During the acquisition process, we may fail or be unable to discover some of the liabilities of companies or products that we acquire.
- We may overuse our cash resources.
- We may experience higher than anticipated acquisition costs and expenses.
- We may not be able to obtain the necessary financing, on favorable terms or at all, to finance any of our potential acquisitions.
- We may fail to integrate acquired companies or products into our business successfully.

Acquired businesses or products may not perform as we expect or we may not be able to obtain the financial improvements and results we anticipate. In addition, the development and integration of new companies or products could disrupt our business and occupy our management s time and attention.

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We face the risk that our existing financial controls, information systems, management resources and human resources will need to grow to support future growth.

We may be unable to preserve key suppliers or distributors of any acquired products.

We may issue equity securities to acquire companies or products, which may result in dilution.

Any acquisition could substantially increase our operating expenses, including amortization of product rights and other definite-lived intangible assets.

For example, in December 2011, we acquired Cardiokine primarily to obtain the pending NDA for LIXAR. We paid $1.0 million shortly after closing and assumed approximately $2.0 million of Cardiokine s current liabilities. During 2012, we invested approximately $2.9 million into the LIXAR development program. In October 2012, we received a CRL from the FDA following its review of the NDA for LIXAR in which they requested that we complete additional clinical studies to further evaluate the efficacy and safety of lixivaptan in both heart failure patients and SIADH patients. We are requesting an End-of-Review meeting with the FDA s Division of Cardiovascular and Renal Drug Products to better understand the contents of the CRL and the nature and scope of the additional clinical trials requested by the agency. Following that meeting, we will determine appropriate next steps for LIXAR, which may result in abandonment of the development program if we determine the anticipated benefits of an approved product are outweighed by the costs and risks of conducting the additional clinical trials requested by the FDA.

If we fail to address adequately the financial, operational or legal risks of our acquisitions or licensing arrangements, or if we are unable to integrate our acquisitions successfully, our results of operations and financial condition could be materially and adversely affected.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the sale of our currently marketed products, previously marketed products that have been withdrawn or discontinued, any other products that we successfully develop and the testing of our product candidates in human clinical trials. If we cannot successfully defend against claims that our products or product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our products or any products that we may develop;

injury to our reputation;

the withdrawal of clinical trial participants;

the recall and/or withdrawal of a product from the market;

costs to defend the related litigation;

substantial monetary damages awards to clinical trial participants or plaintiffs, whether through settlement or trial;

diversion of management time and attention;

loss of revenue; and

inability to commercialize the products that we may develop.

As discussed in the risk factors above, there are concerns regarding the safety of the products containing the API zileuton. In addition, in November 2010, the FDA requested that all products containing the API propoxyphene be voluntarily withdrawn from the market due to safety concerns. All of our products containing propoxyphene have been removed from the market. We are aware of various pending product liability claims which have been asserted in lawsuits against numerous developers, manufacturers and distributors of propoxyphene products. A large number of those lawsuits have been consolidated into multidistrict litigation, or MDL, proceedings in the United States District Court, Eastern District of Kentucky (Northern Division), and a large number have been filed in California state courts. We expect that the large majority of future lawsuits that

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are filed will be consolidated in a complex litigation department in California state court or continue to be consolidated in the MDL proceedings. We have been named in a significant number of those lawsuits, and, to date, we have been served with legal process in five such suits. For a more complete discussion regarding these lawsuits, please see Item 3. Legal Proceedings in this annual report on Form 10-K.

We had a less than 1% share of the market for propoxyphene products, and we believe that the probability that a party alleging injury could definitively link that injury to our products is low based on current facts known to us. In light of recent case law, we believe that plaintiffs will have difficulty explaining why their claims are not preempted by federal regulatory laws. Accordingly, we do not believe that we are likely to face significant liability in connection with the claims asserted against developers, manufacturers and distributors of propoxyphene products based on current facts known to us at this stage of this litigation.

Our contracts with wholesalers and other customers require us to carry product liability insurance. We have primary and excess product liability insurance coverage to meet these obligations. Our primary coverage offers a $10 million per claim and annual aggregate limit. The excess policy offers an additional $10 million per claim and annual aggregate limit. The annual cost of our product liability insurance was approximately $384,000 for the policy year beginning September 13, 2012. In addition, our product liability insurance coverage for such policy year specifically excludes liability related to propoxyphene products.

In the event that we are found liable for injuries caused by our products, if defenses are unsuccessful, or if adverse facts are learned, we could face significant liability that may adversely affect our financial condition and results of operations. We may not be able to maintain insurance coverage at a reasonable cost and the amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur.

The concentration of our product sales to only a few wholesale distributors increases the risk that we will not be able to effectively distribute our products if we need to replace any of these customers, which would cause our sales to decline.

The majority of our sales are to a small number of pharmaceutical wholesale distributors, which in turn sell our products primarily to retail and hospital pharmacies, which ultimately dispense our products to the end consumers. Consolidation within the wholesale drug distribution industry has occurred and may continue to occur. As a result, a small number of large wholesale distributors control a significant share of the market. Sales to our three primary wholesale distributors, AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation, collectively accounted for approximately 93% of our gross product sales during 2012.

The loss of any of these wholesale distributors or a material reduction in their purchases could harm our business, financial condition and results of operations if we are unable to enter into agreements with replacement wholesale distributors on commercially reasonable terms.

Our business could suffer as a result of a failure to manage and maintain our distribution network.

We do not have our own warehouse or distribution capabilities, we lack the resources and experience to establish any of these functions, and we do not intend to establish these functions in the foreseeable future.

We rely on third parties to distribute our products to pharmacies. We have contracted with Cardinal SPS, a third-party logistics company, for the distribution of our products to wholesalers, retail drug stores, mass merchandisers and grocery stores in the United States.

We also depend on the distribution abilities of our wholesale customers to ensure that products are effectively distributed throughout the supply chain. If there are any interruptions in our customers ability to distribute products through their distribution centers, our products may not be effectively distributed, which could cause confusion and frustration among pharmacists and lead to product substitution.

Our distribution network requires significant coordination with our supply chain, sales and marketing and finance organizations. If we are unable to effectively manage and maintain our distribution network, sales of our products could be severely compromised and our business could be harmed. In addition, failure to maintain our third-party contracts or a third party s inability or failure to adequately perform as agreed under its contract with us could negatively impact us.

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If any of the third parties that we rely upon for assistance in researching, developing, manufacturing, promoting and distributing our products and product candidates experience financial distress and are unable to provide this assistance, our operating performance would be adversely affected.

Economic unpredictability could adversely affect the third parties upon whom we rely for researching, developing, manufacturing, promoting and distributing our products and product candidates. We believe that some of the third parties upon which we rely depend on financing from banks, financial institutions and other third-party financing sources in order to finance their operations. The current economic environment may make it more difficult or impossible for these third parties to obtain additional financing or extend the terms of their current financing. Some of these third parties may be highly leveraged, and if they are unable to service their indebtedness, such failure could adversely affect their ability to maintain their operations and to meet their contractual obligations to us, which may have an adverse effect on our financial condition, results of operations and cash flows.

A failure to maintain optimal inventory levels could harm our reputation and subject us to financial losses.

Because accurate product planning is necessary to ensure that we maintain optimal inventory levels, significant differences between our current estimates and judgments and future estimated demand for our products and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. If we are required to recognize charges for excess inventories, such charges could have a material adverse effect on our financial condition and results of operations.

Product acquisitions typically include the purchase of existing inventory. If the previous company has distributed product to the wholesalers and distributors that exceeds current demand, such inventory levels could affect our ability to sell product to the wholesalers. Until the inventory levels decline, revenues for the acquired product could be minimal.

We are also subject to minimum purchase obligations under supply agreements. For example, our development and manufacturing agreement with Baxter Healthcare Corporation requires us to meet an annual purchase obligation in each calendar year with respect to purchases of bags that are used in the manufacture of CARDENE RTU. We were required to pay a penalty with respect to bags that we did not purchase during the year ended December 31, 2012. If we continue to be unable to meet our annual minimum purchase requirements, we will be required to pay penalties in the future in accordance with the agreement, which could have a material adverse effect on our financial condition, results of operations and cash flows

Our ability to maintain optimal inventory levels also depends on the performance of third-party contract manufacturers. In some instances, third-party manufacturers have encountered difficulties obtaining raw materials needed to manufacture our product candidates as a result of DEA regulations and because of the limited number of suppliers of certain APIs. Although these difficulties have not had a material adverse impact on us, such problems could have a material adverse impact on us in the future. If we are unable to manufacture and release inventory on a timely and consistent basis, if we fail to maintain an adequate level of product inventory, if inventory is destroyed or damaged or fails periodic quality testing or if our inventory reaches its expiration date, patients might not have access to our products, our reputation and our brands could be harmed and physicians may be less likely to prescribe our products in the future, each of which could have a material adverse effect on our financial condition, results of operations and cash flows.

If our third-party manufacturers and packagers do not obtain the necessary quota for controlled substances needed to supply us with our product candidates or products or the quotas are not sufficient, our product launches may be delayed or we may be unable to meet commercial demand for our products following launch.

HP/CP ER Suspension contains hydrocodone, a controlled substance which is regulated by the DEA under the Controlled Substances Act. DEA quota requirements limit the amount of controlled substance drug products a manufacturer may manufacture, the amount of API it may use to manufacture those products and the amount of controlled substance drug products a packager may package. We rely on the third-party manufacturer and packager of this product candidate, Neos and Coating Place, respectively, to request and obtain from the DEA the

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annual quota allocation needed to meet our production requirements for this suspension product, and we will continue to rely on Neos and Coating Place to obtain necessary quotas following launch. If Neos and Coating Place are unsuccessful in obtaining quotas, HP/CP ER Suspension could be at risk of a delayed launch or we may be unable to meet commercial demand following launch.

If we or our contract manufacturers or packagers fail to comply with regulatory requirements for any controlled substance products and product candidates, the DEA may take regulatory actions detrimental to our business, resulting in temporary or permanent interruption of distribution, withdrawal of products from the market or other penalties.

We, our contract manufacturers and packagers and our products and product candidates (in particular, HP/CP ER Suspension) are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we and our contract manufacturer and packager for HP/CP ER Suspension must adhere to a number of requirements with respect to this product, including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls; procurement and manufacturing quotas; and certain restrictions on prescription refills. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Failure to maintain compliance with applicable requirements can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition.

Concerns regarding the safety profile of ZYFLO CR and ZYFLO may limit market acceptance of ZYFLO CR.

Market perceptions about the safety of ZYFLO CR and ZYFLO may limit the market acceptance of ZYFLO CR. In the clinical trials that were reviewed by the FDA prior to its approval of ZYFLO, 3.2% of the approximately 5,000 patients who received ZYFLO experienced increased levels of a liver enzyme called alanine transaminase, or ALT, of over three times the levels normally seen in the bloodstream. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin. In clinical trials for ZYFLO CR, 1.94% of the patients taking ZYFLO CR in a three-month efficacy trial and 2.6% of the patients taking ZYFLO CR in a six-month safety trial experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream. Because ZYFLO CR can elevate liver enzyme levels, its product labeling, which was approved by the FDA in May 2007, contains the recommendation that periodic liver function tests be performed on patients taking ZYFLO CR. Some physicians and patients may perceive liver function tests as inconvenient or indicative of safety issues, which could make them reluctant to prescribe or accept ZYFLO CR, ZYFLO or any other zileuton product candidates that we successfully develop and commercialize, which could limit their commercial acceptance.

Safety concerns regarding ZYFLO CR and ZYFLO, actual or perceived, may adversely impact the market for ZYFLO CR and ZYFLO, and could have a material adverse effect on our financial condition and results of operations.

Risks Relating to Product Development and Regulatory Matters

We may not be successful in obtaining necessary clinical results and regulatory approvals for our products and, if we fail to comply with regulatory requirements for our products or if we experience unanticipated problems with them, the FDA may take regulatory actions detrimental to our business, resulting in temporary or permanent interruption of distribution, withdrawal of products from the market or other penalties.

We, our products, our contract manufacturers and our other partners are subject to comprehensive regulation by the FDA. These requirements include filing marketing authorization applications, submissions of safety and other post-marketing information; record-keeping and reporting; annual registration of manufacturing facilities and listing of products with the FDA; ongoing compliance with cGMP regulations; and requirements regarding advertising, promotion and the distribution of samples to physicians and related recordkeeping. For example, we

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received an untitled letter from the FDA s Office of Prescription Drug Promotion on October 31, 2012 relating to certain promotional material for our CUROSURF intratracheal suspension. The FDA asserted that a certain CUROSURF promotional item was false and misleading because it presented unsubstantiated superiority claims regarding the product. Although we did not admit and in fact denied some of FDA s allegations, as part of our response and in connection with the close out of this matter, we ceased dissemination of the relevant promotional materials, disabled and revised the web page, retrieved and destroyed the relevant promotional materials and updated our procedures regarding promotional material. Going forward, if our promotional activities fail to comply with the FDA s regulations and guidelines, we could be subject to additional regulatory actions by the FDA, including product seizure, injunctions and other penalties, and, if so, our business and reputation could be harmed.

Under the Food and Drug Administration Amendments Act of 2007, or FDAAA, the FDA is also authorized, among other things, to require the submission of Risk Evaluation and Mitigation Strategies with NDAs, or post-approval upon the discovery of new safety information, to monitor and address potential product safety issues. The FDAAA also grants the FDA the authority to mandate labeling changes in certain circumstances and establishes requirements for registering and disclosing the results of clinical trials.

Our third-party manufacturers and the manufacturing facilities used to make our products and product candidates are also subject to comprehensive regulatory requirements. While we generally negotiate for the right under our long-term manufacturing contracts to periodically audit our third-party manufacturers performance, we do not have control over our third-party manufacturers compliance with applicable regulations. Our current quality assurance program may not be reasonably designed to, or may not, discover all instances of non-compliance by our third-party manufacturers with these regulations. Our partners noncompliance could have significant negative consequences, such as product approval delays, manufacturing or processing difficulties, product shortages or FDA enforcement actions taken against us, our products, or both. For instance, in 2004, the FDA inspected the predecessor company to one of our current development partners and, as a result of alleged failure of the manufacturer to comply with cGMPs, the FDA issued a warning letter to the manufacturer. Subsequent action by the FDA related to the 2004 warning letter resulted in a permanent injunction, or consent decree, in 2007 against the manufacturer. The manufacturer is working closely with their FDA district office to satisfy the conditions of the injunction; however, the manufacturer remains under the auspices of the consent decree at this point in time.

In addition, the FDA periodically inspects sponsors, marketers and third-party manufacturers for compliance with these requirements. If the FDA is not satisfied with the corrective actions taken in response to its inspections, a company could be subject to further FDA action, including sanctions, and may also be subject to sanctions as a result of discovery of previously unknown problems with its products, manufacturers or manufacturing processes, or failure to comply with applicable regulatory requirements. Possible sanctions include the following:

withdrawal of the products from the market;

restrictions on the marketing or distribution of such products;

restrictions on the manufacturers or manufacturing processes;

warning letters;

refusal to approve pending applications or supplements to approved applications that we submit;

recalls;

fines;

suspension or withdrawal of regulatory approvals;

refusal to permit the import or export of our products;

product seizures; or

injunctions or the imposition of civil or criminal penalties.

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If any of the actions are taken against our company, these actions could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to develop safe and efficacious formulations of our product candidates, or our clinical trials for our product candidates are not successful, we may not be able to develop, obtain regulatory approval for and commercialize our product candidates successfully.

Although it is our strategy to focus our development efforts on late-stage product candidates, some of our product candidates may be in the preclinical stage of development and require clinical testing necessary to obtain the regulatory approvals or clearances required for commercial sale. Our ability to complete the development of such products is subject to all of the risks associated with the commercialization of new products regulated by the FDA. Such risks may include unanticipated technical problems, processing or manufacturing difficulties, and the possibility that we have allocated insufficient funds to complete such development. Depending on the nature of the product candidate, to demonstrate a product candidate s safety and efficacy, we and our collaborators generally must either demonstrate bioequivalence with a drug already approved by the FDA or complete human clinical efficacy trials. We may not be able to obtain permission from the FDA, IRBs or other authorities to commence or complete necessary clinical trials and, even if we are allowed to conduct these clinical trials, we may be required to expend significant time and resources to obtain the required regulatory approvals to market these products. Moreover, if permitted, such clinical testing may not prove that our product candidates are safe and effective to the extent necessary to permit us to obtain marketing approvals or clearances from regulatory authorities. One or more of our product candidates may not exhibit the expected therapeutic results in humans, may cause harmful side effects or may have other characteristics that may delay or preclude submission and regulatory approval, or cause imposition of burdensome post-approval requirements or limit commercial use if approved.

Furthermore, we, one of our collaborators, IRBs or regulatory agencies may order a clinical hold or suspend or terminate clinical trials at any time if it is believed that the subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons, such as non-compliance at a clinical site.

Adverse or inconclusive clinical trial results concerning any of our product candidates could require us to conduct additional clinical trials, result in increased costs and significantly delay the submission for marketing approval or clearance for such product candidates with the FDA or other regulatory authorities or result in failure to obtain approval or approval for a narrower indication. If clinical trials fail, our product candidates would not receive regulatory approval or achieve commercial viability.

If clinical trials for our product candidates are delayed, we would incur additional costs (including increased development expenses), and our receipt of any revenues from sales of the product candidate would be delayed.

We may commence clinical trials with respect to LIXAR in 2013, and could possibly encounter problems with our completed or planned clinical trials that will delay or cause regulatory authorities, IRBs or us to suspend those clinical trials or the analysis of data from such trials.

Any of the following could delay the completion of our planned clinical trials:

- we, the FDA, a third party assisting us with product development or an IRB suspending or stopping a clinical trial;
- discussions with the FDA regarding the scope or design of our clinical trials;
- delay in obtaining, or the inability to obtain, required permissions from regulators, IRBs or other governing entities at clinical sites selected for participation in our clinical trials;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- exposure of participants to unacceptable health risks;

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- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, or we may abandon projects that had appeared to be promising;

- we or our third-party contractors may fail to comply with regulatory requirements or contractual obligations in a timely manner;

- insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct clinical trials; or

- unfavorable FDA inspection and review of a clinical trial site or records of any clinical investigation.

Our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the seasonality of the disease, the availability of effective treatments for the relevant disease, competing trials with other product candidates and the eligibility criteria for the clinical trial. Delays in patient enrollment can result in increased costs and longer development times. In addition, subjects may drop out of clinical trials and thereby impair the validity or statistical significance of the trials.

We have relied and expect to continue to rely on contract research organizations, clinical data management organizations, medical institutions, clinical investigators and academic institutions to conduct, supervise or monitor some or all aspects of the clinical trials for the product candidates we advance into clinical testing. Accordingly, we have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own, which could have an adverse impact on the conduct, timing and completion of our clinical trials and our ability to adhere to FDA regulations (commonly referred to as Good Clinical Practices) for conducting, recording and reporting the results of our clinical trials.

Although we have not previously experienced most of the foregoing risks with respect to our clinical trials, as a result of these risks, we or third parties upon whom we rely may not successfully begin or complete our clinical trials in the time periods forecasted, if at all. If the results of our planned clinical trials for our product candidates are not available when we expect or if we encounter any delays in the analysis of data from our clinical trials, we may be unable to submit results for regulatory approval or clearance or to conduct additional clinical trials on the schedule that we anticipate.

If clinical trials are delayed, the commercial viability of any of our current or future product candidates that require clinical trials may be reduced. If we incur costs and delays in our programs, or if we do not successfully develop and commercialize our products, our future operating and financial results will be materially affected.

If we are unable to obtain required regulatory approvals, we will be unable to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals is expensive, often takes years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved, the nature of the disease or condition to be treated, and the scope of the regulatory approval being sought. Changes in regulatory approval policies during the development period, and changes in or the enactment of additional statutes or regulations or medical and technical developments during the review process, may delay the approval or cause the rejection of an application. The FDA has substantial discretion in the approval process and may require additional clinical or non-clinical data as a condition of reviewing or approving an application. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

For example, we experienced delays in the approval of our new manufacturer for RETAVASE due to (1) additional data elements being requested by the FDA in its December 2012 CRL and (2) the drug product not achieving the established stability specifications. As a result, the delay in approval will increase our development costs and the timing of commercial launch.

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If our clinical trials and other studies do not demonstrate safety and efficacy in humans, we may experience delays, incur additional costs and ultimately be unable to commercialize our product candidates.

Depending upon the nature of the product candidate, obtaining regulatory approval for the sale of our product candidates may require us and our collaborators to fund and conduct clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, uncertain as to outcome and, depending upon the design of the trial, takes several years or more to complete. Clinical data is often susceptible to varying interpretations, and many companies that have believed their products performed satisfactorily in clinical trials were nonetheless unable to obtain FDA approval for their product candidates. Similarly, even if clinical trials of a product candidate are successful in one indication, clinical trials of that product candidate for other indications may be unsuccessful. One or more of our planned clinical trials could fail at any stage of testing.

If we are required to conduct additional clinical trials or other testing of our product candidates, if we are unable to successfully complete our clinical trials or other testing, or if the results of these trials or tests are not positive or are only modestly positive, negative or inconclusive, or if there are safety concerns, we may be delayed in obtaining marketing approval for product candidates, not be able to obtain marketing approval, obtain approval for indications that are not as broad as intended or have the product removed from the market after obtaining marketing approval.

Delays in testing or obtaining approvals could cause our product development costs to increase, shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates, allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

For example, in October 2012, we received a CRL from the FDA following its review of the NDA for LIXAR in which they requested that we complete additional clinical studies to further evaluate the efficacy and safety of lixivaptan in both heart failure patients and SIADH patients. We are requesting an End-of-Review meeting with the FDA s Division of Cardiovascular and Renal Drug Products to better understand the contents of the CRL and the nature and scope of the additional clinical trials requested by the agency. Following that meeting, we will determine appropriate next steps for LIXAR, which may result in abandonment of the development program.

Our sales depend on payment and reimbursement from third-party payers, and a reduction in the payment rate or reimbursement could result in decreased use or sales of our products.

There have been, there are and we expect there will continue to be federal and state legislative and administrative proposals that could limit the amount that government health care programs will pay to reimburse the cost of pharmaceutical products. Furthermore, private payers often implement reimbursement policies that are similar to those of government payers. For a discussion of the more important pharmaceutical pricing and reimbursement issues applicable to us, please see the Pharmaceutical Pricing and Reimbursement section of Item 1. Business and Risks Related to Financial Results below.

Legislative or administrative acts that reduce or discontinue reimbursement for our products could adversely impact our business. Any reduction or discontinuance in reimbursement for our products could materially harm our results of operations. In addition, we believe that the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of our products, which may adversely impact our product sales. Furthermore, when a new product is approved, governmental and private coverage for that product, and the amount for which that product will be reimbursed, are uncertain. We cannot predict the availability or amount of reimbursement for our product candidates, and current reimbursement policies for marketed products may change at any time.

We cannot be certain that our currently marketed products will continue to be, or any of our product candidates still in development will be, included in the Medicare Part D prescription drug benefit. Even if our products are included, the private health plans that administer the Medicare drug benefit can limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class. In addition,

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private managed care plans and other government agencies continue to seek price discounts. Because many of these same private health plans administer the Medicare drug benefit, they have the ability to influence prescription decisions for a larger segment of the population. In addition, certain states have proposed or adopted various programs under their Medicaid programs to control drug prices, including price constraints, restrictions on access to certain products and bulk purchasing of drugs.

If we succeed in bringing additional products to the market, these products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow us to sell our product candidates on a competitive basis to a sufficient patient population. Because our product candidates are in the development stage, we do not know whether payers will cover the products and the level of reimbursement, if any, we will receive for these product candidates if they are successfully developed, and we are unable at this time to determine the cost-effectiveness of these product candidates. We may need to conduct expensive pharmacoeconomic trials in order to demonstrate the cost-effectiveness of our products and product candidates. Moreover, Health Care Reform includes funding for comparative effectiveness research and the establishment of committees, such as the Independent Payment Advisory Board, to analyze different payment systems (including bundled payments) and recommend payment reform and other cost-containment measures, which all could reduce reimbursement for our products.

If the reimbursement we receive for any of our product candidates is inadequate in light of its development and other costs, our ability to realize profits from the affected product candidate would be limited. If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of our products or cause us to reduce the price of our products.

We will spend considerable time and money complying with federal and state laws and regulations, and, if we are found not to be in compliance with such laws and regulations, we could face substantial penalties.

Health care providers play a primary role in the recommendation and prescribing of our products. Our arrangements with health care providers, third-party payers and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we will market, sell and distribute our products. For a discussion of the more important laws and regulations applicable to us, please see the Regulatory Matters, Pharmaceutical Pricing and Reimbursement and Fraud and Abuse Regulation sections of Item 1. Business above.

We participate in the MDRP established by the Omnibus Budget Reconciliation Act of 1990, as amended, effective in 1993. Under the MDRP, we pay a rebate for each unit of our product reimbursed by Medicaid. The amount of the rebate for each product is set by law. We are also required to pay certain statutorily defined rebates on Medicaid purchases for reimbursement on prescription drugs under state Medicaid plans. There have been enhanced political attention, governmental scrutiny and litigation at the federal and state levels regarding the prices paid or reimbursed for pharmaceutical products under Medicaid and other government programs. Although we estimate that less than 3% of our sales qualify for Medicaid rebates, any investigation of our rebate practices could be costly, could divert the attention of our management away from operations and could damage our reputation.

Health Care Reform includes a number of provisions aimed at strengthening the government s ability to pursue federal anti-kickback and federal false claims act cases against health care entities, such as increased funding for health care fraud enforcement activities, enhanced investigative powers and amendments to the federal false claims act to make it easier for the government and whistleblowers to pursue alleged violations. Recently, several pharmaceutical and other health care companies have been prosecuted under the federal fraud and abuse laws for allegedly providing consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company s products, allegedly misrepresenting the pricing data which the federal government uses to set reimbursement rates and calculate Medicaid rebates under the MDRP and allegedly causing false claims to be submitted because of the company s marketing of the product for unapproved, and thus

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non-reimbursable, uses. This new growth in litigation and enforcement action has increased the risk that a pharmaceutical company will have to defend a false claims action, which can be expensive, time consuming and distracting, and can potentially impact its financial performance.

Efforts to help ensure that our business arrangements comply with the extensive federal and state health care laws and regulations to which we are subject are costly. It is possible that governmental authorities may conclude that our business practices do not comply with current or future health care laws or regulations. If our past or present operations, including activities conducted by our sales teams or agents, are found to be in violation of any of these laws or regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from participation in federal health care programs, a corporate integrity agreement (which would require ongoing compliance and reporting obligations to the federal government) and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we do business is found not to be in compliance with applicable laws, they may also be subject to criminal, civil or administrative sanctions, including exclusion from federal health care programs.

Many aspects of the health care laws and regulations to which we are subject have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations, which increases the risk of potential violations. In addition, these laws and their interpretations are subject to change. Any action against us for violation of these laws, even if we successfully defend against the action, could cause us to incur significant legal expenses, divert our management s attention from the operation of our business and damage our reputation, business operations and financial results.

Risks Relating to Intellectual Property and Licenses

If we are unable to obtain and maintain protection for the intellectual property relating to our technology and products, the value of our technology and products will be adversely affected.

Our success depends in part on our ability to obtain and maintain protection for the intellectual property covering or incorporated into our technology and products, whether such technology is owned by us or licensed to us by third parties. Patent protection in the pharmaceutical field is highly uncertain and involves complex legal and scientific questions. We and our licensors may not be able to obtain additional issued patents relating to our respective technology or products. Even if issued, patents issued to us or our licensors may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the longevity of the patent protection we may have for our products. Additionally, changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our owned or licensed patents also may not afford protection against competitors with similar technology. Because patent applications in the United States and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that we or our licensors were the first to file for protection of the inventions set forth in our or our licensors patent applications. If a third party has also filed a U.S. patent application covering our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO in the United States. These proceedings are costly and time-consuming, and it is possible that our efforts could be unsuccessful, resulting in a loss of our U.S. patent protection. In addition, U.S. patents generally expire, regardless of the date of issue, 20 years from the earliest claimed non-provisional filing date. Because the timing for submission of our applications to the FDA for regulatory approval of our product candidates is uncertain and, once submitted, the FDA regulatory process and timing for regulatory approval with respect to our product candidates is unpredictable, our estimates regarding the commercialization dates of our product candidates are subject to change. Accordingly, the length of time, if any, our product candidates, once commercialized, will remain subject to patent protection is uncertain.

Our collaborators and licensors may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not, our ability to maintain and defend our intellectual property rights may be compromised

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by the acts or omissions of these third parties. For example, under our license agreement covering certain patents that we license from SkyePharma PLC and Jagotec and which cover ZYFLO, SkyePharma PLC is responsible for and controls the preparation and prosecution of all patent applications, and has the sole right to enforce the resulting patents against any alleged infringer. If SkyePharma PLC declines to enforce the licensed patents, our only remedy is to cease paying royalties.

We may not have sufficient resources to bring these actions or to bring such actions to a successful conclusion. Even if we are successful in these proceedings, we may incur substantial cost and divert the time and attention of our management and scientific personnel in pursuit of these proceedings, which could have a material adverse effect on our business.

None of our current products or current product candidates except for LIXAR have, or will have, composition of matter patent protection.

Some of our currently marketed products do not have patent protection and may face generic competition. In addition, although we exclusively license United States patents and patent applications with claims directed to the pharmaceutical formulations of our product candidates, methods of use of our product candidates to treat particular conditions, delivery systems for our product candidates, delivery profiles of our product candidates and methods for producing our product candidates, patent protection is not available for composition of matter claims directed to the APIs of any of our products or product candidates except for LIXAR. The composition of matter U.S. patents for lixivaptan that are used in LIXAR will expire in July 2013.

When the composition of matter patents for the API in LIXAR expire, competitors will be able to offer and sell products with the same API so long as these competitors do not infringe any other patents that we or third parties hold, including formulation and method of use patents. However, method of use patents, in particular, are more difficult to enforce than composition of matter patents because of the risk of off-label sale or use of the subject compounds. Physicians are permitted to prescribe an approved product for uses that are not described in the product s labeling. Although off-label prescriptions may infringe our method of use patents, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. Off-label sales would limit our ability to generate revenue from the sale of our product candidates, if approved for commercial sale. In addition, if a third party were able to design around our formulation and process patents and create a different formulation using a different production process not covered by our patents or patent applications, we would likely be unable to prevent that third party from manufacturing and marketing its product.

Our patents may be challenged by ANDA applicants.

If a drug is claimed to be covered by an unexpired patent that the NDA holder has listed with the FDA, an ANDA applicant must certify in a so-called paragraph IV certification that the patent is invalid, unenforceable or not infringed by the product that is the subject of the ANDA. If the holder of the NDA sues the ANDA applicant within 45 days of being notified of the paragraph IV certification, the FDA will not approve the ANDA until the earlier of a court decision favorable to the ANDA applicant or the expiration of 30 months.

Jagotec, the licensed manufacturer and supplier of ZYFLO CR cores, determined a patent that it owned was applicable to ZYFLO CR, and we subsequently listed this patent in the Orange Book in December 2011. Any ANDA applicant whose application was already on file with the FDA at the time of listing of this patent in the Orange Book would not have to certify that either (i) it did not infringe the patent or (ii) the patent was not valid. As a result we would not have the benefit of the 30-month stay associated with such certifications. We would nonetheless be able to enforce this patent by filing suit and seeking an injunction. If we initiate legal proceedings to seek to protect our ZYFLO CR brand, the costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful.

Trademark protection of our products may not provide us with a meaningful competitive advantage.

We use trademarks on most of our currently marketed products and believe that having distinctive marks is an important factor in marketing those products. Distinctive marks may also be important for any additional products that we successfully develop and commercially market. However, we generally do not expect our marks

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to provide a meaningful competitive advantage over other branded or generic products. We believe that efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payers are, and are likely to continue to be, more important factors in the commercial success of our products and, if approved, our product candidates. For example, physicians and patients may not readily associate our trademark with the applicable product or API. In addition, prescriptions written for a branded product are typically filled with the generic version at the pharmacy if an approved generic is available, resulting in a significant loss in sales of the branded product, including for indications for which the generic version has not been approved for marketing by the FDA. Competitors also may use marks or names that are similar to our trademarks or seek to cancel our similar trademarks based on the competitor s prior use. If we initiate legal proceedings to seek to protect our trademarks, the costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We have acquired intellectual property rights relating to most of our products and product candidates under license agreements with third parties and expect to enter into additional licenses in the future. These licenses provide us with rights to intellectual property that is necessary for our business. Our existing licenses impose, and we expect that future licenses will impose, various obligations related to development and commercialization activities, milestone and royalty payments, sublicensing, patent protection and maintenance, insurance and other similar obligations common in these types of agreements. If we fail to comply with our obligations under these agreements, the licensors may have the right to terminate the license in its entirety, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could prevent or impede our ability to develop or market any product candidate or product, respectively, that is covered by the licensed patents. Even if we contest any such termination or claim and are ultimately successful, we could suffer adverse consequences to our operations and business interests. For a description of the licenses covering our more important products, please see Item 1. Business License and Collaboration Agreements.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how. We seek to protect our unpatented proprietary information in part by confidentiality agreements with our current and potential collaborators, employees, consultants, strategic partners, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, our trade secrets may otherwise become known or may be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, our competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

For example, while CUROSURF does not enjoy patent protection, CUROSURF requires a unique and intricate manufacturing process for production. If a competitor obtains the know-how needed to develop its own version of CUROSURF and successfully gains FDA approval for such, our business could be adversely impacted.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business will be adversely affected.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may subsequently issue and to which we do not hold a license or other rights. Third parties may own or control these patents or patent applications in the United States and abroad. These third parties could bring claims against us or our

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collaborators that would cause us to incur substantial expenses and, if such claims are successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement or other similar claims or to avoid potential claims, we or our potential future collaborators may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the USPTO, regarding intellectual property rights with respect to our products and technology. The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Many of our employees were previously employed at other pharmaceutical or biotechnology companies, including competitors or potential competitors. We try to ensure that our employees do not use the proprietary information or know-how of others in their work for us. However, we may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed the intellectual property, trade secrets or other proprietary information of any such employee s former employer. We may be required to engage in litigation to defend against these claims. Even if we are successful in such litigation, the litigation could result in substantial costs to us and/or be distracting to our management. If we fail to defend or are unsuccessful in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

Risks Relating to Financial Results

Legislative or regulatory reform of the health care system in the U.S. may affect our ability to sell and develop our products profitably.

Government regulation in the U.S. can determine the success of our efforts to market or develop our products. We expect the implementation of Health Care Reform to transform the delivery of and payment for health care services in the United States. The combination of these measures will continue to expand health insurance coverage to an estimated 32 million Americans. In addition, there are significant health insurance reforms that will improve patients ability to obtain and maintain health insurance. Such measures include the elimination of lifetime caps, no rescission of policies and no denial of coverage due to preexisting conditions. The expansion of health care insurance and these additional market reforms should result in greater access to our products; however, the substantial increase in the number of Americans with health insurance will not occur until 2014.

Moreover, a number of provisions contained in Health Care Reform may adversely affect reimbursement for our products. Effective January 2, 2010, Health Care Reform retroactively increased the minimum basic Medicaid rebate for brand-name prescription drugs from 15.1% to 23.1% and for generic drugs from 11% to 13%, potentially increased the additional Medicaid rebate calculation for line extensions of oral solid dosage forms of innovator products, expanded the entities eligible for 340B pricing and revised the average manufacturer price definition to remove certain classes of trade. In addition, in March 2010, pharmaceutical manufacturers were required to pay states rebates on prescription drugs dispensed to Medicaid MCO enrollees.

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Beginning on January 1, 2011, Health Care Reform required drug manufacturers to provide a 50% discount on brand-name prescriptions filled in the Medicare Part D coverage gap, also known as the donut hole. The legislation mandates the gradual elimination of the coverage gap, beginning in 2011 and finishing in 2020. Moreover, Health Care Reform reduces Part D premium subsidies for higher-income beneficiaries, expands medication therapy management requirements and makes a number of other revisions to Part D program requirements. The elimination of the coverage gap may result in greater access to our products for Part D beneficiaries.

Beginning in 2011, Health Care Reform imposed a significant annual fee (which is not tax deductible) payable to the federal government on all companies that manufacture or import branded prescription drug products, which annual fee will increase through 2019. The total annual fee payable by the industry will be allocated based on a company s market share of all branded prescription drug sales to certain government programs during a certain period. Substantial new provisions affecting compliance are also included, which may require us to modify the manner in which we advertise, promote and distribute product samples to health care practitioners. Furthermore, Health Care Reform created the Independent Payment Advisory Board to recommend and implement proposals to limit Medicare spending, which could impact reimbursement for prescription drugs.

We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of Health Care Reform or legal and legislative challenges to all or portions of Health Care Reform. The financial impact of Health Care Reform may be affected by certain additional factors over the next few years, including pending implementation guidance, certain proposed reforms, repeals and legal challenges and state legislatures reactions stemming from state budget deficits. Health Care Reform and further changes in the law or regulatory framework that reduce our net product sales or increase our costs could also have a material adverse effect on our business, financial condition and results of operations.

We have incurred and may in the future incur significant indebtedness, which may restrict the manner in which we conduct business and limit our ability to implement elements of our growth strategy.

On June 21, 2012, we incurred significant indebtedness by entering into a credit agreement, or Credit Agreement, with Chiesi in connection with our acquisition of EKR. Subject to the terms of our existing indebtedness, we may also incur additional indebtedness to meet future financing needs, which would increase our total debt. Our current indebtedness contains (and any future indebtedness may contain) restrictions on the manner in which we conduct our business and limitations on our ability to implement elements of our growth strategy, including with respect to:

- limitations on our ability to obtain additional debt financing;
- the allocation of a substantial portion of our cash flow from operations to service our debt, thus reducing the amount of our cash flow available for other purposes;
- requiring us to issue debt or equity securities or to sell some of our core assets, possibly on unfavorable terms, to meet payment obligations;
- compromising our flexibility to plan for, or react to, competitive challenges in our business;
- the possibility that we are put at a competitive disadvantage relative to competitors that do not have as much debt as us, and competitors that may be in a more favorable position to access additional capital resources; and
- limitations on our ability to execute business development activities to support our strategies.

To service our senior secured term loan facility with Chiesi, or Term Loan Facility, we will require a significant amount of cash. Our ability to generate cash depends on many factors beyond our control.

Our ability to make the payments required under our Term Loan Facility will depend on our ability to generate cash in the future. Our ability to generate cash is, to a certain extent, subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. Our business may not

generate sufficient cash flow from operations to enable us to pay our indebtedness or to fund our other liquidity needs. We may need to refinance all or a portion of our indebtedness on or before maturity, sell assets, reduce or delay capital expenditures, seek additional equity financing or seek third-party financing to satisfy such obligations. We may not be able to refinance any of our indebtedness on commercially reasonable terms or at all. Our inability to satisfy our obligations under our existing and any future indebtedness could materially and adversely affect our financial condition and business.

If we do not comply with the covenants in the Credit Agreement governing the Term Loan Facility or otherwise default under the Credit Agreement, we may not have the funds necessary to pay all of our indebtedness that could become due.

The Credit Agreement requires us to comply with certain covenants, including a prepayment provision if our ratio of consolidated secured debt to Consolidated EBITDA (as defined in the Credit Agreement) is at least 2 to 1 for any fiscal year ending on or after December 31, 2013. In addition, the Credit Agreement prohibits us from incurring any additional indebtedness, except in specified circumstances. The Credit Agreement also restricts our ability to acquire and dispose of assets, engage in mergers and reorganizations, or make investments. A violation of any of these covenants could cause an event of default under the Credit Agreement.

If we default under the Credit Agreement because of a covenant breach or otherwise, all outstanding amounts could become immediately due and payable. We may not have sufficient funds or the ability to raise sufficient funds to repay all of the outstanding amounts, and any acceleration of amounts due under the Credit Agreement would materially and adversely affect our financial condition and our business.

We may need additional funding and may be unable to raise capital when needed, which could force us to delay, reduce or eliminate our product development, commercialization or acquisition efforts.

We have incurred and expect to continue to incur significant development expenses in connection with our ongoing activities, particularly if and when we conduct clinical trials for product candidates. In addition, we incur significant commercialization expenses related to our currently marketed products for sales, marketing, manufacturing and distribution. We expect these commercialization expenses to increase in future periods if we are successful in obtaining FDA approval to market our product candidates or any newly acquired products. We have used, and expect to continue to use, revenue from sales of our marketed products to fund a significant portion of the development costs of our product candidates and to expand our sales and marketing infrastructure. However, we may need substantial additional funding for these purposes and may be unable to raise capital when needed or on acceptable terms, which would force us to delay, reduce or eliminate our development programs or commercialization efforts.

As of December 31, 2012, we had $56.3 million of cash and cash equivalents on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents and revenue from product sales are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for at least the next 12 months.

Our future capital requirements will depend on many factors, including:

- the level of product sales and product returns of our currently marketed products and any additional products that we may market in the future;
- the scope, progress, results and costs of development activities for our current product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, additional product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;

the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates and products;

the extent to which we acquire or invest in products, businesses and technologies;

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- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products and product candidates; and

- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending claims related to intellectual property owned by or licensed to us.

The terms of any additional capital funding that we require may not be favorable to us or our stockholders.

To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

If we raise additional funds by issuing equity securities, as we did in our transaction with Chiesi, our stockholders will experience dilution. Debt financing requires that payments of principal and interest be made at specified times and such payments may represent a significant portion of or our revenues. Additionally such financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any agreements governing debt or equity financing may also contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, we may be required to relinquish valuable rights to our future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

Our operating results are likely to fluctuate from period to period.

We anticipate that there may be fluctuations in our future operating results. Potential causes of future fluctuations in our operating results may include:

- acquisition activity;

- new product launches, which could increase revenues but also increase sales and marketing expenses;

- charges for inventory expiration or product quality issues;

- changes in the amount and timing of sales of our products due to changes in product pricing, changes in the prevalence of disease conditions or generic competition from period to period or other factors;

- the timing of operating expenses, including selling and marketing expenses and the costs of maintaining a direct sales force;

- changes in research and development expenses resulting from the acquisition of product candidates or from general and industry-specific economic conditions;

- changes in the competitive, regulatory or reimbursement environment, including the amounts of rebates, discounts, holdbacks, chargebacks and returns, which could decrease revenues or increase sales and marketing, product development or compliance costs;

- unexpected product liability or intellectual property claims and lawsuits;

significant payments, such as milestones, required under collaboration, licensing and development agreements before the related product or product candidate has received FDA approval or been sold in commercial quantities;

marketing exclusivity, if any, which may be obtained on certain new products;

the dependence on a small number of products for a significant portion of net revenues and net income;

price erosion and customer consolidation;

the results of ongoing and planned clinical trials of our product candidates;

the results of regulatory reviews relating to the development or approval of our product candidates; and

production problems occurring at our third-party manufacturers.

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We may incur losses in accordance with GAAP in the future.

We experienced a GAAP net loss in 2012 and 2011, and we may be unable to generate profits on a GAAP basis, even if we are able to commercialize additional products. We incur significant non-cash expenses including amortization of product rights, stock compensation and changes in our acquisition-related contingent payments. These non-cash expenses may continue to result in future GAAP net losses. Our non-GAAP net income for the years ending December 31, 2012, 2011 and 2010 was $16.3 million, $9.2 million and $18.9 million, respectively. For information on our non-GAAP financial measures used by management for planning and forecasting, refer to Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Reconciliation of Non-GAAP Financial Measures .

To date, we have financed our operations primarily with revenue from product sales and debt and equity financings. We have devoted substantially all of our efforts to:

establishing a sales and marketing infrastructure;

acquiring marketed products, product candidates and related technologies;

commercializing marketed products; and

developing product candidates, including conducting clinical trials.

We expect to continue to incur significant development and commercialization expenses as we:

advance the development of product candidates; and

seek regulatory approvals for product candidates that successfully complete clinical testing.

We may never succeed in these activities and may never generate revenue that is sufficient to regain and then sustain or increase GAAP profitability on a quarterly or annual basis. Any failure to regain and then sustain and increase profitability could impair our ability to raise capital, expand our business, diversify our product offerings and continue operations.

If the estimates that we make, or the assumptions upon which we rely, in preparing our financial statements prove inaccurate, the actual results may vary from those reflected in our estimates and our financial condition and results of operations could be materially impacted.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, stockholders equity, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. For example, at the same time we recognize revenues for product sales, we also record an adjustment, or decrease, to revenue for estimated chargebacks, rebates, discounts, vouchers and returns, which management determines on a product-by-product basis as its best estimate at the time of sale based on each product s historical experience adjusted to reflect known changes in the factors that impact such reserves. Actual sales allowances may exceed our estimates for a variety of reasons, including unanticipated competition, regulatory actions or changes in one or more of our contractual relationships. In addition, if we divest any of our products, we make estimates of our continuing liabilities for chargebacks, rebates, discounts, vouchers and returns based upon the terms of the divestiture transaction and expected market conditions and sales performance of the buyer. Our estimates, or the assumptions underlying them, including the sales performance of the buyers of our divested products, may prove to be incorrect.

If goodwill or other intangible assets that we record in connection with acquisitions become impaired, we may be required to record significant charges against earnings.

In connection with the accounting for our recent acquisitions, we recorded significant amounts of goodwill and other intangible assets. Under GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite-lived intangible assets has been impaired. In addition,

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amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations.

Risks Relating to Employee Matters and Managing Growth

If we fail to attract and retain qualified personnel, or to retain our executive management team, we may be unable to successfully develop or commercialize our products and product candidates.

Recruiting and retaining highly qualified commercial, scientific, technical and managerial personnel and research partners is critical to our success. Future acquisitions of companies or products may require expansion of our commercial team and expansion into areas and activities requiring additional expertise, such as clinical trials, governmental approvals and contract manufacturing, which will place additional requirements on our management, operational and financial resources. These demands may require us to hire additional personnel and will require our existing management personnel to develop additional expertise. We face competition for personnel. The failure to attract and retain personnel or to develop such expertise could impair our ability to independently market and promote our products or delay or halt the development, regulatory approval and commercialization of our product candidates. If we experience difficulties in hiring and retaining personnel in key positions, we could suffer from delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect operating results. We also experience competition for the hiring of scientific personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by third parties and may have commitments under consulting or advisory contracts with third parties that may limit their availability to us.

We depend to a great extent on the principal members of our management. The loss of the services of any of our key personnel might significantly delay or prevent the achievement of our business objectives and could cause us to incur additional costs to recruit replacements. Each member of our executive management team may terminate his employment at any time. We do not maintain key person life insurance with respect to any of our executives. Furthermore, if we decide to recruit new executive personnel, we will incur additional costs. We may not be able to replace key personnel internally or without additional costs in the future. Our inability to attract and retain the executive talent necessary to manage and grow our company could have an adverse effect on our business, financial condition and results of operations.

Risks Relating to Common Stock

Our stock price is subject to fluctuation, which may cause an investment in our stock to suffer a decline in value.

The market price of our common stock may fluctuate significantly in response to factors that are beyond our control. The stock market in general has recently experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of our common stock.

Some of the factors that may cause the market price of our common stock to fluctuate include, but are not limited to the following, as they relate to us and (as applicable) our competitors:

- the results of non-clinical studies and clinical trials;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments.
- the entry into, amendment or termination of key agreements, including licensing and collaboration agreements;
- the results and timing of regulatory reviews relating to the approval of product candidates;

the initiation of material developments in or conclusion of litigation to enforce or defend intellectual property rights;

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failure of any product candidates, if approved, to achieve commercial success;

general and industry-specific economic conditions that may affect research and development expenditures;

issues in manufacturing products or product candidates;

recall or withdrawal of a product or products;

the loss of key employees;

the acquisition, development or introduction of technologies, product candidates or products;

changes in the structure of health care payment systems;

regulatory actions with respect to products;

our financial results, including period-to-period fluctuations in those results;

changes in estimates or recommendations by securities analysts, if any, who cover our common stock; and

future sales of our common stock.

In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our financial condition, results of operations and reputation.

Chiesi has substantial control over us and could delay or prevent a change in corporate control, including a transaction in which our stockholders could sell or exchange their shares for a premium, as well as prevent us from entering into certain transactions.

As a result of our July 28, 2009 strategic transaction with Chiesi, Chiesi acquired a majority of our common stock and assumed substantial control over our company. The governance agreement with Chiesi that we entered into in connection with the Chiesi transaction terminated on July 28, 2011. Since Chiesi continues to own a majority of our common stock and the governance agreement was not renewed or replaced by a similar arrangement, Chiesi has the ability to exercise significant control over our company. Delaware law provides that directors, including those appointed by Chiesi, have fiduciary duties to all stockholders and also provides safeguards in certain situations to ensure that all stockholders are treated fairly. As a majority stockholder, Chiesi may nonetheless be able, without a meeting or prior notice to our other stockholders, to (1) remove our directors with or without cause; (2) approve or disapprove significant corporate actions, such as a sale of our company; (3) cause the removal of our management, including our executive officers; and (4) take or cause to be taken or not take or cause not to be taken other significant corporate actions.

As a result of Chiesi s ownership and control over our company, we consider ourselves to be a Controlled Company under NASDAQ rules, which means, among other things, that NASDAQ does not require us to maintain a majority of independent directors or nominating and compensation committees comprised solely of independent directors. We cannot be certain that the interests of Chiesi will be consistent with the interests of our other stockholders. In addition, Chiesi s majority ownership of and control over our company may have the effect of delaying or preventing a change in control, merger or tender offer, which could deprive our stockholders of an opportunity to receive a premium for their

shares of common stock and may negatively affect the market price of our common stock. Moreover, Chiesi, either alone or with other existing stockholders (including members of our management), could effectively receive a premium for transferring ownership to third parties that would not inure to the benefit of other stockholders.

In addition, although the Governance Agreement has expired, our certificate of incorporation still provides that, so long as Chiesi beneficially owns (together with its affiliates) not less than 40% of our outstanding common stock on a fully diluted basis (as defined in our certificate of incorporation) we must seek approval from Chiesi to, among other things, (1) consummate an acquisition of any business or assets for a price in excess of $25,000,000; (2) sell, lease, transfer or otherwise dispose of a business or assets for a price in excess of

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$25,000,000 (other than a sale in the ordinary course of business); (3) issue any equity security or other capital stock other than pursuant to employee incentive plans or upon the exercise of any option, warrant, or similar right; and (4) repurchase or redeem any equity security other than redemptions required by the terms thereof, purchases made at fair market value in connection with any deferred compensation plan and repurchases of unvested or restricted stock issued pursuant to any employee, officer, director or consultant compensation plan. As a result of these provisions, Chiesi has the right to prevent us from entering into certain transactions that have been approved by our management or our Board of Directors, which could prevent us from pursuing our preferred growth strategy or otherwise taking actions that our management and Board of Directors believe to be in the best interests of our company.

The proposal made by our majority stockholder, Chiesi, to acquire all of our outstanding common stock may not result in a definitive offer, and even if the proposal results in a definitive offer, we may fail to enter into an agreement with Chiesi and this or any other transaction may not be approved or consummated. The absence of a proposal to acquire our common stock could have an adverse effect on the market price of our common stock.

On February 18, 2013, our Board of Directors received the proposal from Chiesi, our majority stockholder, described in Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Going-Private Proposal. We caution our stockholders and others considering trading in our securities that, as of March 14, 2013, no decisions have been made by our Board of Directors or the Special Committee of our Board with respect to our response to this proposal. The proposal submitted was not a definitive offer, and a definitive offer may not be made, an agreement may not be executed or a definitive offer, if made with respect to the proposal or any other transaction, may not be approved or consummated. On the last trading day prior to the announcement of the proposal, the closing trading price of our common stock was $5.50 per share. After the announcement, the trading price of our common stock increased and traded closer to the $6.40 to $6.70 per share proposal price range. However, the trading price of our common stock has been subject to significant volatility since the announcement. If this proposal were rejected or withdrawn and if no similar transaction presented itself, our stock price could fall below its current trading range. In addition, costs associated with the evaluation of the proposal and any related processes may be considerable regardless of whether any definitive agreement is entered into or any transaction is consummated.

ITEM 1B. ***UNRESOLVED STAFF COMMENTS***

Not applicable.

ITEM 2. ***PROPERTIES***

We lease approximately 21,000 square feet of office space in Cary, North Carolina. The lease expires on March 31, 2016, and we have an option to extend the term of the lease for an additional five years through March 2021. We believe our existing facilities are sufficient to meet our needs for the foreseeable future.

ITEM 3. ***LEGAL PROCEEDINGS***

ONY Litigation

On December 2, 2011, ONY, Inc., or ONY, the maker of Infasurf®, a natural lung surfactant that is a competitor to CUROSURF, filed suit in United States District Court for the Western District of New York against us, Chiesi and various other individuals and entities in connection with an article appearing in the September 2011 issue of the *Journal of Perinatology*. The article was based on a retrospective study sponsored by Chiesi that concluded that Infasurf was associated with significantly higher mortality rates than CUROSURF. ONY alleged that the article was false and misleading because it did not discuss all of the relevant data and literature and the underlying study was based on manipulated data. ONY asserted a claim under federal law against us for false advertising based on our dissemination of and references to the article in our promotional activities, as well as state law claims for tortious interference with existing and prospective contracts, injurious falsehood and violation of New York s deceptive trade practices statute.

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On January 17, 2012, we filed a motion to dismiss the action for failure to state a claim on which relief could be granted and on May 18, 2012, the Court issued an order granting the motion to dismiss. On June 14, 2012, ONY notified the United States Court of Appeals for the Second Circuit that it intended to appeal that order. The appeal has been fully briefed but has not proceeded to oral argument at this time.

Propoxyphene Litigation

On January 11, 2012, we were served with a complaint in the California Superior Court for the County of San Francisco by Mary and George Keene and 30 other individual plaintiffs. The suit names numerous pharmaceutical companies, including Cornerstone BioPharma, Inc., or BioPharma, and Cornerstone BioPharma Holdings, Inc., or Cornerstone BioPharma, which are two of our subsidiaries. The plaintiffs allege that they (or decedents) suffered personal injury related to their ingestion of prescription medication containing the API propoxyphene marketed and sold as generic and/or brand-name drugs under various names by the defendant companies. The damages that the plaintiffs seek include compensatory and exemplary damages. The suit was removed on January 23, 2012 and transferred to the pending MDL proceedings in the United States District Court, Eastern District of Kentucky (Northern Division) on March 2, 2012. On July 4, 2012, the plaintiffs filed a motion to remand the case to the California Superior Court for the County of San Francisco, and that motion was granted and the case remanded on September 13, 2012. The suit was removed again to the United States District Court for the Northern District of California on November 20, 2012, and on January 3, 2013, the plaintiffs filed a motion to remand, which is still pending.

In February 2012, we were served with complaints in four additional cases: one in Tennessee (*Anderson v. Eli Lilly and Company*, U.S. District Court, Eastern District of Tennessee (Greeneville), filed November 18, 2011); another in Tennessee (*Holland individually and as Administrator of the Estate of Mary Taylor v. Eli Lilly and Company*, U.S. District Court, Western District of Tennessee (Jackson), filed November 18, 2011); one in Mississippi (*McAlpine v. Eli Lilly and Company*, U.S. District Court, Northern District of Mississippi (Western Division), filed November 18, 2011); and one in Louisiana (*Reynolds v. Eli Lilly and Company*, U.S. District Court, Eastern District of Louisiana (New Orleans), filed November 17, 2011). The suits name numerous pharmaceutical companies, including BioPharma and Cornerstone BioPharma, and one suit names Aristos. The plaintiffs in the lawsuits generally allege that they (or decedents) suffered personal injury related to their ingestion of prescription medication containing the API propoxyphene, marketed and sold as generic and/or brand-name drugs under various names by the defendant companies. The damages that the plaintiffs seek include compensatory and exemplary damages. All four cases were consolidated with the MDL proceedings in the United States District Court, Eastern District of Kentucky (Northern Division).

On November 15, 2011, a motion was filed to dismiss plaintiffs complaints in multiple cases pending in the MDL proceedings on the basis of preemption. On June 22, 2012, the court issued an order dismissing all generic defendants from the cases pending in the MDL proceedings, including our wholly owned subsidiaries BioPharma, Cornerstone BioPharma and Aristos from the *Anderson*, *Holland*, *McAlpine* and *Reynolds* cases. The rulings in the *Anderson* and *McAlpine* cases were not appealed and are final. The rulings in the *Holland* and *Reynolds* cases have been appealed to the United States Court of Appeals for the Sixth Circuit, but the court has not yet set a briefing schedule.

ITEM 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

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EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and their positions as of March 7, 2013 are as follows:

Name	Age	Position
Craig A. Collard	47	Chief Executive Officer
Ken McBean	47	President
Alastair McEwan	57	Chief Financial Officer and Treasurer
Andrew K. W. Powell	55	Executive Vice President, General Counsel and Secretary
Joshua B. Franklin	43	Vice President, Strategy and Business Development
Alan T. Roberts	46	Vice President, Scientific Affairs

Craig A. Collard has served as our Chief Executive Officer and the chairman of our Board of Directors since our merger with Cornerstone BioPharma on October 31, 2008 (whereby Cornerstone BioPharma became a wholly owned subsidiary of the Company). Mr. Collard also served as our Interim Chief Financial Officer from July 2010 through January 2011 and our President from October 2008 to September 2011. In March 2004, Mr. Collard founded Cornerstone BioPharma Holdings, Ltd. (the assets and operations of which were restructured as Cornerstone BioPharma in May 2005), and served as its President and Chief Executive Officer and a director from March 2004 to October 2008. Before founding Cornerstone BioPharma, Mr. Collard s principal occupation was serving as President and Chief Executive Officer of Carolina Pharmaceuticals, Inc., a specialty pharmaceutical company he founded in May 2003. From August 2002 to February 2003, Mr. Collard served as Vice President of Sales for Verum Pharmaceuticals, Inc., a specialty pharmaceutical company in Research Triangle Park, North Carolina. From 1998 to 2002, Mr. Collard worked as Director of National Accounts at DJ Pharma, Inc., a specialty pharmaceutical company which was eventually purchased by Biovail Pharmaceuticals, Inc., or Biovail. His pharmaceutical career began in 1992 as a field sales representative at Dura Pharmaceuticals, Inc., or Dura. He was later promoted to several other sales and marketing positions within Dura. Mr. Collard is a member of the Board of Directors of Hilltop Home Foundation, a Raleigh, North Carolina, non-profit corporation as well as the Triangle Chapter of the Cystic Fibrosis Foundation in addition to our Board of Directors. Mr. Collard holds a B.S. in Engineering from the Southern College of Technology (now Southern Polytechnic State University) in Marietta, Georgia. As our founder and Chief Executive Officer, and as a former sales representative and/or executive at several other specialty pharmaceutical companies, Mr. Collard brings to our management team and Board of Directors a depth of sales and executive experience both in the specialty pharmaceutical industry in general and at our company in particular.

Kenneth McBean assumed the title of President from Craig Collard in September 2011. Mr. McBean joined us from Covidien plc, or Covidien, where he held the position of Vice President and General Manager of Specialty Pharmaceuticals from March 2009 until May 2011. At Covidien, Mr. McBean was responsible for executing a successful turnaround of Covidien s branded pharmaceutical products division. In 2006, Mr. McBean co-founded Tribute Pharmaceuticals Ltd., a Canadian-based pharmaceutical company, and served as its Senior Vice President of Commercial Affairs and Business Development from January 2006 through March 2009. In 2004, Mr. McBean co-founded Legacy Pharmaceuticals, Inc., a specialty pharmaceutical company, and served as its Senior Vice President of Commercial Affairs from July 2004 until October 2005. Prior to founding Legacy Pharmaceuticals, Inc., Mr. McBean was the Vice President of Marketing and Commercial Development for Biovail Pharmaceuticals, Inc., or Biovail, and its predecessor company, DJ Pharma, Inc., in the United States. His earlier career involved various U.S. and global positions at Glaxo Wellcome and Marion Merrell Dow in commercial strategy, product management, market research, and sales. Mr. McBean holds a B.S. in Business from Kansas State University.

Alastair McEwan was appointed as our Chief Financial Officer and Treasurer on November 5, 2012. Mr. McEwan joined the Company from his role as a pharmaceutical industry consultant. In this role, from July 2006 to November 2012, Mr. McEwan consulted on various drug development initiatives and advised potential investors in numerous public and private mergers, acquisitions, divestments and capital restructuring initiatives. Mr. McEwan previously served on the Board following the completion of the Company s merger with

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Cornerstone BioPharma on October 31, 2008 until July 28, 2009, the date of the completion of the original investment in the Company by Chiesi Farmaceutici S.p.A., the Company s majority stockholder, or the Chiesi Transaction. Mr. McEwan joined Cornerstone BioPharma s board of directors in August 2005 and became chairman of its board of directors in January 2006, serving in such capacities until the completion of the Chiesi Transaction. From October 2005 through December 2005, Mr. McEwan served as Cornerstone BioPharma s interim Chief Financial Officer. Prior to joining Cornerstone BioPharma, from June 1996 to December 2004, Mr. McEwan served in a variety of positions at Inveresk Research Group, Inc., or Inveresk, including as Group Executive Vice President, as President of Inveresk Global Clinical Operations and President of Inveresk Clinical Americas operations. Mr. McEwan also served as a member of the Group Executive Board of Inveresk from 1999 to 2004. Mr. McEwan served as director of Averion International Corp., a publicly traded international contract research organization, from February 2006 until December 2009. Mr. McEwan qualified as a Chartered Accountant in 1979 with the Institute of Chartered Accountants of Scotland and holds a Bachelor of Commerce from the University of Edinburgh.

Andrew K. W. Powell, Esq. has served as our Executive Vice President, General Counsel and Secretary since October 2009. Mr. Powell has practiced law for more than 25 years. He began his career at the firm of Gibson, Dunn & Crutcher in 1986, before joining Baxter International, or Baxter. From 1989 to 2004 he held positions at Baxter of increasing responsibility, playing key roles in a series of transactions that established the company throughout Asia, and heading up the global law function at Baxter Bioscience. From September 2004 to June 2008 he was a leader in the management team that successfully developed CollaGenex Pharmaceuticals into a publicly traded commercial company that was sold to Galderma Laboratories. From July 2008 until January 2009 he was Senior Vice President and General Counsel at ImClone Systems, Inc. where he managed the sale of that company to Eli Lilly & Co. Mr. Powell holds a B.A. from the University of North Carolina at Chapel Hill and a J.D. from Stanford Law School.

Joshua B. Franklin has served as our Vice President, Strategy and Business Development since May 2012. Prior to that, Mr. Franklin served as our Vice President, Corporate Strategy from March 2011 to May 2012, Vice President, Sales and Marketing from December 2008 to March 2011 and, before that, as Vice President of Marketing since our merger with Cornerstone BioPharma. Before joining Cornerstone, Mr. Franklin served in a variety of marketing positions at Ther-Rx Corporation (a subsidiary of K-V Pharmaceutical Company) from July 2003 to September 2008, including most recently as Vice President, Marketing. Prior to joining Ther-Rx Corporation, Mr. Franklin held various marketing roles with Biovail from January 2002 to July 2003 and the Ross Products Division of Abbott Laboratories from August 1999 to January 2002. Mr. Franklin is a U.S. Army veteran and holds a B.S. in Business Administration from Methodist University and M.H.A. and M.B.A. degrees from The Ohio State University.

Alan T. Roberts has served as our Vice President, Scientific Affairs since May 2009. In December 2007, Mr. Roberts founded Tybeam Pharma Consulting, LLC, or Tybeam, and serves as its President. Prior to founding Tybeam, Mr. Roberts served as Senior Vice President and Chief Scientific Officer for Auriga Laboratories, Inc., or Auriga, from February 2006 to December 2007. In January 2006, Mr. Roberts was named Vice President, Global Manufacturing and Development. He had served as Vice President, Scientific Affairs for First Horizon Pharmaceutical Corporation, or First Horizon since January 2005. Prior to becoming Vice President, Mr. Roberts was First Horizon s Director of Regulatory, Quality and Manufacturing from June 2000 to June 2002, and Senior Director, Regulatory and Technical Affairs through 2004. From June 1999 to February 2000, Mr. Roberts was Vice President, Research and Development for Mikart, Inc., a private pharmaceutical contract manufacturer. Prior positions with Mikart were Research and Development Manager and Director of Research and Development from July 1993 to June 1999. Additional experience also includes key management positions in regulatory and development with Solvay Pharmaceuticals, Inc. and the Medical University of South Carolina s Pharmaceutical Development Center, respectively. Mr. Roberts holds a B.S. in Microbiology from Clemson University.

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NON-EMPLOYEE DIRECTORS OF THE REGISTRANT

Our non-employee directors, their ages, principal occupation and name of their employer as of March 7, 2013 are as follows:

Name	Age	Principal Occupation and Employer
Christopher Codeanne	45	Executive Vice President, Finance and Chief Financial Officer, Premier Research Group Limited
Michael Enright	51	President, OckhamCRO, Ockham Development Group, Inc.
Anton Giorgio Failla	47	Head of Business Development, Chiesi Farmaceutici S.p.A.
James Harper	65	Board Member
Michael Heffernan	48	Co-Founder, President and Chief Executive Officer, Collegium Pharmaceuticals, Inc.
Laura Shawver	55	Chief Executive Officer and Director, Cleave Biosciences, Inc.
Robert M. Stephan	70	Board Member
Marco Vecchia	52	Head of Legal and Corporate Affairs, Chiesi Farmaceutici S.p.A.

Christopher Codeanne has served on our Board of Directors since October 2008. Since December 2010, Mr. Codeanne has served as the Executive Vice President, Finance, Chief Financial Officer and Director of Premier Research Group Limited, an international pharmaceutical and medical device services company. From April 2008 through November 2010, Mr. Codeanne served as Chief Operating Officer and Chief Financial Officer of Oncology Development Partners, LLC (d/b/a Oncopartners), a specialized international oncology contract research organization. During 2010, Mr. Codeanne also served as an advisor for private equity firm Warburg Pincus. From December 2006 through April 2008, Mr. Codeanne served as the Chief Financial Officer of Averion International Corp., or Averion, a publicly traded international contract research organization. Prior to Averion, from 2002 through July 2006, Mr. Codeanne was the Chief Financial Officer of SCIREX Corporation (which was acquired by Premier Research Group plc in 2006), or SCIREX, an international, full-service clinical research organization. From 1999 to 2002, Mr. Codeanne served as Director of Finance of SCIREX. Mr. Codeanne is a member of the American Institute of Certified Public Accountants. Mr. Codeanne holds a B.A. in Accounting from Fairfield University and an M.B.A. from the University of Connecticut. He brings to our Board of Directors a depth of experience in financial, operational and public company matters and knowledge regarding pharmaceutical development and working with contract research organizations.

Michael Enright has served on our Board of Directors since October 2008. Since February 2011, Mr. Enright has served as the President of OckhamCRO, a division of Ockham Development Group Inc., or Ockham, a global contract research organization. Prior to becoming President of OckhamCRO, Mr. Enright had served as the Chief Financial Officer for Ockham since its merger with Atlantic Search Group, Inc., a staff augmentation and functional outsourcing services organization serving pharmaceutical companies and contract research organizations in the United States and India, where he held the same position since 1995. Prior to 1995, Mr. Enright held positions in employee benefits administration with Hauser Insurance Group and The Prudential Insurance Company, and in financial management with General Electric Company s aerospace business group. Mr. Enright holds a B.A. in Finance from Villanova University and an M.B.A. from the Kenan-Flagler School of Business of the University of North Carolina at Chapel Hill. He brings to our Board of Directors a depth of experience in strategic planning and organizational development and human resources.

Anton Giorgio Failla has served on our Board of Directors since July 2009. Since July 2008, Dr. Failla has served as Head of Business Development of Chiesi. Prior to his employment at Chiesi, from 2004 to 2008, Dr. Failla served as the CFO of Sorin Group, a medical device company, based in Milan, Italy and as its Senior Vice President of Operations based in Denver, Colorado. From 2000 to 2004, Dr. Failla served as Vice President, Business Development and Strategic Planning at Novartis Consumer Health, or Novartis, at its Headquarters in Switzerland. Prior to Novartis, Dr. Failla held various positions in business development at Medtronic Inc., both in the U.S. and in Europe. Dr. Failla has served on the boards of directors of several private companies in Europe

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and the United States: Bellco S.r.l. (April 2004 to January 2007), Sorin Biomedica Cardio S.r.l. (April 2004 to April 2005), Biofin Holding International N.V. (July 2004 to June 2006), Ela Medical S.a.s. (April 2004 to June 2006), Sorin Biomedica CRM S.r.l. (April 2007 to July 2008), Sorin Group International S.A. (December 2005 to June 2006), Casino Municipale Campione d Italia (August 2007 to June 2009), and Phenomix Corporation Inc. (February 2010 to September 2010). Dr. Failla holds a Master in Business Administration from SDA Bocconi and a doctorate in Electronic Engineering from Polytechnic of Turin. He brings to our Board of Directors a depth of experience in the areas of strategic planning, finance, business development and operations management.

James Harper has served on our Board of Directors since December 2011. Mr. Harper has over 30 years of experience in the pharmaceutical and medical device industries. He has also served on multiple corporate and not-for-profit boards of directors. He is currently Chair of Phenomix Corporation (Chair from December 2009 to present and director from July 2007 to present), a director of Baylor Regional Medical Center (March 2012 to present), and an advisor to Nomura Phase4 Ventures (July 2007 to present). Prior to his retirement, Mr. Harper held a number of management and senior executive positions at Eli Lilly and Company (January 1974 to April 2004), including Group Vice President of Global Marketing and Sales and Chief Marketing Officer (January 2001 to April 2004), President of Diabetes and Growth Disorders Product Group (January 1994 to January 2001), and President and CEO of Advanced Cardiovascular Systems, a Lilly subsidiary (December 1990 to December 1992). In addition, Mr. Harper has served on the boards of directors of Anesiva, Inc. (May 2007 to December 2008), Corcept Therapeutics (October 2004 to May 2011), Inoveon Corporation (June 2002 to April 2004) and Zymogenetics, Inc. (July 2004 to October 2010). On these boards, he served on various committees including compensation, governance, and audit committees. Mr. Harper was a member of the National Board of Directors of the American Diabetes Association (July 1993 to June 1997), where he was a member of the Research Policy Committee (July 2000 to June 2001) and Vice Chair of the Research Foundation Board (2003 to 2006). He was also on the National Osteoporosis Foundation Corporate Advisory Board (July 1995 to June 1997). Mr. Harper is a member of the National Association of Corporate Directors (March 2006 to present). A veteran Navy flight officer, he holds a B.A. in Biology from Vanderbilt University and an M.B.A. in Marketing/Finance from The Wharton School. He brings to our Board of Directors a depth of operational experience.

Michael Heffernan has served on our Board of Directors since October 2008. Since 2002, Mr. Heffernan has served as President and Chief Executive Officer of Collegium Pharmaceutical, Inc., a specialty pharmaceutical company that develops and commercializes products to treat central nervous system, respiratory and skin-related disorders. From 1999 to 2001, Mr. Heffernan served as President and Chief Executive Officer of PhyMatrix Corp., an integrated health care services company. From 1995 to 1999, Mr. Heffernan served as President and Chief Executive Officer of Clinical Studies Ltd., a pharmaceutical clinical development company. From 1987 to 1994, Mr. Heffernan served in a variety of sales and marketing positions with Eli Lilly and Company, a pharmaceutical company. Mr. Heffernan has also served on the Board of Directors of TyRx Pharma, Inc. since 2002, the Board of Directors of PreCision Dermatology, Inc. since 2010 and the Board of Directors of Advanced Cell Technology, Inc. since April 2012. Mr. Heffernan holds a B.S. in Pharmacy from the University of Connecticut and is a Registered Pharmacist. He brings to our Board of Directors a depth of experience in sales, marketing, and licensing and knowledge regarding pharmaceutical development and working with contract research organizations.

Laura Shawver has served on our Board of Directors since June 2012. Dr. Shawver has more than 20 years of experience in the biotechnology and pharmaceutical industry. In 2011, she participated in the founding of Cleave Biosciences, Inc., a development stage company, and currently serves as its Chief Executive Officer and Director. From October 2010 to August 2011, she was Entrepreneur in Residence for 5AM Ventures, an early stage venture capital firm focused on building next-generation life science companies. In prior years, Dr. Shawver served as Chief Executive Officer and Director of Phenomix Corporation, a development stage company, from June 2002 to September 2010, and President of Sugen, Inc. (Sugen) from October 2000 to May 2002, after holding various positions there since 1992. Sugen was a publicly traded company from 1994 to 1999 when it was acquired by Pharmacia and Upjohn Company, Inc. Dr. Shawver began her drug development career in 1989 at Triton Biosciences, Inc. (later Berlex Biosciences Inc.), which was acquired by Schering AG in 1990. She has extensive operational, drug development and regulatory expertise, and also has assisted a number of pharmaceutical companies with transition and integration activities following product licensing and acquisition

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transactions. Dr. Shawver has served on the Board of Directors of Antipodean Pharmaceuticals, Inc. and Anaphore, Inc., and she is the founder and a current Director of The Clearity Foundation, a non-profit corporation. Dr. Shawver holds a B.S. in Microbiology and a Ph.D. in Pharmacology, both from the University of Iowa. She brings to our Board of Directors executive experience in the pharmaceutical industry and knowledge regarding pharmaceutical development.

Robert M. Stephan has served on our Board of Directors since July 2009. Mr. Stephan is a retired business attorney with over 40 years experience, including in private law practice and with public corporations. Since 1997, until his retirement in 2012, Mr. Stephan operated the Law Office of Robert M. Stephan, where he concentrated his law practice on domestic and international business transactions and serves as chief counsel to small and mid-sized companies and local counsel to foreign companies with operations in the United States. Mr. Stephan also served as Vice President and Secretary from 1997 to 2012 and as a director from April 2009 to 2012, of Chiesi Pharmaceuticals Inc., USA, a subsidiary of Chiesi. Prior to opening his private practice in 1997 and after initial training with the Office of the General Counsel of the SEC in Washington D.C. and the law firm of Day, Berry & Howard in Hartford, Connecticut, Mr. Stephan embarked on a career as in-house counsel with publicly traded corporations. He served as Vice President and Group General Counsel for General Mills Inc; Vice President and Associate General Counsel for US Surgical Corporation; Vice President, General Counsel and Secretary for Erbamont N.V. (Montedison Group); and Vice President, General Counsel and Secretary for American Maize Products Corporation. Mr. Stephan has advised boards of directors on corporate governance matters and is a former member of the National Association of Corporate Directors. Mr. Stephan is a former Captain/Judge Advocate in the United States Marine Corps and an Assistant Attorney General for the State of Wisconsin. Mr. Stephan holds a B.A. in economics and political science from Lawrence University and a J.D. from the University of Wisconsin Law School. He brings to our Board of Directors a depth of experience in all areas of corporate governance, with particular emphasis on the governance of transnational joint ventures.

Marco Vecchia has served on our Board of Directors since May 2010. Since 1987, Mr. Vecchia has served as Head of Legal and Corporate Affairs at Chiesi. Mr. Vecchia has also served on the boards of directors of the following companies: Chiesi S.A., Belgium, since June 2010; Chiesi Pharmaceuticals Shanghai Co. Ltd. (Wfoe), China, since June 2008; Cheshire Healthcare Limited, England, since January 2003; Chiesi Limited, England, since May 1999; Chiesi Healthcare Limited, England, since May 1999; Chiesi S.A., France, since April 2002; Chiesi Hellas Pharmaceuticals S.A., Greece, since April 1998; Chiesi Int. H. B.V., Holland, since April 2008; Chiesi Pharmaceuticals B.V., Holland, since February 2007; Opocrin S.P.A., Italy, since November 2008; Opocrin S.r.l., Italy, since November 2008; Novadynamics Healthcare S.r.l., Italy, since May 2007; Chiesi Pharmaceuticals Pvt Limited, Pakistan, since November 2001; Chiesi España S.A., Spain, since April 2000; Chiesi Pharmaceuticals Inc., USA, since April 1992. Mr. Vecchia holds a degree in law from the University of Parma. He brings to our Board of Directors a depth of experience in the areas of mergers and acquisitions and transnational joint ventures, pharmaceutical IP licensing, risk management and corporate governance.

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PART II

ITEM 5. ***MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES***

Market Price of and Dividends on Cornerstone Therapeutics Inc. s Common Stock and Related Stockholder Matters

Our common stock trades on the NASDAQ Capital Market under the symbol CRTX. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock on the NASDAQ Stock Market.

Year Ended December 31, 2012	High	Low
First Quarter (from January 1 to March 31)	$ 6.96	$ 4.66
Second Quarter (from April 1 to June 30)	$ 6.35	$ 4.88
Third Quarter (from July 1 to September 30)	$ 7.99	$ 3.10
Fourth Quarter (from October 1 to December 31)	$ 5.39	$ 4.56

Year Ended December 31, 2011	High	Low
First Quarter (from January 1 to March 31)	$ 7.19	$ 5.06
Second Quarter (from April 1 to June 30)	$ 9.08	$ 6.28
Third Quarter (from July 1 to September 30)	$ 9.20	$ 6.29
Fourth Quarter (from October 1 to December 31)	$ 7.89	$ 4.45

On March 7, 2013, the closing price per share of our common stock as reported on the NASDAQ Capital Market was $6.99, and we had approximately 148 stockholders of record. This number does not include beneficial owners for whom shares are held by nominees in street name.

We have never paid or declared any cash dividends on our common stock. We currently intend to retain earnings, if any, to finance the growth and development of our business, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our Board of Directors.

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Performance Graph

The following information in this Item 5 of this annual report on Form 10-K is not deemed to be soliciting material or to be filed with the SEC or subject to Regulation 14A or 14C under the Exchange Act or to the liabilities of Section 18 of the Exchange Act, and will not be deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, except to the extent we specifically incorporate it by reference into such filing.

The following graph compares our cumulative total stockholder return from December 31, 2007 with those of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes that U.S. $100 was invested on December 31, 2007 in (1) our common stock, (2) the NASDAQ Composite Index and (3) the NASDAQ Biotechnology Index. The measurement points utilized in the graph consist of the last trading day in each calendar year, which closely approximates the last day of our respective fiscal year. The historical stock performance presented below is not intended to and may not be indicative of future stock performance.

Comparison of 5-Year Cumulative Total Return

among Cornerstone Therapeutics Inc. (known as Critical Therapeutics, Inc. prior to October 31, 2008),

the NASDAQ Composite Index and the NASDAQ Biotechnology Index

	12/31/07	12/31/08	12/31/09	12/31/09	12/31/11	12/31/12
CRTX	$ 100	$ 21	$ 48	$ 46	$ 44	$ 37
NASDAQ Composite Index	$ 100	$ 59	$ 86	$ 100	$ 98	$ 114
NASDAQ Biotech Index	$ 100	$ 87	$ 101	$ 116	$ 130	$ 171

Recent Sales of Unregistered Securities; Uses of Proceeds From Registered Securities

Not applicable.

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Issuer Purchases of Equity Securities

The following table lists all repurchases during the fourth quarter of the year ended December 31, 2012 of our common stock by or on behalf of us or any affiliated purchaser.

	Total Number of Shares Purchased(1)	Average Price Paid per Share(2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
October 1, 2012 October 31, 2012		$	$	$
November 1, 2012 November 30, 2012	1,022	4.85		
December 1, 2012 December 31, 2012				
Total	1,022	$ 4.85	$	$

(1) Represents shares that were surrendered to us by holders of restricted common stock under the 2004 Stock Incentive Plan to satisfy employee tax withholding obligations arising in connection with the vesting of their shares. We subsequently retired all of these surrendered shares.

(2) Represents the average price paid per share for shares surrendered to us in satisfaction of employee tax withholding obligations.

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ITEM 6. ***SELECTED FINANCIAL DATA***

The selected statement of (loss) income and balance sheet data with respect to the years ended December 31, 2012, 2011, 2010, 2009 and 2008 set forth below are derived from our consolidated financial statements. The selected financial data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations contained in Item 7 below, and our consolidated financial statements and the notes contained in Item 8 below. Historical results are not necessarily indicative of our future results.

	Year Ended December 31,				
	2012(3)	2011	2010	2009	2008(4)
	(In thousands, except per share and share amounts)				
Statement of (Loss) Income Data:					
Net revenues	$ 116,084	$ 101,422	$ 125,317	$ 109,564	64,867
Costs and expenses:					
Cost of product sales(1)	42,579	37,823	45,015	38,232	22,144
Selling, general and administrative	46,404	45,877	53,198	45,731	27,082
Research and development	4,273	1,624	4,488	3,608	3,679
Amortization of product rights	17,929	14,368	14,378	6,115	1,334
Change in acquisition-related contingent payments	(11,896)				
Transaction-related expenses	8,354	467			
Other operating expenses, net	35,779	2,500	350		
Total costs and expenses	143,422	102,659	117,429	93,686	54,239
(Loss) income from operations	(27,338)	(1,237)	7,888	15,878	10,628
Other expense, net	(3,795)	(128)	(110)	(128)	(1,221)
(Loss) income before income taxes	(31,133)	(1,365)	7,778	15,750	9,407
Benefit from (provision for) income taxes	19,245	672	(1,609)	(5,547)	(414)
Net (loss) income	$ (11,888)	$ (693)	$ 6,169	$ 10,203	$ 8,993
Net (loss) income per share, basic	$ (0.46)	$ (0.03)	$ 0.24	$ 0.58	$ 1.29
Net (loss) income per share, diluted	$ (0.46)	$ (0.03)	$ 0.24	$ 0.54	$ 1.14
Weighted-average common shares, basic	26,115,266	25,684,593	25,412,636	17,651,668	6,951,896
Weighted-average common shares, diluted	26,115,266	25,684,593	26,036,544	18,776,588	7,861,119

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	2012(3)	2011	December, 31 2010	2009	2008(4)
			(In thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 56,250	$ 73,968	$ 50,945	$ 18,853	$ 9,286
Accounts receivable, net	14,368	11,894	76,476	16,548	12,987
Inventories, net	11,384	9,419	15,174	18,106	11,222
Working capital	35,741	58,393	54,610	28,312	3,157
Total assets	369,375	232,314	285,459	203,322	69,889
Deferred revenue		1,428	57,194		
Debt obligations, including current portion(2)	89,657	146	1,597	2,409	4,856
Acquisition-related contingent payments	33,208	8,800			
Total stockholders equity	166,173	174,803	172,398	163,868	29,426
Shares of common stock outstanding	26,348	25,804	25,473	25,023	12,024

(1) Excludes amortization of product rights.

(2) Includes line of credit, license agreement liability, note payable and capital leases.

(3) Amounts for 2012 include the impact of the EKR business acquisition in June 2012. For more information regarding the EKR acquisition, see Note 3 of our Notes to the Consolidated Financial Statements in Item 8 of this Form 10-K.

(4) Amounts for 2008 include the impact of our merger with Cornerstone BioPharma in October 2008.

ITEM 7. ***MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

The following discussion is designed to provide a better understanding of our consolidated financial statements, including a brief discussion of our business and products, key factors that impacted our performance, and a summary of our operating results. You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and the related notes included in this annual report on Form 10-K. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors including, but not limited to, those set forth in the Risk Factors section of this annual report on Form 10-K.

Executive Overview

Strategy

We are a specialty pharmaceutical company focused on commercializing products for the hospital and adjacent specialty markets. We are actively seeking to expand our portfolio of products for these markets through the acquisition of companies and products and through internal development.

Our strategy is to:

Focus our commercial and development efforts in the hospital and adjacent specialty markets within the U.S. pharmaceutical marketplace;

Acquire companies, marketed or registration-stage products, and late-stage development products that fit within our focus areas; and

Market approved generic products through Aristos, our wholly owned subsidiary.

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2012 Highlights

Key Strategic Initiatives

The following summarizes our execution and continued efforts on our key initiatives:

Growing revenue from our existing product portfolio.

During 2012, net product sales from CUROSURF and ZYFLO increased $23.0 million, or 35%, as compared to 2011, primarily due to an increase in ZYFLO net product sales resulting from price increases, partially offset by lower unit volume and increases in sales allowances. During 2012, our market share for CUROSURF increased three percentage points to 52% of the surfactant market, while aggregate sales in the surfactant market declined 6%.

Evaluating and executing upon strategic alternatives for our anti-infective products.

In March 2012, we executed our strategy to withdraw from the business of promoting products to the primary care market by entering into a series of transactions to sell all of our rights to our anti-infective products, Factive and Spectracef, and to engage a co-promotion partner to promote ZYFLO to primary care providers. Pursuant to an asset purchase agreement, we sold all of our rights to Factive to Merus Labs International Inc., or Merus, in exchange for cash consideration and the assumption of certain product-related liabilities. Pursuant to a separate asset purchase agreement, we sold all of our rights to Spectracef to Vansen Pharma Inc., or Vansen, in exchange for cash consideration and the assumption of certain product-related liabilities, Pursuant to a separate co-promotion agreement, we agreed to pay Vansen to co-promote our ZYFLO products to certain physicians for an initial period of 24 months. In connection with this divestiture, Vansen offered certain of our respiratory sales force personnel employment to continue to support distribution and sales of Factive and Spectracef. Divesting of these products and product rights, together with the associated commercial infrastructure, allows us to focus our resources and efforts towards growing our hospital and adjacent specialty market presence in the United States. The divestiture of all of the assets we used to promote products to the primary care market allows us to focus on the hospital and adjacent specialty markets.

Gaining regulatory approval and launching HP/CP ER Suspension.

On June 29, 2012, the FDA approved our ANDA for HP/CP ER Suspension, which is a generic equivalent for the product currently sold under the Tussionex brand name. We are targeting launch of HP/CP ER Suspension in 2013.

Advancing our product pipeline, in particular LIXAR.

On October 31, 2012, we received a CRL from the FDA following their review of our NDA for LIXAR, for the treatment of symptomatic hypervolemic and euvolemic hyponatremia associated with heart failure and SIADH. The FDA has requested that we complete additional clinical studies to further evaluate the efficacy and safety of lixivaptan in both heart failure patients and SIADH patients. We are requesting an End-of-Review meeting with the Division of Cardiovascular and Renal Drug Products of the FDA to better understand the contents of the CRL and the nature and scope of the additional clinical trials requested by the FDA. Following such meeting, we will determine appropriate action regarding our LIXAR development program, which may result in abandonment of the development program.

Acquiring specialty products and companies.

On June 26, 2012, we completed our acquisition of EKR, a specialty pharmaceutical company focused on serving the acute-care hospital setting, for an estimated consideration of approximately $164.2 million. As part of the transaction, we acquired the product rights to EKR s cardiovascular products, CARDENE I.V. and RETAVASE. We made an upfront payment of $126.4 million, subject to customary post-closing adjustments, and may pay a series of contingent consideration payments related to RETAVASE of up to $25 million if certain milestones are achieved. The fair value for contingent consideration was determined to be $37.8 million, of

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which $23.9 million related to a contingent consideration arrangement related to the ready-to-use formulation of CARDENE I.V. that existed prior to the acquisition date. We were able to integrate EKR into our existing operations within 90 days post-closing realizing significant cost synergies primarily through the elimination of duplicative administrative functions. Alignment of our combined sales force significantly expanded our reach in the U.S hospital market and expansion of our commercial infrastructure to include a national accounts team. This expansion enables us to enter into contracts more efficiently upon launch of new hospital products and react more quickly to changes in the hospital market.

In connection with our acquisition of EKR, we entered into the Credit Agreement with Chiesi. The credit agreement governs the Term Loan Facility, which is comprised of two five-year term loans, or the Term Loans. The Term Loans were funded on June 25, 2012 and the acquisition of EKR closed on June 26, 2012. The proceeds of the Term Loans were used, together with our cash on hand, to finance the acquisition and the related fees and expenses incurred by us in connection with the acquisition. All obligations under the Term Loan Facility are guaranteed by our domestic subsidiaries, and are secured by a security interest in substantially all of our assets and the assets of our domestic subsidiaries.

On November 6, 2012, we entered into a license and distribution agreement with Chiesi pursuant to which Chiesi granted us an exclusive license to market and sell their BETHKIS product in the United States. BETHKIS is an FDA-approved inhaled tobramycin-based product indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa. In consideration for the grant of the license, we made an initial payment of $1.0 million and will make a milestone payment of $2.5 million upon the first commercial sale of the product in the United States. We will also be required to pay certain costs related to a Phase IV clinical trial with respect to the product and quarterly royalties based on a percentage of net sales.

Key Financial Results

The following summarizes certain key financial results for the year ended December 31, 2012:

- Net product sales increased $14.8 million to $116.1 million in 2012 from $101.3 million in 2011, representing 15% year-over-year growth.

- On a GAAP basis, loss from operations increased $26.1 million to a loss of $27.3 million in 2012 compared to a loss of $1.2 million in 2011 and net loss increased $11.2 million to a loss of $11.9 million in 2012 compared to a loss of $693,000 in 2011;

- On a non-GAAP basis, income from operations increased $11.7 million, or 64%, to $30 million during 2012 and net income increased $7 million, or 76%, to $16.3 million in 2012;

- Cash and cash equivalents decreased $17.7 million, or 24%, to $56.3 million as of December 31, 2012 compared to December 31, 2011.

Opportunities and Trends

We continue to execute on our strategic plan, which calls for promoting CUROSURF and CARDENE I.V. with our hospital-based sales force and managing the life cycle of ZYFLO. We believe that the additions of CARDENE I.V. and, if approved, RETAVASE to our product portfolio will give us the opportunity to strengthen our existing relationships within the cardiology community and position us for long-term growth in the hospital and adjacent specialty markets. In addition, we continue to expand our product portfolio by acquiring or in-licensing products, including our recent license of BETHKIS.

As we continue to focus on the growth of our existing products and product candidates, we also continue to position ourselves to execute acquisitions that will drive our next phase of growth. We are systematically focusing our efforts on acquiring products and companies whose products will fit strategically with the focus and strengths of our sales force. We believe that we can continue to operate efficiently and that we will find opportunities that will drive future growth. We will need to continue to maintain our strategic focus, manage and deploy our available cash efficiently and strengthen our alliance and partner relationships in order to execute our strategy successfully. We believe these actions, combined with the experience and expertise of our management team, position us well to drive the future growth of our revenue and income.

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In 2013, we will focus on the following priorities:

- acquiring products and companies in the hospital and adjacent specialty markets;
- growing revenue from our existing product portfolio;
- launching BETHKIS pursuant to our license agreement with Chiesi;
- launching HP/CP ER Suspension, which we expect to be distributed by Aristos; and
- progressing toward FDA approval of a new API supplier and certain manufacturing process changes to allow for re-launch of RETAVASE.

See Item 1. Business for a more complete description of our products, product candidates and more important agreements.

Going-Private Proposal

On February 18, 2013, our Board of Directors received a proposal from Chiesi, the owner of approximately 60% of the outstanding shares of our common stock, to acquire the shares of our common stock that it does not already own for a cash purchase price of between $6.40 and $6.70 per share. Our Board of Directors has formed a Special Committee comprised of five independent directors to coordinate our response to this proposal. As of March 14, 2013, no decisions have been made by the Special Committee with respect to our response to the proposal.

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Results of Operations

Comparison of the Years Ended December 31, 2012 and 2011

The following table sets forth certain consolidated statements of comprehensive (loss) income data and certain non-GAAP financial information for the periods indicated (in thousands, except percentages and per share data):

	Year Ended December 31,		Change	
	2012	2011	$	%
Net Product Sales				
CARDENE I.V. product family	$ 24,807	$	$ 24,807	NM
CUROSURF	34,972	34,852	120	NM
ZYFLO product family	53,553	30,674	22,879	75
AlleRx Dose Pack products	(1,407)	23,263	(24,670)	(106)
Anti-infective products	3,374	14,387	(11,013)	(77)
Other products	781	(1,875)	2,656	NM
Total net product sales	116,080	101,301	14,779	15
License and royalty agreement revenues	4	121	(117)	(97)
Net revenues	116,084	101,422	14,662	14
Cost of product sales (exclusive of amortization of product rights)	42,579	37,823	4,756	13
Selling, general and administrative	46,404	45,877	527	1
Research and development	4,273	1,624	2,649	163
Amortization of product rights	17,929	14,368	3,561	25
Change in acquisition-related contingent payments	(11,896)		(11,896)	NM
Transaction-related expenses	8,354	467	7,887	1,689
Other operating expenses, net	35,779	2,500	33,279	1,331
(Loss) income from operations	(27,338)	(1,237)	(26,101)	NM
Total other expenses, net	(3,795)	(128)	(3,667)	NM
(Loss) income before income taxes	(31,133)	(1,365)	(29,768)	NM
Benefit from (provision for) income taxes	19,245	672	18,573	2,764
Net (loss) income	$ (11,888)	$ (693)	$ (11,195)	NM
Net (loss) income per share, diluted	$ (0.46)	$ (0.03)	$ (0.43)	NM
Non-GAAP income from operations(1)	$ 29,967	$ 18,305	$ 11,662	64%
Non-GAAP net income(1)	$ 16,253	$ 9,228	$ 7,025	76%
Non-GAAP net income per share, diluted(1)	$ 0.59	$ 0.35	$ 0.24	69%

(1) A reconciliation of our non-GAAP financial measures to the comparable GAAP financial measures is included below.
NM Not Meaningful.

Net Revenues

Net Product Sales.

CARDENE I.V. net product sales were $24.8 million during 2012. We acquired the CARDENE I.V. product rights in our acquisition of EKR on June 26, 2012.

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CUROSURF net product sales were relatively flat during 2012 compared to 2011, primarily due to an increase in our estimated rate for expected product returns, which offset higher unit volume.

ZYFLO CR and ZYFLO net product sales increased $22.9 million, or 75%, during 2012 compared to 2011. This increase was primarily due to price increases, partially offset by lower unit volume and increases in sales allowances.

AlleRx Dose Pack net product sales decreased $24.7 million during 2012 compared to 2011. During 2011, deferred revenue related to 2010 sales was recognized as revenue when prescriptions were filled. We do not expect any future sales of AlleRx Dose Pack based on management s reasonable belief that all inventory in the channel has been previously sold and adequate reserves have been established for anticipated returns. In addition, during 2012, we recorded an additional reduction to revenue of $1.6 million for product returns.

Net product sales from our anti-infective products decreased $11.0 million, or 77%, during 2012 compared to 2011. This decrease was primarily due to our divestiture of the anti-infective product rights and certain related assets and liabilities in early March 2012, partially offset by adjustments made to our prior estimates of sales allowances.

Net product sales from other products increased $2.7 million during 2012 compared to 2011. The primary reason for this increase was approximately $4.6 million of propoxyphene/acetaminophen product returns in 2011 resulting from our voluntary withdrawal of these products from the market. Excluding the impact of these returns, our net product sales from other products decreased approximately $1.9 million due to the elimination of certain products from our portfolio.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $17.9 million and $14.4 million in 2012 and 2011, respectively) increased $4.8 million, or 13% during 2012 compared to 2011. Cost of product sales consists primarily of standard costs for each of our commercial products, distribution costs, royalties and inventory allowances.

Gross profit (exclusive of license and royalty agreement revenues and amortization of product rights) was as follows (dollars in thousands):

	Year Ended December 31,		Change	
	2012	2011	$	%
Net product sales	$ 116,080	$ 101,301	$ 14,779	15%
Cost of product sales (exclusive of amortization of product rights)	42,579	37,823	4,756	13
Gross profit	$ 73,501	$ 63,478	$ 10,023	16%
Gross margin	63%	63%		

Gross margin of net product sales for 2012 remained flat compared to 2011. Cost of product sales for 2012 included $4.2 million of acquisition accounting adjustments related to acquired CARDENE I.V. inventory that was sold during the year. The impact of the acquisition accounting adjustments on gross margin during 2012 was a decrease of approximately four percentage points.

Selling, General and Administrative Expenses. Selling, general and administrative expenses remained relatively flat during 2012 compared to 2011. During 2012, reductions in salaries, travel, other related employee benefits and sample costs resulting from our divestiture of our anti-infective product rights and our respiratory sales force in March were offset by increases in copromotion expense and spending for marketed product support related to ZYFLO.

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Research and Development Expenses. The following table summarizes our research and development expenses for 2012 and 2011 and for current projects under development from project inception through December 31, 2012 (dollars in thousands):

	Project Inception to December 31, 2012	Year Ended December 31, 2012	2011	Change $	Change %
HP/CP ER Suspension	$ 7,043	$ 857	$ 838	$ 19	2%
LIXAR	2,871	2,871		2,871	100
RETAVASE	409	409		409	100
Other projects(1)		136	786	(650)	(83)
Total		$ 4,273	$ 1,624	$ 2,649	163

(1) Other projects include costs related to discontinued products and product candidates that are in the early stages of development. Research and development expenses increased $2.6 million during 2012 compared to 2011. This increase was primarily driven by development costs of $2.9 million related to LIXAR. These costs were partially offset by a reduction in spend due to the cessation of our development program for our anti-asthma product candidate, CRTX 073.

Our product development expenses for particular product candidates will continue to vary significantly from year to year depending on the product development stage and the nature and extent of the activities undertaken to advance the product candidate s development in a given year. We expect to continue to incur significant development expenses as we seek to advance the development and FDA approval of our product candidates and seek regulatory approvals for our product candidates that successfully complete clinical testing.

Amortization of Product Rights. Amortization of product rights increased $3.6 million, or 25%, during 2012 compared to 2011, primarily due to amortization of CARDENE I.V. which was acquired in June 2012, partially offset by a reduction in CUROSURF amortization resulting from a change in estimate regarding the expected term of our license, effective October 1, 2012. The effect of this change in estimate was a reduction of amortization expense of $1.1 million, an increase in net income of $431,000, and an increase in basic and diluted earnings per share of $0.02 for the year ended December 31, 2012.

Change in Acquisition-related Contingent Payments. The change in acquisition-related contingent payments was $11.9 million during 2012 primarily due to fair value adjustments to reduce the contingent liability related to LIXAR to zero and adjust the contingent consideration for RETAVASE based on revised assumptions regarding the timing of commercial launch. For additional information regarding the change in acquisition-related contingent payments, refer to Item 8. Financial Statements and Supplementary Data Notes to the Consolidated Financial Statements, Note 6 and 12 .

Transaction-related Expenses. Transaction-related expenses were $8.4 million during 2012 compared to $467,000 during 2011. Approximately $7.6 million of the transaction-related expenses incurred during 2012 related to our acquisition of EKR.

Other operating expenses, net. Other operating expenses, net increased $33.3 million during 2012 compared to 2011 primarily due to our CARDENE I.V. charitable inventory donation of $11.7 million, write-off of $14.6 million of RETAVASE inventory determined to no longer be saleable based on expected delays in approval and commercial launch and impairment of LIXAR in-process research and development of $11.5 million, partially offset by a $2.0 million gain on our divestiture of our anti-infective product rights in March 2012. For additional information regarding the in-process research and development impairment, refer to Item 8. Financial Statements and Supplementary Data Notes to the Consolidated Financial Statements, Note 6 .

Other expenses, net. Other expenses, net increased $3.7 million during 2012 compared to 2011 primarily due to interest expense related to our Term Loan Facility entered into in connection with our acquisition of EKR.

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Benefit from (Provision for) Income Taxes

The benefit from income taxes was $19.2 million during 2012, compared to a benefit from of $672,000 in 2011. Our effective tax rates for 2012 and 2011 were 61.8% and 49.2%, respectively. The increase in the effective tax rate for 2012 compared to 2011 is primarily due to an additional tax benefit associated with the release of a portion of the valuation allowance as well a benefit we recorded associated with our pre-tax book loss for the period.

Quarterly Results of Operations

See Note 18 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for a presentation of our unaudited quarterly results of operations for 2012 and 2011.

Comparison of the Years Ended December 31, 2011 and 2010

The following table sets forth certain consolidated statements of comprehensive (loss) income data and certain non-GAAP financial information for the periods indicated (in thousands, except percentages and per share data):

	Year Ended December 31,		Change	
	2011	2010	$	%
Net Product Sales				
CUROSURF	$ 34,852	$ 33,621	$ 1,231	4%
ZYFLO product family	30,674	30,619	55	0
Factive	6,296	5,126	1,170	23
Spectracef product family	8,091	5,327	2,764	52
AlleRx Dose Pack products	23,263	27,305	(4,042)	(15)
Hyomax product family	2,128	10,071	(7,943)	(79)
Other products	(4,003)	11,675	(15,678)	(134)
Total net product sales	101,301	123,744	(22,443)	(18)
License and royalty agreement revenues	121	1,573	(1,452)	(92)
Net revenues	101,422	125,317	(23,895)	(19)
Cost of product sales (exclusive of amortization of product rights)	37,823	45,015	(7,192)	(16)
Selling, general and administrative	45,877	53,198	(7,321)	(14)
Research and development	1,624	4,488	(2,864)	(64)
Amortization of product rights	14,368	14,378	(10)	
Transaction-related expenses	467		467	100
Other operating expenses, net	2,500	350	2,150	614
(Loss) income from operations	(1,237)	7,888	(9,125)	(116)
Total other expenses, net	(128)	(110)	(18)	(16)
(Loss) income before income taxes	(1,365)	7,778	(9,143)	(118)
Benefit from (provision for) income taxes	672	(1,609)	(2,281)	(142)
Net(loss) income	$ (693)	$ 6,169	$ (6,862)	(111)%
Net (loss) income per share, diluted	$ (0.03)	$ 0.24	$ (0.27)	(113)%
Non-GAAP income from operations(1)	$ 18,305	$ 23,955	$ (5,650)	(24)%
Non-GAAP net income(1)	$ 9,228	$ 18,912	$ (9,684)	(51)%

Non-GAAP net income per share, diluted(1)	$ 0.35	$ 0.73	$ (0.38)	(52)%

(1) A reconciliation of our non-GAAP financial measures to the comparable GAAP financial measures is included below.

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Net Revenues

Net Product Sales.

CUROSURF net product sales increased $1.2 million, or 4%, during 2011 compared to 2010 primarily due to an increase in price, partially offset by an increase in the estimated fees to be paid to our distributors.

ZYFLO CR and ZYFLO net product sales were relatively flat during 2011 compared to 2010. Excluding the impact of an additional reserve of $1.9 million recorded in 2010 to account for an increase in actual returns compared to management s initial estimate at the time of the merger with Cornerstone BioPharma Holdings, Inc. (Cornerstone BioPharma) in October 2008, net product sales decreased approximately $2.0 million, or 6%, during 2011. This decrease was primarily due to lower unit volume and increases in government rebates and the estimated fees to be paid to our distributors, partially offset by a price increase.

Factive net product sales increased $1.2 million, or 23%, during 2011 compared to 2010. Excluding the impact of additional reserves of $1.6 million recorded in 2010 to account for an increase in our estimated rate of future returns, net product sales decreased approximately $400,000, or 6%, during 2011. This decrease was primarily due to relatively flat unit volume along with increased voucher redemption as a result of additional promotional efforts for our anti-infective products, partially offset by a price increase.

Spectracef net product sales increased $2.8 million, or 52%, during 2011 compared to 2010. Excluding the impact of an additional reserve of $2.5 million for potential returns of discontinued product and increases in our estimated rates for product returns on net product sales during 2010, net product sales increased approximately $300,000, or 4%, during 2011. This increase was primarily due to increases in unit volume as a result of additional promotional efforts for our anti-infective products, increases in price and a reduction in Medicaid rebates, partially offset by increased voucher redemption.

AlleRx Dose Pack net product sales decreased $4.0 million, or 15%, during 2011 compared to 2010. Deferred revenue related to 2010 sales was recognized in 2011 as revenue when prescriptions were filled. The decrease in product sales was primarily due to the FDA announcement in March 2011, or the March 2011 FDA Announcement, that the FDA intended to initiate enforcement action against marketed unapproved prescription cough, cold and allergy products manufactured on or after June 1, 2011 or shipped on or after August 30, 2011, which caused a decline in prescriptions. In addition, we received approximately $30.1 million in returns related to product for which revenue had been deferred. As of December 31, 2011, $915,000 remained in deferred revenue.

Hyomax net product sales decreased $7.9 million, or 79%, during 2011 compared to 2010. This decrease was primarily due to lower net prices and lower unit volume as a result of increased competition from other manufacturers. During 2011, revenue has been recognized as prescriptions were filled instead of our historic practice of recognizing revenue at the time of sale. This change was due to our inability to estimate product returns as a result of changes in market dynamics, large amounts of channel inventory and extended payment terms offered on certain sales. As of December 31, 2011, $513,000 remains in deferred revenue.

Net product sales from other products decreased $15.7 million, or 134%, during 2011 compared to 2010 primarily due to our November 2010 withdrawal from the market of our propoxyphene/acetaminophen products. Net product sales for propoxyphene/acetaminophen products during 2010 were $11.8 million, whereas we had no product sales from propoxyphene/acetaminophen products during 2011. During 2011, we also recorded returns in excess of our original estimates related to our propoxyphene/acetaminophen products resulting in an additional $4.6 million decrease in net product sales.

License and Royalty Agreement Revenues.

License and royalty agreement revenues decreased $1.5 million, or 92%, during 2011 compared to 2010 primarily due to the one-time, upfront nonrefundable payment of $1.5 million we received in August 2010 in accordance with our license agreement with Targacept, Inc. under which we out-licensed certain rights with respect to our alpha-7 receptor technology.

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Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of $14.4 million and $14.4 million in 2011 and 2010, respectively) decreased $7.2 million, or 16% during 2011 compared to 2010. Cost of product sales consists primarily of standard costs for each of our commercial products, distribution costs, royalties and inventory allowances.

Gross profit (exclusive of license and royalty agreement revenues and amortization of product rights) was as follows (dollars in thousands):

	Year Ended December 31,		Change	
	2011	2010	$	%
Net product sales	$ 101,301	$ 123,744	$ (22,443)	(18)%
Cost of product sales (exclusive of amortization of product rights)	37,823	45,015	(7,192)	(16)
Gross profit	$ 63,478	$ 78,729	$ (15,251)	(19)%
Gross margin	63%	64%		(1)%

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $7.3 million, or 14%, during 2011 compared to 2010. This decrease was primarily due to decrease in labor and benefits-related costs as a result of the realignment of our respiratory sales force; decrease in co-promotion expenses from the withdrawal of our propoxyphene/acetaminophen products; decreased sample usage for ZYFLO CR; and decreased advertising and promotional expenses. These decreases were partially offset by higher stock-based compensation, regulatory fees and marketed product support during 2011.

Research and Development Expenses. The following table summarizes our research and development expenses for 2011 and 2010 and for projects under development (other than LIXAR, which we acquired through our acquisition of Cardiokine on December 30, 2011) from project inception through December 31, 2011 (dollars in thousands):

	Project Inception to December 31, 2011	Year Ended December 31,		Change	Change
		2011	2010	$	%
HP/CP ER Suspension	$ 6,186	$ 838	$ 2,290	$ (1,452)	(63)%
CRTX 073	2,012	708	1,057	(349)	(33)
Other projects		78	1,141	(1,063)	(93)
Total		$ 1,624	$ 4,488	$ (2,864)	(64)%

Research and development expenses decreased $2.9 million, or 64%, during 2011 compared to 2010. This decrease was driven by realignment of our development pipeline with our focus on hospital and adjacent specialty markets. As a result, we ceased work on our allergy product candidates as well as our cough/cold product candidates, CRTX 069, CRTX 072 and CRTX 074.

Other operating expenses, net. Other operating expenses, net increased $2.2 million during 2011 compared to 2010. During 2011, we focused our product development projects to align with our strategic direction. This decision resulted in the write-off of $2.5 million of capitalized product rights.

Benefit from (Provision for) Income Taxes

The benefit from income taxes was $672,000 during 2011, compared to a provision for $1.6 million in 2010. Our effective tax rates for 2011 and 2010 were 49.2% and 20.7%, respectively. The increase in the effective tax rate for 2011 compared to 2010 is due primarily to the fact that we

recorded a benefit associated with our pre-tax book loss for the period as well as an additional tax benefit associated with the release of a portion of the valuation allowance.

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Reconciliation of Non-GAAP Financial Measures

To supplement the consolidated financial statements presented in accordance with GAAP, we use non-GAAP measures of certain components of financial performance. These non-GAAP measures include non-GAAP operating income, non-GAAP net income and non-GAAP net income per diluted share. Our management regularly uses supplemental non-GAAP financial measures to understand, manage and evaluate our business and make operating and compensation decisions. These non-GAAP measures are among the primary factors management uses in planning for and forecasting future periods.

These non-GAAP measures are not in accordance with, or an alternative to, measures prepared in accordance with GAAP and may be different from similarly titled non-GAAP measures used by other companies. In addition, these non-GAAP measures are not based on any comprehensive set of accounting rules or principles. The additional non-GAAP financial information presented herein should be considered in conjunction with, and not as a substitute for, or superior to, the financial information presented in accordance with GAAP (such as operating income (loss), net income (loss) and earnings (loss) per share) and should not be considered measures of our liquidity. These non-GAAP measures should only be used to evaluate our results of operations in conjunction with the corresponding GAAP measures.

The non-GAAP financial measures reflect adjustments for stock-based compensation expense, amortization and impairment of product rights, transaction-related expenses, acquisition adjustments related to inventory, our CARDENE I.V. charitable inventory donation, our RETAVASE inventory write-off, changes in acquisition-related contingent payments, and the gain on the divestiture of certain product rights. Transaction-related expenses consist of (1) costs incurred to complete product or company acquisitions or other strategic transactions, including due diligence and legal, consulting and other related fees; (2) integration costs related to our completed transactions; and (3) transaction-related fees associated with transactions that are not consummated. We exclude these expenses from our non-GAAP measures because we believe that their exclusion provides an additional means to assess the extent to which our efforts and execution of our strategy are reflected in our operating results. In particular, stock-based compensation expense is excluded primarily because it is a non-cash expense that is determined based on subjective assumptions, amortization and impairment of product rights are excluded because they are not reflective of the cash-settled expenses incurred related to product sales; and the transaction-related expenses, acquisition adjustments related to inventory, our CARDENE I.V. charitable inventory donation, our RETAVASE inventory write-off, changes in acquisition contingent payments, and our gain on the divestiture of certain product rights are excluded because management believes they have no direct correlation to current operating results. Our management believes that these non-GAAP measures, when shown in conjunction with the corresponding GAAP measures, enhance investors and management s overall understanding of our current financial performance and our prospects for the future.

The non-GAAP measures are subject to inherent limitations because (1) they do not reflect all of the expenses associated with the results of operations as determined in accordance with GAAP and (2) the exclusion of these expenses involve the exercise of judgment by management. Even though we have excluded stock-based compensation expense, amortization and impairment of product rights, transaction-related expenses, acquisition adjustments related to inventory, our CARDENE I.V. charitable inventory donation, our RETAVASE inventory write-off, changes in acquisition-related contingent payments, and the gain from the divestiture of product rights from the non-GAAP financial measures, stock-based compensation is an integral part of our compensation structure, the acquisition of additional companies and/or product rights and the divestiture of our anti-infective product rights are an important part of our business strategy, transaction-related expenses, whether or not the transaction is successfully closed, may be significant cash expenses and the disposition of our assets other than through product sales has a negative impact on our results of operations and cash flows.

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The following tables reconcile our non-GAAP measures to the most directly comparable GAAP financial measures (in thousands, except share and per share amounts):

	For the Year Ended December 31,		
	2012	2011	2010
GAAP (loss) income from operations	$ (27,338)	$ (1,237)	$ 7,888
Add: stock-based compensation	2,961	2,207	1,339
Add: amortization and impairment of product rights	29,429	16,868	14,728
Add: transaction-related expenses	8,354	467	
Add: acquisition adjustments related to inventory	4,178		
Add: CARDENE I.V. charitable inventory donation	11,662		
Add: RETAVASE inventory write-off	14,586		
Less: change in acquisition-related contingent payments	(11,896)		
Less: gain on divestiture of product rights	(1,969)		
Non-GAAP income from operations	$ 29,967	$ 18,305	$ 23,955
GAAP net (loss) income	$ (11,888)	$ (693)	$ 6,169
Add: stock-based compensation	2,961	2,207	1,339
Add: amortization and impairment of product rights	29,429	16,868	14,728
Add: transaction-related expenses	8,354	467	
Add: acquisition adjustments related to inventory	4,178		
Add: CARDENE I.V. charitable inventory donation	11,662		
Add: RETAVASE inventory write-off	14,586		
Less: change in acquisition-related contingent payments	(11,896)		
Less: gain on divestiture of product rights	(1,969)		
Less: tax effects related to above items(1)	(29,164)	(9,621)	(3,324)
Non-GAAP net income	$ 16,253	$ 9,228	$ 18,912
GAAP net (loss) income per share, diluted	$ (0.46)	$ (0.03)	$ 0.24
Non-GAAP net income per share, diluted(2)	$ 0.59	$ 0.35	$ 0.73
Shares used in diluted net (loss) income per share calculation:			
GAAP net (loss) income	26,115,266	25,684,593	26,036,544
Non-GAAP net income	28,669,855	26,232,333	26,036,544

(1) Income taxes typically represent a complex element of our consolidated statement of comprehensive (loss) income, and effective tax rates can vary widely between different periods. As such, for the year ended December 31, 2012, we calculated non-GAAP net income by applying our statutory tax rate of 37.9% to non-GAAP income before taxes. The tax effect for 2012 represents the difference between our GAAP tax benefit of $19.2 million and our calculated non-GAAP tax expense of $9.9 million. Tax effects for 2011 and 2010 were calculated using the effective tax rates of 49.2% and 20.7%, respectively.

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(2) The convertible term loan was determined to be dilutive to non-GAAP net income per share, diluted for the year ended December 31, 2012. As such, for the year ended December 31, 2012, non-GAAP net income was adjusted for $645,000 of interest expense related to the convertible term loan, net of tax effects. Non-GAAP net income adjusted for the related interest expense, net of tax effects, was divided by the sum of the weighted-average number of common shares and dilutive common share equivalents outstanding during the year, as adjusted for the impact of the shares related to the convertible debt of approximately 2.2 million shares for the year ended December 31, 2012.

Liquidity and Capital Resources

Sources of Liquidity

We require cash to meet our operating expenses and for capital expenditures, acquisitions and in-licenses of rights to products. To date, we have funded our operations primarily from product sales, royalty agreement revenues, and an investment from Chiesi. In June 2012, we entered into the Term Loans with Chiesi with proceeds of $90.0 million, which are described below. We used the proceeds from the Term Loans, together with $36.4 million of cash on hand, to fund our acquisition of EKR. As of December 31, 2012, we had $56.3 million in cash and cash equivalents.

Cash Flows

The following table provides information regarding our cash flows (in thousands):

	Year Ended December 31,		
	2012	**2011**	**2010**
Cash provided by (used in):			
Operating activities	$ 18,387	$ 24,172	$ 32,989
Investing activities	(125,196)	(616)	(623)
Financing activities	89,091	(533)	(274)
Net (decrease) increase in cash and cash equivalents	$ (17,718)	$ 23,023	$ 32,092

Net Cash Provided By Operating Activities

Our primary sources of operating cash flows are product sales. Our primary uses of cash in our operations are for funding working capital, selling, general and administrative expenses and royalties.

Net cash provided by operating activities in 2012 reflected our net loss of $11.9 million, adjusted by non-cash expenses totaling $38.8 million and changes in operating assets and liabilities totaling $8.5 million. Non-cash items consisted primarily of amortization and depreciation of $18.7 million, CARDENE I.V. charitable inventory donation of $11.7 million, RETAVASE inventory write-off of $14.6 million, impairment of LIXAR product rights of $11.5 million, offset by fair value adjustments to acquisition-related contingent payments of $11.9 million primarily related to delays in regulatory approval of LIXAR and RETAVASE and changes in deferred income taxes of $16.1 million primarily comprised of the recognition of the deferred tax liability related to the tax effects of the acquisition accounting adjustments on inventory and the release of the valuation allowance related to federal net operating losses. Changes in operating assets and liabilities were primarily affected by accounts receivable, prepaid expenses and other assets of $1.7 million, offset by decreases in accounts payable, accrued expenses and other liabilities of $4.5 million and an increase in inventories of $2 million and income tax receivable of $2.2 million. Change in our acquisition-related assets and liabilities relate primarily to severance paid to former employees before reimbursement from the former shareholders of EKR.

Net cash provided by operating activities in 2011 reflected our net loss of $693,000, adjusted by non-cash expenses totaling $32.9 million and changes in accounts receivable, inventories, income tax receivable, accrued expenses and other operating assets and liabilities totaling $57.8 million.

Net cash provided by operating activities in 2010 reflected our net income of $6.2 million, adjusted by non-cash expenses totaling $76.0 million and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling $49.1 million.

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Net Cash Used in Investing Activities

Our primary uses of cash in investing activities are the purchase of property and equipment and the acquisition and licensing of product rights.

Net cash used in investing activities in 2012 primarily reflected $126.9 million of cash paid for our acquisition of EKR and Cardiokine, net of cash acquired, and $1.0 million paid for the acquisition of the BETHKIS license, partially offset by $3.0 million of proceeds allocated to the divested anti-infective product rights.

Net cash used in investing activities in 2011 reflected the purchase of property and equipment for $616,000.

Net cash used in investing activities in 2010 primarily reflected the purchase of property and equipment for $373,000 and the purchase of product rights for $250,000, partially offset by proceeds from the sale of equipment.

Net Cash Provided by (Used in) Financing Activities

Our primary sources of historical cash flows from financing activities are the investment by and Term Loan Facility with Chiesi. Going forward, we expect our primary sources of cash flows from financing activities to be equity or debt issuances or arrangements we may make or enter into. Our primary uses of cash in financing activities are to acquire companies, and marketed, registration-stage, or late-stage development products that fit within our focus areas.

Net cash provided by financing activities in 2012 primarily reflected the proceeds from our long-term debt of $90.0 million and proceeds from common stock option exercises and related excess tax benefits of $1.4 million, partially offset by contingent payments relating to the acquisition-related contingent consideration with respect to CARDENE I.V. of $1.6 million and payment of debt financing costs of $511,000.

Net cash used in financing activities in 2011 reflected $1.4 million in principal payments on our license agreement liability and capital leases, partially offset by proceeds of $369,000 from common stock option exercises and related tax benefits of $522,000.

Net cash used in financing activities in 2010 reflected $1.3 million in principal payments on our license agreement liability and capital leases, partially offset by proceeds of $544,000 from common stock option exercises and related tax benefits of $478,000.

Funding Requirements

Our future capital requirements will depend on many factors, including:

- the level of product sales and product returns of our currently marketed products and any additional products that we may market in the future;
- the scope, progress, results and costs of development activities for our current product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, additional product candidates that we pursue;
- the extent to which we acquire or invest in products, businesses and technologies;
- the costs of commercialization activities, including product marketing, sales and distribution;

the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates and products;

the extent to which we are required to make certain contingent payments in connection with our acquisitions;

the extent to which we may be required to prepay our indebtedness under the Term Loan Facility;

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- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products and product candidates; and

- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending claims related to intellectual property owned by or licensed to us.

To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. We have no committed external sources of funds. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

As of December 31, 2012, we had $56.3 million of cash and cash equivalents on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents and anticipated revenues from product sales are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for at least the next 12 months.

Term Loan Facility

On June 21, 2012, we entered into the Credit Agreement with Chiesi in connection with our acquisition of EKR. The Credit Agreement governs the senior secured Term Loan Facility with Chiesi, which is comprised of a five-year Term Loan A of $60.0 million and five-year Term Loan B of $30.0 million, which we refer to as the Term Loans. The Term Loans were funded on June 25, 2012 and the acquisition of EKR closed on June 26, 2012. The proceeds of the Term Loan Facility were used, together with our cash on hand, to finance the acquisition of EKR and the related fees and expenses incurred by us in connection with the acquisition. All obligations under the Term Loan Facility are guaranteed by our domestic subsidiaries, and are secured by a security interest in substantially all of our assets and our domestic subsidiaries assets. Under the Credit Agreement, Chiesi is the administrative agent and collateral agent in respect of the Term Loan Facility.

Term Loan A and Term Loan B bear interest at rates of 7.5% and 6.5% per year, respectively, payable quarterly in arrears on the last business day of each fiscal quarter beginning on September 28, 2012. Term Loan A requires quarterly principal payments of $3.5 million commencing on the fiscal quarter ending December 31, 2014 with any balance due at maturity. The Term Loans are due and payable on June 23, 2017, unless previously prepaid or in the case of Term Loan B, converted into shares of common stock, prior to such date.

We may prepay the Term Loans, in whole or in part without any premium or penalty, provided any prepayments of principal amounts are $5.0 million or whole multiples of $1.0 million in excess thereof, plus any accrued and unpaid interest. The prepayments will be applied first, ratably to the remaining installments of principal of the Term Loan A (excluding the payment due at maturity), second, to any remaining amounts outstanding on Term Loan A, and third, to the outstanding principal on Term Loan B.

We are required to prepay all or a portion of the Term Loan Facility under the following conditions: (i) if our ratio of consolidated secured debt to Consolidated EBITDA (as defined in the Credit Agreement) is at least 2 to 1 for any fiscal year ending on or after December 31, 2013, by using 50% of our Consolidated Excess Cash (as defined in the Credit Agreement), or (ii) if we undertake certain asset sales or sales of capital stock and do not reinvest the proceeds according to the terms of the Credit Agreement.

Term Loan B contains a conversion option for a two-year period, expiring on June 21, 2014, which provides Chiesi the option, exercisable in its sole discretion, to convert all or a portion of the Term Loan B into shares of common stock at a conversion price equal to $7.098 per share, subject to adjustment under certain conditions. Conversions shall be no less than $5.0 million unless the remaining principal amount of Term Loan B is less than $5.0 million.

The Term Loans are collateralized by substantially all of our assets, including the assets of our subsidiaries that are guarantors of the Term Loans. The Credit Agreement contains customary representations, covenants and events of default. Upon an Event of Default (as defined in the Credit Agreement), (i) the interest rates for Term Loan A and Term Loan B will each increase by 2% and (ii) Chiesi may declare all outstanding principal and accrued but unpaid interest under the Term Loan Facility to be immediately due and payable. In addition, we are

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subject to covenants prohibiting the payment of any dividends (other than stock dividends) and restricting or limiting other restricted payments, certain corporate activities, transactions with affiliates, incurrence of debt (which debt limit expressly permits, among other things, a secured working capital facility of up to $25 million), liens on properties and asset dispositions. We are not subject to any financial covenants other than the mandatory prepayment provisions discussed above.

In connection with the Term Loans, we incurred $511,000 of debt financing costs, which primarily consisted of legal and other professional fees. These costs are being amortized and are recorded as additional interest expense through the maturity of the loans.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, contingent royalty payments and/or scientific, regulatory or commercial milestone payments under development agreements. The following table summarizes our contractual obligations as of December 31, 2012 (in thousands):

		Payments Due by Period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Long-term debt obligations(1)	$ 115,708	$ 6,540	$ 29,911	$ 79,257	$
Capital lease obligations	80	41	39		
Operating lease obligations(2)	1,900	565	1,183	152	
Purchase obligations(3)	85,872	30,884	25,630	29,330	28
Total(4)	$ 203,560	$ 38,030	$ 56,763	$ 108,739	$ 28

(1) Long-term debt obligations represent future minimum principal and interest payments due under both our Term Loan A and Term Loan B assuming that the loans remain outstanding until maturity, the conversion option for Term Loan B is not exercised and the default rate of interest is not triggered.

(2) Operating leases represent minimum payments under leases for our facilities and automobiles. Our total minimum lease payments for our corporate headquarters are $536,000 in 2013, $584,000 in 2014, $599,000 in 2015, $152,000 in 2016 and $0 thereafter.

(3) Purchase obligations represent fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers of $56.4 million; clinical trial and research agreements with contract research organizations and consultants of $1.1 million; agreements with providers of marketing analytical services of $4.1 million; and open purchase orders for the acquisition of goods and services in the ordinary course of business of $24.2 million.

(4) Excluded from the contractual obligations table are (i) potential payments of up to $167.5 million for contingent consideration that we may be required to pay in connection with our acquisitions of Cardiokine and EKR; (ii) $8.4 million in potential future milestone payments as part of our other licensing, distribution and development agreements; (iii) a contingent liability of $909,000 related to our divestiture of Factive; and (iv) anticipated payments under the assumed contingent consideration arrangement related to the ready-to-use formulation of CARDENE I.V., which is based on a percentage of net sales. We have excluded these potential liabilities and milestone payments from the contractual obligations table because we are unable to precisely predict the timing or ultimate cash settlement amounts of these payments. See Note 3 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for more information regarding the potential payments related to our acquisition of Cardiokine and milestone payments related to our licensing, distribution and development agreements.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet arrangements, including structured finance, special purpose entities or variable interest entities.

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Effects of Inflation

We do not believe that inflation has had a significant impact on our revenues or results of operations since inception. We expect our cost of product sales and other operating expenses will change in the future in line with periodic inflationary changes in price levels. Because we intend to retain and continue to use our property and equipment, we believe that the incremental inflation related to the replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources. While our management generally believes that we will be able to offset the effect of price-level changes by adjusting our product prices and implementing operating efficiencies, any material unfavorable changes in price levels could have a material adverse effect on our financial condition, results of operations and cash flows.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with GAAP. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and other financial information. We base these estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances, and these estimates form the basis for our judgments concerning the carrying values of assets and liabilities that are not readily apparent from other sources. We periodically evaluate our estimates and judgments based on available information and experience. Actual results could differ from our estimates under different assumptions and conditions. If actual results significantly differ from our estimates, our financial condition and results of operations could be materially impacted.

We believe that the accounting policies described below are critical to understanding our business, results of operations and financial condition because they involve more significant judgments and estimates used in the preparation of our consolidated financial statements. An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that could have been used, or changes in the accounting estimate that are reasonably likely to occur periodically, could materially impact our consolidated financial statements. See Note 2 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for a description of our significant accounting policies and methods used in preparation of our consolidated financial statements.

Revenue Recognition

We record revenue from product sales, license agreements and royalty agreements when realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed or determinable; and (4) collectability is reasonably assured.

Net Product Sales

Product Sales. We recognize revenue from our product sales upon transfer of title, which occurs when product is received by our customers. We sell our products primarily to large national wholesalers, which have the right to return the products they purchase. We estimate the amount of future returns at the time of revenue recognition. We recognize product sales net of estimated allowances for product returns, rebates, price adjustments, chargebacks, and prompt payment and other discounts. When we cannot reasonably estimate the amount of future product returns, we record revenues when the risk of product return has been substantially eliminated. Deferred revenue is recorded net of estimated allowances for rebates, price adjustments, chargebacks, and prompt payment and other discounts. The deferred revenue is recognized when the product is sold through to the end user based upon prescriptions filled. To estimate product sold through to end users, we rely on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sell-through to customers.

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When we implement a price increase, we generally offer our existing customers an opportunity to purchase a limited quantity of product at the previous list price. Shipments resulting from these programs generally are not materially in excess of ordinary levels; therefore, we recognize the related revenue when the product is received by the customers and include the shipments in estimating our various product related allowances. In the event we determine that these shipments represent purchases of inventory in excess of ordinary levels for a given wholesaler, the potential impact on product returns exposure is specifically evaluated and reflected as a reduction in revenue at the time of such shipments.

Product Returns. Consistent with industry practice, we offer contractual return rights that allow our customers to return the majority of our products within an 18-month period that begins six months prior to and ends twelve months subsequent to expiration of the products. Our products have an 18- to 24-month expiration period from the date of manufacture. In determining our return allowance, we consider various relevant factors, including:

Actual and historical return rates for expired lots. Our historical return rates for expired lots vary by product and approximate, on a product by product basis, our current return rates.

Historical and forecasted product sales and consumer consumption data reported by external information management companies. Management reviews sales forecasts and consumption data on a product by product basis to assist it in estimating whether product is expected to become short-dated and thus subject to return.

Estimated expiration dates or remaining shelf life of inventory in the distribution channel. Our products generally have remaining shelf lives of between 12 to 22 months at time of shipment.

Levels of inventory in the distribution channel and any significant changes to these levels. Levels of inventory in the distribution channel typically range from three to eight weeks of product demand.

Competitive issues such as new product entrants and other known changes in sales trends.

Based on the above factors, management determines an estimated return rate for each product and applies that rate to the quantity of units sold that is subject to future return. As of December 31, 2012, our estimated return rates for products currently subject to return ranged from 1% to 17% depending on the product.

We routinely assess our experience with product returns and adjust our reserves accordingly. The amount of actual product returns could be either higher or lower than the amounts we have accrued. Changes in our returns estimates are charged to income in the period in which the information that gives rise to the change becomes known.

If our estimates of returns differ from our actual results, there could be a material impact on our financial statements. Based on historical experience, our average actual return rates vary based on our product mix. We consider a one-percentage point variation to be a reasonably possible change in the percentage of our product returns to related gross sales on a product by product basis. A one-percentage point increase or decrease in each of the individual products estimated product returns rate would have had an approximate $1.8 million, or 2%, effect on our net revenues recognized in 2012.

Expense recognized for product returns was $10.2 million, $15.5 million and $20.1 million in 2012, 2011 and 2010, respectively, representing 6%, 9% and 11% of gross product sales in 2012, 2011 and 2010, respectively. Expense recognized during 2012 for product returns related to current year sales was $8.7 million, or 5% of gross product sales. Expense recognized during 2012 for product returns related to sales made in prior years was $1.5 million, or 1% of gross product sales, which primarily related to products we no longer market.

Rebates. The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program s administrator.

Expense recognized for rebates was $4.4 million, $4.5 million and $4.7 million in 2012, 2011 and 2010, respectively, representing approximately 2%, 3% and 3% of gross product sales in 2012, 2011 and 2010, respectively. There were no significant current period

adjustments during 2012 related to prior period provisions for rebates. We do not expect future changes in our estimates for rebates to be material.

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Price Adjustments and Chargebacks. Our estimates of price adjustments and chargebacks are based on our estimated mix of sales to various third-party payers, which are entitled either contractually or statutorily to discounts from the listed prices of our products. These estimates are also based on the contract fees we pay to certain group purchasing organizations, or GPOs. We make these estimates based on the facts and circumstances known to us in accordance with GAAP. In the event that the sales mix to third-party payers or the contract fees paid to GPOs are different from our estimates, we may be required to pay higher or lower total price adjustments and/or chargebacks than we have estimated.

From time to time, we offer certain promotional incentives to our customers for our products, and we expect that we will continue this practice in the future. These programs include certain product incentives to pharmacy customers and other sales stocking allowances. We have voucher programs for ZYFLO CR whereby we offer a point-of-sale subsidy to retail consumers. We estimate our liability for each promotional program and record the liabilities as price adjustments. We estimate our liability for these voucher programs based on the historical redemption rates for similar completed programs used by other pharmaceutical companies as reported to us by a third-party claims processing organization and actual redemption rates for our completed programs. In addition, we offer a customer loyalty program for CARDENE I.V. We estimate our liability for this program based on historical participation and redemption rates as well as projected sales for individual customers during the program evaluation period. We account for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

Expense recognized for price adjustments and chargebacks was $42.9 million, $40.6 million and $34.5 million in 2012, 2011 and 2010, respectively, representing approximately 24%, 25% and 18% of gross product sales in 2012, 2011 and 2010, respectively. There were no current period adjustments during 2012 related to prior period provisions for price adjustments and chargebacks. We do not expect future changes in our estimates for price adjustments and chargebacks to be material.

Prompt Payment Discounts. We typically require our customers to remit payments within the first 30 to 35 days, depending on the customer and the products purchased. In addition, we offer wholesale distributors a prompt payment discount if they make payments within these deadlines. This discount is generally 2%, but may be higher in some instances due to product launches or customer and/or industry expectations. Because our wholesale distributors typically take the prompt payment discount, we accrue 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of our original sale to them, and we apply earned discounts at the time of payment. We adjust the accrual periodically to reflect actual experience. Historically, these adjustments have not been material. We do not anticipate that future changes to our estimates of prompt payment discounts will have a material impact on our net revenue.

Expense recognized for prompt payment discounts was $3.5 million, $3.4 million and $3.9 million in 2012, 2011 and 2010, respectively, representing approximately 2% of gross product sales in each year.

See Schedule II Valuation and Qualifying Accounts included in Item 8. Financial Statements and Supplementary Data for a reconciliation of our sales allowances and related accrual balances.

License and Royalty Agreement Revenues

Payments from our licensees are recognized as revenue based on the nature of the arrangement (including its contractual terms), the nature of the payments and applicable accounting guidance. Non-refundable fees where we have no continuing performance obligations are recognized as revenues when there is persuasive evidence of an arrangement and collection is reasonably assured. If we have continuing performance obligations, nonrefundable fees are deferred and recognized ratably over the estimated performance period. At-risk milestone payments, which are typically related to regulatory, commercial or other achievements by our licensees, are recognized as revenues when the milestone is accomplished and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed.

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Goodwill and Intangible Assets

Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. If the acquired net assets do not constitute a business, the transaction is accounted for as an asset acquisition and no goodwill is recognized. Other intangibles including product rights and acquired in-process research and development (IPR&D) are capitalized and recorded at fair value. Acquisitions of businesses may involve contingent consideration to be potentially paid based upon the occurrence of future events. Acquisition-related contingent consideration is initially recognized at fair value and then remeasured each reporting period.

Product rights are amortized over the estimated useful life of the product or the remaining trademark or patent life on a straight-line or other basis to match the economic benefit received. Amortization begins once FDA approval has been obtained and commercialization of the product begins, which we target launching shortly following regulatory approval. We evaluate our product rights on an ongoing basis to determine whether a revision to their useful lives should be made. This evaluation is based on our projection of the future cash flows associated with the products.

Acquired IPR&D is initially characterized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. When the related research and development is completed, the asset will be assigned a useful life and amortized. Our acquired IPR&D is classified as product rights on the accompanying consolidated balance sheets.

We evaluate the recoverability of our long-lived assets, including property and equipment and identifiable intangible assets, on an exception basis whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets is not recoverable. Events or circumstances that may be indicative of impairment include a significant adverse change in the business climate that could affect the value of the rights or a change in the extent or manner in which the rights are used such as regulatory actions. We measure the recoverability of assets to be held and used by comparing the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. Our assumptions about future revenues and expenses require significant judgment associated with the forecast of the performance of our products. Actual revenues and costs could vary significantly from these forecasted amounts. If actual cash flows are significantly different than our forecasted amounts, we could determine that some or all of our capitalized product rights are impaired. If such assets are considered to be impaired, the impairment equals the amount by which the carrying amount of the assets exceeds the fair value of the assets. Any write-downs are recorded as permanent reductions in the carrying amount of the assets. As of December 31, 2012, we had an aggregate of $232.1 million in capitalized product rights, which we expect to amortize over remaining periods of approximately three to fifteen years.

Goodwill and indefinite-lived intangible assets, including acquired IPR&D, are reviewed for impairment on an annual basis or more frequently if events or circumstances indicate that goodwill or indefinite-lived intangible assets may be impaired. Examples of those events or circumstances that may be indicative of impairment include a significant adverse change in the business climate or changes in our cash flow projections or forecast that demonstrate losses. Our goodwill evaluation is based on both qualitative and quantitative assessments regarding the fair value of goodwill relative to its carrying value. We assess qualitative factors to determine if our sole reporting unit s fair value is more likely than not to exceed its carrying value, including goodwill. Factors assessed in the qualitative approach are cash flow forecasts of our reporting unit, the strength of our balance sheet, changes in strategic outlook or organizational structure, industry and market changes and macroeconomic indicators. In the event we determine that it is more likely than not that our reporting unit s fair value is less than its carrying amount, quantitative testing is performed comparing recorded values to estimated fair values. Fair values are based on discounted cash flows using a discount rate determined by our management to be consistent with industry discount rates and the risks inherent in our current business model. Other assumptions include, but are not limited to, our estimation of the amount and timing of future cash flows from products and product candidates and the estimation of related costs that are dependent on the size of our sale forces and research and development activity. If the fair value exceeds the carrying value, goodwill is not impaired. If the carrying value exceeds the fair value, then we would calculate the potential impairment loss by comparing the implied fair value

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of goodwill with the book value. If the implied fair value of goodwill is less than the carrying value, then an impairment charge would be recorded. We perform our annual evaluation of goodwill as of October 1 of each fiscal year. At December 31, 2012, we had $33.4 million in goodwill. There was no impairment to goodwill during the year ended December 31, 2012. Due to uncertain market conditions and potential changes in our strategy, product portfolio or reportable segments, it is possible that the forecasts we use to support goodwill could change in the future, which could result in goodwill impairment charges that would adversely affect our results of operations and financial condition.

Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of the asset to its carrying value, without consideration of any recoverability test. During December 2012, we recognized an impairment charge of $11.5 million related to our acquired IPR&D asset, LIXAR. The impairment charge was based on our determination of the fair value of the asset on December 31, 2012 considering the CRL received in October 2012. We determined the fair value using a probability-weighted income approach with a risk adjusted discount rate of 20%. The resulting fair value was determined to be zero resulting in a full impairment of the carrying value. The impairment charge is included in other operating expenses, net in the accompanying consolidated statements of comprehensive (loss) income.

Acquisition-related contingent consideration recognized at fair value as of the acquisition date must be remeasured each reporting period, or whenever events or changes in circumstances indicate that the fair value may have changed. The estimates of fair value contain uncertainties as they involve assumptions about the likelihood and timing of achieving specified milestone criteria, projections of future financial performance and assumed discount rates. A change in any of these assumptions could result in a different fair value, which could have a material impact on our results of operations. In connection with our acquisition of EKR, we recorded $37.8 million of acquisition-related contingent consideration, of which $13.9 million related to amounts potentially payable for RETAVASE. We used a discounted cash flow analysis incorporating the probability of estimated future cash flows related to the future payment of potential milestones and royalty payments based on the current regulatory status of RETAVASE, using risk-adjusted discount rates. Changes to the discount rate would have an inverse effect on the liability s fair values. During the fourth quarter of 2012, we experienced delays in the approval of our new manufacturer for RETAVASE due to (1) additional data elements being requested by the FDA in its December 2012 CRL and (2) the drug product not achieving the established stability specifications. As a result, we decreased the fair value of the contingent consideration by $1.5 million and recorded a corresponding gain which is included in change in acquisition-related contingent payments in the accompanying consolidated statements of comprehensive (loss) income.

Similarly, we recorded an $8.8 million contingent liability for potential payments payable under our merger agreement with Cardiokine. The initial fair value of this liability was determined using a discounted cash flow analysis incorporating the estimated future cash flows related to the future payment of potential milestones and royalty payments based on the current regulatory status and the probability of the FDA s approval of LIXAR, using risk-adjusted discount rates. During the fourth quarter of 2012, we received a CRL from the FDA following the FDA s review of a NDA for LIXAR. The FDA has requested we complete additional clinical studies to further evaluate the efficacy and safety of lixivaptan in both heart failure patients and syndrome of inappropriate antidiuretic hormone patients. As a result, we decreased the fair value of the contingent payments by $8.8 million based on revised assumptions of the probability of the FDA s approval of LIXAR and recorded a corresponding gain included in change in acquisition-related contingent payments in the accompanying consolidated statements of comprehensive (loss) income.

Inventory

Inventory consists of raw materials, work in process and finished goods. Raw materials include the API for a product to be manufactured, work in process includes the bulk inventory of tablets that are in the process of being coated and/or packaged for sale, and finished goods include pharmaceutical products ready for commercial sale or distribution as samples. Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out, or FIFO, method. Our estimate of the net realizable value of our inventories is subject to judgment and estimation. The actual net realizable value of our inventories could vary significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting

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period. In evaluating whether inventory is stated at the lower of cost or market, we consider such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. On a quarterly basis, we analyze our inventory levels and record allowances for inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory that is in excess of expected demand based upon projected product sales. As of December 31, 2012, we had $13.5 million in inventory and an inventory reserve of $2.1 million.

We expense costs relating to the purchase and production of pre-approval inventories for which the sole use is research and development in the period incurred until such time as we believe future commercialization is probable and future economic benefit is expected to be recognized. With respect to capitalization of unapproved product candidates, we produce inventory in preparation for the launch of the product and in amounts sufficient to support forecasted initial market demand. Typically, capitalization of such inventory does not begin until the product candidate is considered to have a high probability of regulatory approval. This generally will occur only after we have submitted an NDA to the FDA, and only if our assessment of the status of the regulatory review has led us to conclude there is a high probability of receiving regulatory approval. If we are aware of any specific risks or contingencies that are likely to impact the regulatory approval process or if there are any specific issues identified during our research and development process relating to safety, efficacy or manufacturing of the product candidate, we would not capitalize the related inventory.

We manage the levels of inventory at each stage of the manufacturing process to optimize the shelf life of the inventory and avoid product expiration issues relative to anticipated market demand following launch. On a quarterly basis, we evaluate all inventory, including inventory capitalized for which regulatory approval has not yet been obtained, to determine if any lower of cost or market adjustment is required. As our evaluation relates to pre-approval inventory, we consider several factors, including expected timing of FDA approval, projected sales volume, expiration dates of the inventory and estimated selling price. Projected sales volume is based on several factors including market research, sales of similar products and competition in the market. Estimated sales price is based on the price of existing products sold for the same indications, market research and expected market demand.

Once we have capitalized inventory for a product candidate that is not yet approved, we will monitor, on a quarterly basis, the status of such candidate within the regulatory approval process. We could be required to expense previously capitalized costs related to pre-approval inventory upon a change in our judgment of future commercialization and future economic benefit expected to be recognized, including due to a denial or delay of approval by the FDA, a delay in the timeline for commercialization or other potential factors. At December 31, 2012, inventories included $752,000 of costs capitalized as raw materials prior to regulatory approval of the sBLA for RETAVASE. During the fourth quarter of 2012, we determined that $14.6 million of previously capitalized inventory would no longer be saleable at the expected time of commercial launch. The inventory write-off is included in other operating expenses, net in the accompanying consolidated statements of comprehensive (loss) income. The sBLA is intended to qualify SCIL as the new API supplier for RETAVASE, and to modify the existing approved BLA to include an intermediate step in the finished good manufacturing process.

Stock-Based Compensation

We measure stock-based compensation for share-based payment awards granted to employees and non-employee directors on the grant date at fair value. We account for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued, whichever is more reliably measured. Stock-based compensation related to share-based payment awards granted to non-employees is adjusted each reporting period for changes in the fair value of our stock until the measurement date. The measurement date is generally considered to be the date when all services have been rendered or the date that options are fully vested.

We currently use the Black-Scholes-Merton option-pricing model to calculate the fair value of stock-based compensation awards. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of

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complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, the expected term of the award, the risk-free interest rate and any expected dividends.

The expected stock price volatility was based our historical volatility for the five year period preceding the grant date. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The expected life was estimated based on historical exercise patterns for previous grants, taking into account employee exercise strategy and cancellation behavior.

We do not intend to pay dividends on our common stock in the foreseeable future and, accordingly, we use a dividend rate of zero in the option-pricing model. We are required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting forfeitures and record stock-based compensation expense only for those awards that are expected to vest. All stock-based payment awards that vest based on service, including those with graded vesting schedules, are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods. As of December 31, 2012, there was $2.9 million and $672,000 of total unrecognized compensation cost related to stock options and unvested restricted stock, respectively. These costs are expected to be recognized over a weighted-average period of 2.24 and 1.55 years, respectively.

If factors change and we employ different assumptions for estimating stock-based compensation expense in future periods or if we decide to use a different valuation model, the stock-based compensation expense we recognize in future periods may differ significantly from what we have recorded in the current period and could materially affect our operating income, net income and earnings per share. This may result in a lack of consistency in future periods and materially affect the fair value estimate of stock-based payments. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

Income Taxes

We had an effective tax rate of 61.8%, 49.2% and 20.7% in 2012, 2011 and 2010, respectively. In 2012, the increase in the effective tax rate was primarily attributable to an additional tax benefit associated with the release of a portion of the valuation allowance as well the fact that we recorded a benefit associated with our pre-tax book loss for the period. We anticipate that our future annual effective income tax rate will approximate the appropriate statutory tax rates of each of the jurisdictions in which we operate and we expect that our cash payments for taxes will exceed our income tax expense during the next three years. This difference is primarily due to our large temporary differences, or deferred tax liabilities related to amortization, reversing over the next three years.

We account for income taxes under the asset and liability method, which requires that we recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and the tax basis of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse. Our deferred tax assets and liabilities are recorded at an amount calculated using appropriate federal and state statutory tax rates of each of the jurisdictions in which we operate.

We record net deferred tax assets to the extent we believe these assets will more likely than not be realized. In making such determinations, we consider all available positive and negative evidence, including reversals of existing temporary differences, projected future taxable income, tax planning strategies and recent financial operations. A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. We review deferred tax assets periodically for recoverability and make estimates and judgments in assessing the need for a valuation allowance.

As of December 31, 2012, we had approximately $77.5 million in deferred tax assets. We determined that a $54.1 million valuation allowance relating to deferred tax assets for net operating losses and tax credits from the merger with Critical Therapeutics, Inc. in October 2008 and our acquisition of Cardiokine in December 2011 was necessary. If the estimates and assumptions used in our determination change in the future, we could be required

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to revise our estimates of the valuation allowances against our deferred tax assets and adjust our provision for income taxes accordingly.

We recognize a tax benefit from uncertain positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. During 2012, we had a change in judgment related to a tax position taken in a prior period. The change was a result of additional guidance provided by the Internal Revenue Service. We reduced our unrecognized tax position by $382,000 during the second quarter. As of December 31, 2012, we had no unrecognized tax benefits. We do not expect to have any additional unrecognized tax benefits during the next twelve months.

Recently Issued Accounting Pronouncements

Indefinite-Lived Intangible Assets Impairment Testing

In July 2012, the Financial Accounting Standards Board issued Accounting Standards Update 2012-02 Testing Indefinite-Lived Intangible Assets for Impairment, final guidance concerning the testing of indefinite-lived intangible assets for impairment. This guidance modifies both annual and interim impairment testing to allow the inclusion of qualitative factors in the assessment of whether a quantitative impairment test is necessary. Thus, entities are no longer required to calculate the fair value of an indefinite-lived intangible asset unless they conclude through an assessment of qualitative factors that it is more likely than not that the carrying value of the indefinite-lived intangible asset exceeds its fair value. When an entity s qualitative assessment reveals that indefinite-lived intangible asset impairment is more likely than not, the entity must perform the quantitative impairment test. The amendments did not change the existing accounting guidance on how this impairment test is performed. This guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. The adoption of this guidance is not expected to have a significant impact on our consolidated financial statements.

See Note 17 of our Notes to Consolidated Financial Statements of this annual report on Form 10-K for a description of recently adopted accounting pronouncements.

ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

Interest Rate Risk

Our exposure to market risk is confined to our cash equivalents, all of which have maturities of less than three months and bear and pay interest in U.S. dollars. Since we invest in highly liquid, relatively low yield investments, we do not believe interest rate changes would have a material impact on us.

Our risk associated with fluctuating interest expense is limited to future capital leases and other short-term debt obligations we may incur in our normal operations. The impact of fluctuations in interest expense related to future capital leases is expected to be immaterial to our consolidated financial statements. The interest rates on our existing long-term debt borrowings are fixed and as a result, interest due on borrowings are not impacted by changes in market-based interest rates. We do not have any other instruments with interest rate exposure.

Foreign Currency Exchange Risk

The majority of our transactions occur in U.S. dollars and we do not have investments in foreign countries. Therefore, we are not subject to significant foreign currency exchange risk. We currently have one supply contract denominated in Euros and two development agreements denominated in foreign currencies, Euros and Swiss francs. Unfavorable fluctuations in these exchange rates could have a negative impact on our consolidated financial statements. The impact of changes in the exchange rates related to these contracts was immaterial to our consolidated financial statements for the years ended December 31, 2012, 2011 and 2010. We do not believe a fluctuation in these exchange rates would have a material impact on us. To date, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. These circumstances may change.

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ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

Cornerstone Therapeutics Inc.

We have audited the accompanying consolidated balance sheet of Cornerstone Therapeutics Inc. and subsidiaries as of December 31, 2012, and the related consolidated statements of comprehensive loss, stockholders equity, and cash flows for the year ended December 31, 2012. Our audit also included the financial statement schedule for the year ended December 31, 2012 listed in the index at Item 8. These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cornerstone Therapeutics Inc. and subsidiaries as of December 31, 2012, and the consolidated results of their operations and their cash flows for the year ended December 31, 2012, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ ERNST & YOUNG LLP

Raleigh, North Carolina

March 14, 2013

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Cornerstone Therapeutics Inc.

We have audited the accompanying consolidated balance sheet of Cornerstone Therapeutics Inc. (a Delaware corporation) and subsidiaries as of December 31, 2011, and the related consolidated statements of comprehensive (loss) income, stockholders equity, and cash flows for each of the two years in the period ended December 31, 2011. Our audits of the basic consolidated financial statements included the financial statement schedule listed for each of the two years in the period ended December 31, 2011 in the index appearing under Item 8. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cornerstone Therapeutics Inc. and subsidiaries as of December 31, 2011, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements referred to above taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ GRANT THORNTON LLP

Raleigh, North Carolina

March 6, 2012

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 56,250	$ 73,968
Accounts receivable, net	14,368	11,894
Inventories, net	11,384	9,419
Prepaid expenses	3,343	3,753
Income tax receivable	4,094	1,900
Deferred tax asset	1,614	2
Acquisition-related current assets	11,134	5,618
Other current assets	379	494
Total current assets	102,566	107,048
Property and equipment, net	1,310	1,574
Product rights, net	232,111	106,960
Goodwill	33,356	15,218
Amounts due from related parties		38
Deferred tax asset, less current portion		523
Other assets	32	953
Total assets	$ 369,375	$ 232,314
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 12,439	$ 5,526
Accrued expenses	37,379	34,993
Acquisition-related contingent payments	6,846	
Deferred revenue		1,428
Acquisition-related current liabilities	9,636	6,618
Other current liabilities	525	90
Total current liabilities	66,825	48,655
Acquisition-related contingent payments, less current portion	26,362	8,800
Long-term debt	89,540	
Deferred tax liability	15,683	
Other long-term liabilities	4,792	56
Total liabilities	203,202	57,511
Commitments and contingencies, Note 12		
Stockholders equity		
Preferred stock $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding		
Common stock $0.001 par value, 90,000,000 shares authorized; 26,348,470 and 25,803,864 shares issued and outstanding as of December 31, 2012 and December 31, 2011, respectively	26	26

Additional paid-in capital	167,461	163,203
(Accumulated deficit) retained earnings	(1,314)	11,574
Total stockholders equity	166,173	174,803
Total liabilities and stockholders equity	$ 369,375	$ 232,314

The accompanying notes are an integral part of these consolidated financial statements.

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

(In thousands, except share and per share data)

	Year Ended December 31,		
	2012	2011	2010
Net revenues	$ 116,084	$ 101,422	$ 125,317
Costs and expenses:			
Cost of product sales (exclusive of amortization of product rights)	42,579	37,823	45,015
Selling, general and administrative	46,404	45,877	53,198
Research and development	4,273	1,624	4,488
Amortization of product rights	17,929	14,368	14,378
Change in acquisition-related contingent payments	(11,896)		
Transaction-related expenses	8,354	467	
Other operating expenses, net	35,779	2,500	350
Total costs and expenses	143,422	102,659	117,429
(Loss) income from operations	(27,338)	(1,237)	7,888
Other expenses, net:			
Interest expense, net	(3,496)	(128)	(85)
Other expense, net	(299)		(25)
Total other expenses	(3,795)	(128)	(110)
(Loss) income before income taxes	(31,133)	(1,365)	7,778
Benefit from (provision for) income taxes	19,245	672	(1,609)
Net (loss) income	$ (11,888)	$ (693)	$ 6,169
Comprehensive (loss) income	$ (11,888)	$ (693)	$ 6,169
Net (loss) income per share, basic	$ (0.46)	$ (0.03)	$ 0.24
Net (loss) income per share, diluted	$ (0.46)	$ (0.03)	$ 0.24
Weighted-average common shares, basic	26,115,266	25,684,593	25,412,636
Weighted-average common shares, diluted	26,115,266	25,684,593	26,036,544

The accompanying notes are an integral part of these consolidated financial statements.

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Total Stockholders Equity
	Shares	Amount			
Balance as of December 31, 2009	25,022,644	$ 25	$ 157,745	$ 6,098	$ 163,868
Stock-based compensation			1,339		1,339
Issuance of common stock to employees under stock incentive plan	410,319		544		544
Tax effect of stock-based awards			478		478
Vesting of restricted stock	40,000				
Net income				6,169	6,169
Balance as of December 31, 2010	25,472,963	$ 25	$ 160,106	$ 12,267	$ 172,398
Stock-based compensation			2,207		2,207
Issuance of common stock to employees under stock incentive plan	273,181	1	368		369
Tax effect of stock-based awards			522		522
Vesting of restricted stock	57,720				
Net loss				(693)	(693)
Balance as of December 31, 2011	25,803,864	$ 26	$ 163,203	$ 11,574	$ 174,803
Stock-based compensation			2,961		2,961
Issuance of common stock to employees under stock incentive plan	438,449		1,159		1,159
Tax effect of stock-based awards			265		265
Vesting of restricted stock	128,370				
Settlement of restricted stock for tax withholding obligations	(22,213)		(127)		(127)
Dividend to related party for acquired product rights				(1,000)	(1,000)
Net loss				(11,888)	(11,888)
Balance as of December 31, 2012	26,348,470	$ 26	$ 167,461	$ (1,314)	$ 166,173

The accompanying notes are an integral part of these consolidated financial statements.

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CORNERSTONE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2012	**2011**	**2010**
Cash flows from operating activities			
Net (loss) income	$ (11,888)	$ (693)	$ 6,169
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Amortization and depreciation	18,660	14,896	14,778
Amortization of debt costs	51		
Provision for prompt payment discounts	3,474	3,448	3,903
Provision for other receivables	1,457		
Provision for inventory allowances	1,277	209	1,340
Acquisition accounting adjustment on inventory	4,178		
CARDENE® I.V. charitable inventory donation	11,662		
RETAVASE® inventory write-off	14,586		
Gain on sale of product rights	(1,969)		
Loss on disposal of property and equipment	299		25
Change in acquisition-related contingent payments	(11,896)		
Impairment of product rights	11,500	2,500	350
Stock-based compensation	2,961	2,207	1,339
Deferred revenue	(1,428)	(55,766)	57,194
Benefit from deferred income taxes	(16,062)	(388)	(2,977)
Changes in operating assets and liabilities:			
Accounts receivable	1,453	61,134	(63,831)
Inventories	(2,007)	5,546	1,592
Prepaid expenses and other assets	231	8,528	(8,743)
Accounts payable, accrued expenses, and other liabilities	(4,460)	(15,746)	23,653
Acquisition-related current assets and liabilities	(1,498)		
Income taxes receivable	(2,194)	(1,703)	(1,803)
Net cash provided by operating activities	18,387	24,172	32,989
Cash flows from investing activities			
Acquisition of businesses, net of cash acquired	(126,921)		
Purchase of product rights	(1,000)		(250)
Purchase of property and equipment	(275)	(616)	(373)
Proceeds from sale of product rights	3,000		
Net cash used in investing activities	(125,196)	(616)	(623)
Cash flows from financing activities			
Proceeds from term loans	90,000		
Payment of debt financing costs	(511)		
Proceeds from exercise of common stock options	1,159	369	544
Excess tax benefit from stock-based compensation	265	522	478
Payments related to net settlement of restricted stock	(127)		
Acquisition-related contingent payments	(1,603)		
Principal payments on license agreement liability		(1,341)	(1,250)
Principal payments on capital lease obligation	(92)	(83)	(46)

Net cash provided by (used in) financing activities	89,091	(533)	(274)
Net (decrease) increase in cash and cash equivalents	(17,718)	23,023	32,092
Cash and cash equivalents as of beginning of year	73,968	50,945	18,853
Cash and cash equivalents as of end of year	$ 56,250	$ 73,968	$ 50,945
Supplemental disclosure of cash flow information			
Cash paid during the year for interest	$ 3,059	$ 177	$ 318
Cash paid during the year for income taxes	$	$ 1,379	$ 6,780

The accompanying notes are an integral part of these consolidated financial statements.

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CORNERSTONE THERAPEUTICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: ORGANIZATION AND BASIS OF PRESENTATION

Nature of Operations

Cornerstone Therapeutics Inc., together with its subsidiaries (collectively, the Company), is a specialty pharmaceutical company focused on commercializing products for the hospital and adjacent specialty markets. Key elements of the Company s strategy are to focus its commercial and development efforts in the hospital and adjacent specialty markets within the U.S. pharmaceutical marketplace; continue to seek out opportunities to acquire companies and marketed or registration-stage products that fit within the Company s focus areas; and generate revenues by marketing approved generic products through the Company s wholly owned subsidiary, Aristos Pharmaceuticals, Inc.

Principles of Consolidation

The Company s consolidated financial statements include the accounts of Cornerstone Therapeutics Inc. and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Reclassifications

Acquisition-related current assets and liabilities previously included in other current assets and accrued expenses are stated separately on the accompanying consolidated balance sheets. In addition, certain accrued expenses previously included in accounts payable have been reclassified into accrued expenses in the accompanying consolidated balance sheets. Impairment charges related to the write-down of product rights previously included as amortization of product rights and the gain on divestiture of product rights previously classified separately are both included in other operating expenses, net. Such reclassifications had no effect on net (loss) income or stockholders equity as previously reported.

Going-Private Proposal

On February 18, 2013, the Company s Board of Directors received a proposal from Chiesi Farmaceutici S.p.A., the owner of approximately 60% of the outstanding shares of the Company s common stock (Chiesi), to acquire the shares of the Company s common stock that it does not already own for a cash purchase price of between $6.40 and $6.70 per share. The Company s Board of Directors has formed a Special Committee comprised of five independent directors to coordinate the Company s response to this proposal. As of March 14, 2013, no decisions have been made by the Special Committee with respect to the Company s response to the proposal.

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. The more significant estimates reflected in the Company s consolidated financial statements include certain judgments regarding revenue recognition, goodwill and intangible assets, inventory, stock-based compensation and income taxes. Actual results could differ from those estimates or assumptions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. The Company maintains its cash deposits with two federally insured banks. As of December 31, 2012, the majority of the Company s cash deposits were federally insured.

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Accounts Receivable

The Company typically requires its customers to remit payments within the first 30 to 35 days, depending on the customer and the products purchased. In addition, the Company offers wholesale distributors a prompt payment discount if they make payments within these deadlines. This discount is generally 2%, but may be higher in some instances due to product launches or customer and/or industry expectations. Because the Company s wholesale distributors typically take the prompt payment discount, the Company accrues 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of sale, and the Company applies earned discounts at the time of payment. The Company adjusts the accrual periodically to reflect actual experience. Historically, these adjustments have not been material. The allowance for prompt payment discounts was $320,000 and $585,000 as of December 31, 2012 and 2011, respectively.

The Company performs ongoing credit evaluations and does not require collateral. As appropriate, the Company establishes provisions for potential credit losses. In the opinion of management, no allowance for doubtful accounts was necessary as of December 31, 2012 or 2011. The Company writes off accounts receivable when management determines they are uncollectible and credits payments subsequently received on such receivables to bad debt expense in the period received. There were no write-offs during the years ending December 31, 2012, 2011, or 2010.

Inventories

Inventories are stated at the lower of cost or market value with cost determined under the first-in, first-out method and consist of raw materials, work in process and finished goods. Raw materials include the active pharmaceutical ingredient (API) for a product to be manufactured, work in process includes the bulk inventory of tablets or liquids that are in the process of being coated and/or packaged for sale, and finished goods include pharmaceutical products ready for commercial sale or distribution as samples.

Pre-approval inventory is expensed until it is probable that the inventory will be saleable. The Company capitalizes inventory costs associated with marketed products and certain products prior to regulatory approval and product launch, based on management s judgment of probable future commercial use and net realizable value. Capitalization of this inventory does not begin until the product candidate is considered to have a high probability of regulatory approval, which is generally after the Company has submitted a filing with the U.S. Food and Drug Administration (the FDA). If the Company is aware of any specific risks or contingencies that are likely to impact the expected regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling of the product candidate, the Company does not capitalize the related inventory. Once the Company capitalizes inventory for a product candidate that is not yet approved, the Company monitors, on a quarterly basis, the status of this candidate within the regulatory approval process, its projected sales volume and estimated selling price. The Company could be required to expense previously capitalized costs related to pre-approval inventory upon a change in its judgment of future commercial use and net realizable value, including due to a denial or delay of approval by regulatory bodies, a delay in the timeline for commercialization or other potential factors. At December 31, 2012, inventories included $752,000 of costs capitalized as raw materials prior to regulatory approval of the Supplemental Biologics License Application (sBLA) for RETAVASE. During the fourth quarter of 2012, the Company determined that $14.6 million of previously capitalized inventory would no longer be saleable at the expected time of approval and commercial launch. The inventory write-off was included in other operating expenses, net in the accompanying consolidated statements of comprehensive (loss) income. The sBLA is intended to qualify SCIL Proteins Production in Germany as a new supplier of reteplase, the API for RETAVASE, and to modify the existing approved Biologics License Application to include an intermediate step in the finished good manufacturing process.

On a quarterly basis, the Company analyzes its inventory levels and records allowances for inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected demand based upon projected product sales.

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Property and Equipment

The Company records property and equipment at cost. Major replacements and improvements are capitalized, while general repairs and maintenance are expensed as incurred. The Company depreciates its property and equipment over the estimated useful lives of the assets ranging from three to seven years using the straight-line method. Leasehold improvements are amortized over the lesser of their estimated useful lives or the lives of the underlying leases, whichever is shorter. Both depreciation and amortization expense for leasehold improvements has been included in selling, general and administrative expenses in the accompanying consolidated statements of comprehensive (loss) income.

Goodwill and Intangible Assets

Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. If the acquired net assets do not constitute a business, the transaction is accounted for as an asset acquisition and no goodwill is recognized. Other intangibles including product rights and acquired in-process research and development (IPR&D) are capitalized and recorded at fair value.

Product rights are amortized over the estimated useful life of the product or the remaining trademark or patent life on a straight-line or other basis to match the economic benefit received. Amortization begins once FDA approval has been obtained and commercialization of the product begins, which the Company targets launching shortly following regulatory approval. The Company evaluates its product rights on an ongoing basis to determine whether a revision to their useful lives should be made. This evaluation is based on management s projection of the future cash flows associated with the products.

Acquired IPR&D is initially characterized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. When the related research and development is completed, the asset will be assigned a useful life and amortized. The Company s acquired IPR&D is classified as product rights on the accompanying consolidated balance sheets.

The Company evaluates the recoverability of its long-lived assets, including property and equipment and identifiable intangible assets on an exception basis whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets is not recoverable. The Company measures the recoverability of assets to be held and used by comparing the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment equals the amount by which the carrying amount of the assets exceeds the fair value of the assets. Any write-downs are recorded as permanent reductions in the carrying amount of the assets.

Goodwill and indefinite-lived intangible assets including acquired IPR&D are reviewed for impairment on an annual basis or more frequently if events or circumstances indicate that goodwill or indefinite-lived intangible assets may be impaired. The Company s goodwill evaluation is based on both qualitative and quantitative assessments regarding the fair value of goodwill relative to its carrying value. The Company assesses qualitative factors to determine if its sole reporting unit s fair value is more likely than not to exceed its carrying value, including goodwill. In the event the Company determines that it is more likely than not that its reporting unit s fair value is less than its carrying amount, quantitative testing is performed comparing recorded values to estimated fair values. If the fair value exceeds the carrying value, goodwill is not impaired. If the carrying value exceeds the fair value, then the Company would calculate the potential impairment loss by comparing the implied fair value of goodwill with the carrying value. If the implied fair value of goodwill is less than the carrying value, then an impairment charge would be recorded. The Company performs its annual evaluation of goodwill as of October 1 of each fiscal year. There was no impairment to goodwill during 2012.

Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of the asset to its carrying value, without consideration of any recoverability test. During December 2012, the Company recognized an impairment charge of $11.5 million related to its acquired IPR&D asset, LIXAR®. For further discussion of the impairment, refer to Note 6 below.

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Revenue Recognition

The Company s consolidated net revenues represent the Company s net product sales and license and royalty agreement revenues. The following table sets forth the categories of the Company s net revenues (in thousands):

	Year Ended December 31,		
	2012	2011	2010
Gross product sales	$ 177,104	$ 165,383	$ 187,856
Sales allowances	(61,024)	(64,082)	(64,112)
Net product sales	116,080	101,301	123,744
License and royalty agreement revenues	4	121	1,573
Net revenues	$ 116,084	$ 101,422	$ 125,317

The Company records all of its revenue from product sales, license agreements and royalty agreements when realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed or determinable; and (4) collectability is reasonably assured.

Net Product Sales

Product Sales. The Company recognizes revenue from its product sales upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to large national wholesalers, which have the right to return the products they purchase. The Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns, rebates, price adjustments, chargebacks, and prompt payment and other discounts. When the Company cannot reasonably estimate the amount of future product returns, it defers revenues until the risk of product return has been substantially eliminated.

As of December 31, 2012 and 2011, the Company had $0 and $1.4 million of deferred revenue related to sales for which future returns could not be reasonably estimated at the time of sale. The deferred revenue was recognized when the product was sold through to the end user based upon prescriptions filled. To estimate product sold through to end users, the Company relied on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sell-through to customers. Deferred revenue was recorded net of estimated allowances for rebates, price adjustments, chargebacks, and prompt payment and other discounts. Estimated allowances are recorded and classified as accrued expenses in the accompanying consolidated balance sheets as of December 31, 2012 and 2011. During the third quarter of 2012, the remaining balance of deferred revenue was reclassified to accrued expenses.

Product Returns. Consistent with industry practice, the Company offers contractual return rights that allow its customers to return the majority of its products within an 18-month period that begins six months prior to and ends twelve months subsequent to expiration of the products. The Company s products have an 18- to 24-month expiration period from the date of manufacture. The Company adjusts its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include actual and historical return rates for expired lots, historical and forecasted product sales and consumer consumption data reported by external information management companies, estimated expiration dates or remaining shelf life of inventory in the distribution channel, estimates of inventory levels of its products in the distribution channel and any significant changes to these levels, and competitive issues such as new product entrants and other known changes in sales trends. The Company evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve through charges to income in the period in which the information that gives rise to the adjustment becomes known.

Rebates. The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program s administrator.

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Price Adjustments and Chargebacks. The Company s estimates of price adjustments and chargebacks are based on its estimated mix of sales to various third-party payers, which are entitled either contractually or statutorily to discounts from the Company s listed prices of its products. These estimates are also based on the contract fees the Company pays to certain group purchasing organizations (GPOs). In the event that the sales mix to third-party payers or the contract fees paid to GPOs are different from the Company s estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it has estimated.

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include certain product incentives to pharmacy customers and other sales stocking allowances. The Company has voucher programs for ZYFLO CR® whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on the historical redemption rates for similar completed programs used by other pharmaceutical companies as reported to the Company by a third-party claims processing organization and actual redemption rates for the Company s completed programs. In addition, the Company offers a customer loyalty program for CARDENE I.V. The Company estimates its liability for this program based on historical participation and redemption rates as well as projected sales for individual customers during the program evaluation period. The Company accounts for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

Prompt Payment Discounts. The Company typically offers its wholesale customers a prompt payment discount of 2% as an incentive to remit payments within the first 30 to 35 days after the invoice date depending on the customer and the products purchased (see Accounts Receivable above).

License and Royalty Agreement Revenues

Payments from the Company s licensees are recognized as revenue based on the nature of the arrangement (including its contractual terms), the nature of the payments and applicable accounting guidance. Non-refundable fees where the Company has no continuing performance obligations are recognized as revenues when there is persuasive evidence of an arrangement and collection is reasonably assured. If the Company has continuing performance obligations, nonrefundable fees are deferred and recognized ratably over the estimated performance period. At-risk milestone payments, which are typically related to regulatory, commercial or other achievements by the Company s licensees, are recognized as revenues when the milestone is accomplished and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed.

Research and Development

Research and development expenses consist of product development expenses incurred in identifying, developing and testing product candidates. Product development expenses consist primarily of labor, benefits and related employee expenses for personnel directly involved in product development activities; fees paid to professional service providers for monitoring and analyzing clinical trials; expenses incurred under joint development agreements; regulatory costs; costs of contract research and manufacturing of inventory used in testing and clinical trials; and the cost of facilities used by the Company s product development personnel.

Product development expenses are expensed as incurred and reflect costs directly attributable to product candidates in development during the applicable period and to product candidates for which the Company has discontinued development. Additionally, product development expenses include the cost of qualifying new current Good Manufacturing Practice (cGMP) third-party manufacturers for the Company s products, including expenses associated with any related technology transfer. All indirect costs (such as salaries, benefits or other costs related to the Company s accounting, legal, human resources, purchasing, information technology and other general corporate functions) associated with individual product candidates are included in general and administrative expenses.

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Advertising

Advertising costs, which include promotional expenses and the cost of samples, are expensed as incurred. Advertising expenses were $2.7 million, $4.2 million and $8.2 million for the years ended December 31, 2012, 2011 and 2010, respectively, and are included in selling, general and administrative expenses in the accompanying consolidated statements of comprehensive (loss) income.

Shipping and Handling Costs

The Company includes shipping and handling costs within cost of product sales. Shipping and handling costs were $1.3 million, $1.1 million and $1.2 million for the years ended December 31, 2012, 2011 and 2010, respectively.

Stock-Based Compensation

The Company measures compensation cost for share-based payment awards granted to employees and non-employee directors at fair value using the Black-Scholes-Merton option-pricing model. Compensation expense is recognized on a straight-line basis over the service period for awards expected to vest. Stock-based compensation cost related to share-based payment awards granted to non-employees is adjusted each reporting period for changes in the fair value of the Company s stock until the measurement date. The measurement date is generally considered to be the date when all services have been rendered or the date that options are fully vested.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and the tax basis of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse.

Net deferred tax assets are recognized to the extent the Company s management believes these assets will more likely than not be realized. In making such determination, management considers all positive and negative evidence, including reversals of existing temporary differences, projected future taxable income, tax planning strategies and recent financial operations. A valuation allowance is recorded to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Management periodically reviews its deferred tax assets for recoverability and its estimates and judgments in assessing the need for a valuation allowance.

The Company recognizes a tax benefit from uncertain positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized.

Net (Loss) Income Per Share

Basic net (loss) income per share is computed by dividing net (loss) income by the weighted-average number of common shares outstanding during each period. Diluted net (loss) income per share is computed by dividing net (loss) income by the sum of the weighted-average number of common shares and dilutive common share equivalents outstanding during the period. Dilutive common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and warrants and the impact of non-vested restricted stock grants.

Segment and Geographic Information

The Company operates in a single industry and operating segment which acquires, develops and commercializes prescription pharmaceutical drugs. Accordingly, our business is classified as a single reportable segment.

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The following table presents net product sales by product (in thousands):

	Year Ended December 31,		
	2012	2011	2010
Net Product Sales			
CARDENE I.V. product family	$ 24,807	$	$
CUROSURF®	34,972	34,852	33,621
ZYFLO® product family	53,553	30,674	30,619
AlleRx® Dose Pack products	(1,407)	23,263	27,305
Anti-infective products	3,374	14,387	10,453
Other products	781	(1,875)	21,746
Total net product sales	116,080	101,301	123,744
License and royalty agreement revenue	4	121	1,573
Net revenues	$ 116,084	$ 101,422	$ 125,317

The majority of the Company s revenues are generated in the United States. As of December 31, 2012, 99% of the Company s total assets are located in the United States. The remaining 1% of the Company s assets consisted of inventory on hand at international locations.

Fair Value Measurements

The carrying amounts of the Company s cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximated their fair values as of December 31, 2012 and December 31, 2011 due to the short-term nature of these financial items.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The fair value for contingent consideration potentially payable related to the acquisition of EKR Holdings, Inc. and its wholly owned subsidiary, EKR Therapeutics, Inc. (collectively EKR), at June 26, 2012 was $37.8 million, of which $23.9 million related to a contingent consideration arrangement that existed prior to the acquisition date. The fair value of these liabilities is a Level 3 measurement in the fair value hierarchy which is defined as one with unobservable inputs. The Company uses a discounted cash flow analysis incorporating the probability of estimated future cash flows from potential milestones and royalty payments using risk-adjusted discount rates. Changes to the discount rate would have an inverse effect on the liability s fair value. Contingent consideration includes the following potential payments for RETAVASE: (1) $4.0 million payable after relaunch approval, (2) $2.0 million payable on or before the first anniversary of the relaunch approval, and (3) three years of annual royalty payments based on a percentage of revenue. Contingent consideration also includes quarterly payments for CARDENE I.V. that are based on a percentage of CARDENE I.V. net revenue through July 2017. The liabilities are evaluated for remeasurement at the end of each reporting period and any changes are recorded in the Company s consolidated statements of comprehensive (loss) income. The carrying amount of the liability may fluctuate significantly and actual amounts paid may be materially different from the carrying value of the liability.

The following table presents a reconciliation of contingent consideration obligations related to the EKR acquisition measured on a recurring basis using significant unobservable inputs (Level 3) for the year ended December 31, 2012 (in thousands):

	December 31, 2011	Issuances(1)	Payments(2)	Adjustments(3)	December 31, 2012
Acquisition-related contingent consideration(4)	$	$ 37,788	$ (1,603)	$ (2,977)	$ 33,208

(1) Relates to the EKR acquisition as described below in Note 3 and consisting of approximately $13.9 million potentially payable for RETAVASE and $23.9 million potentially payable for CARDENE I.V.

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(2) Relates to payments of acquisition-related contingent consideration with respect to CARDENE I.V.

(3) This amount includes primarily fair value adjustments to the acquisition-related contingent consideration for CARDENE I.V. and RETAVASE. The adjustment is recognized as change in acquisition-related contingent payments in the consolidated statements of comprehensive (loss) income.

(4) Acquisition-related contingent consideration is classified as acquisition-related contingent payments in the accompanying consolidated balance sheets.

Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

As of December 31, 2012, the Company s assets and liabilities measured at fair value on a non-recurring basis subsequent to initial recognition included acquired IPR&D and contingent payments related to LIXAR, which were acquired in 2011 as part of the acquisition of Cardiokine, Inc. (Cardiokine). The Company recognized impairment charges of $11.5 million related to the acquired IPR&D and fully reduced the associated $8.8 million liability related to the acquired contingent payments. These charges reduced the carrying amounts of both the asset and liability to zero as of December 31, 2012. The adjusted carrying values were determined to be the estimated fair values using Level 3 inputs, discounted cash flows incorporating the probability of estimated future cash flows under various scenarios using risk-adjusted discount rates. For further information see Notes 6 and 12.

NOTE 3: BUSINESS COMBINATIONS

Acquisition of EKR

Description of Transaction

On June 26, 2012, the Company completed its acquisition of EKR, a specialty pharmaceutical company focused on serving the acute-care hospital setting, for an estimated consideration of approximately $164.2 million. As part of the transaction, the Company acquired the product rights to the cardiovascular products CARDENE I.V. and RETAVASE. The Company made an upfront payment of $126.4 million, subject to customary post-closing adjustments, and may pay a series of contingent consideration payments related to CARDENE I.V. and RETAVASE if certain milestones are achieved. The fair value for contingent consideration was determined to be $37.8 million.

Basis of Presentation

The transaction has been accounted for as a business combination under the acquisition method of accounting, which requires, among other things, that the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. The results of operations of EKR were consolidated beginning on the date of the merger. Acquisition-related costs are not included as a component of the acquisition accounting, but are recognized as expenses in the periods in which the costs are incurred. Any changes within the measurement period resulting from facts and circumstances that existed as of the acquisition date may result in retrospective adjustments to the provisional amounts recorded at the acquisition date.

Fair Value of Consideration Transferred

A summary of the purchase price is as follows (in thousands):

Cash paid for EKR s outstanding shares	$ 126,437
Acquisition-related contingent consideration	37,788
Total fair value of consideration	$ 164,225

Assets Acquired and Liabilities Assumed

The total purchase price was allocated to the acquired tangible and intangible assets and assumed liabilities of EKR based on their estimated fair values as of June 26, 2012. The excess of the purchase price over the estimated fair values of the assets acquired and liabilities assumed was allocated to goodwill.

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The following table presents the preliminary allocation of the total fair value of consideration transferred, as shown above, to the acquired tangible and intangible assets and assumed liabilities of EKR based on their estimated fair values as of the closing date of the transaction, measurement period adjustments recorded since the acquisition date and the as adjusted allocations of the total fair value (in thousands):

	June 26, 2012 (As initially reported)	Measurement Period Adjustments(1)	June 26, 2012 (As adjusted)
Cash	$ 516	$	$ 516
Accounts receivable, net	7,724	(323)	7,401
Inventory, net	32,226		32,226
Prepaid expenses and other assets	14,704	(22)	14,682
Identifiable intangibles	154,123		154,123
Deferred tax assets	28,873	6,206	35,079
Accounts payable	(2,690)		(2,690)
Accrued liabilities	(29,437)	(78)	(29,515)
Deferred tax liability related to intangibles acquired	(64,069)	(1,666)	(65,735)
Total identifiable net assets	$ 141,970	$ 4,117	$ 146,087
Goodwill	22,255	(4,117)	18,138
Total fair value of consideration	$ 164,225	$	$ 164,225

(1) The measurement period adjustments primarily reflect changes in other receivables, prepaid expenses, accrued liabilities and estimated sales allowances. The measurement period adjustments were made to reflect facts and circumstances existing as of the acquisition date, and did not result from intervening events subsequent to the acquisition date. The Company believes that this information provides a reasonable basis for estimating the fair values but is waiting for additional information necessary to finalize these amounts, including potential post-closing working capital and other measurement period adjustments that existed at the closing date. Thus, the Company s provisional measurements of fair value are subject to change.

The Company recorded $154.1 million in identifiable intangibles at fair value, consisting of $158.4 million in acquired product rights, partially offset by $4.3 million related to an unfavorable contract liability. The fair value of the product rights was allocated as $131.6 million for CARDENE I.V. and $26.9 million for RETAVASE. CARDENE I.V. product rights will be amortized over 15 years. RETAVASE product rights will be amortized over approximately 12 years beginning upon commercial launch. The unfavorable contract liability resulted from an existing supply contract that was determined to have terms that were less favorable than market. The liability was recorded at fair value determined based on the discounted cash flows resulting from the Company s estimated loss that will be incurred on the manufacturing of RETAVASE inventory for the provider of RETAVASE in the European market. The fair value of the unfavorable contract liability as of June 30, 2012 was $4.3 million and is classified in other long-term liabilities on the consolidated balance sheet as of December 31, 2012. The value of the contract will be amortized and recorded as an offset to cost of product sales based on inventory movement over the life of the contract.

Acquired inventory was recorded at fair value and includes an acquisition accounting adjustment of approximately $19.4 million to increase inventory to its fair value.

The Company initially recorded indemnification assets of $3.2 million and indemnification liabilities of $9.9 million, which are offset by corresponding liabilities and assets, respectively. The indemnification balances relate to (i) certain litigation and contractual liabilities included in accrued expenses and (ii) anticipated income tax refunds related to federal net operating loss (NOL) carryback claims and EKR s 2012 short period tax return. EKR s former shareholders are responsible for specified litigation and contractual liabilities included in acquisition-related current liabilities and for tax liabilities related to pre-closing periods and are obligated to fully indemnify the Company against losses related to these matters. EKR s former shareholders are also generally entitled to the benefit of tax refunds associated with pre-closing periods. These indemnification assets and

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liabilities are classified in acquisition-related current assets and liabilities. The measurement period adjusted balances are reflected on the accompanying consolidated balance sheet as of December 31, 2012. The Company expects the full amount of the liabilities related to these matters to be covered by the EKR shareholders.

At the closing of the acquisition, the fair value for contingent consideration potentially payable was $37.8 million, of which $23.9 million related to a contingent consideration arrangement related to the ready-to-use formulation of CARDENE I.V. that existed prior to the acquisition date. The fair value of these liabilities was determined using a discounted cash flow analysis incorporating the estimated future cash flows from potential milestones and royalty payments. The liabilities were evaluated as of December 31, 2012 as discussed above in Note 2. The Company will continue to evaluate these liabilities for remeasurement at the end of each reporting period and any change will be recorded in the Company s consolidated statement of comprehensive (loss) income. The carrying amount of the liability may fluctuate significantly and actual amounts paid may be materially different from the carrying value of the liability.

Goodwill was calculated as the difference between the fair value of the consideration and the preliminary values assigned to the assets acquired and liabilities assumed. The purchase price and goodwill allocation are expected to be finalized during 2013 as the Company finalizes any potential post-closing working capital and other measurement period adjustments that existed at the closing date. None of the goodwill will be deductible for tax purposes.

In connection with the acquisition, during the years ended December 31, 2012 and 2011, the Company incurred $7.6 million and $52,000, respectively, of transaction-related costs, which include severance expenses and the costs of advisory, legal, valuation and accounting services. These costs were expensed as incurred and are included in transaction-related expenses on the accompanying consolidated statements of comprehensive (loss) income.

Net revenues and net loss for EKR of $24.8 million and $6.2 million, respectively, are included in the Company s consolidated statements of comprehensive (loss) income from the acquisition date, June 26, 2012, through December 31, 2012.

Pro Forma Impact of the Acquisition of EKR (Unaudited)

The following table presents pro forma consolidated results of operations as if the EKR transaction had been consummated on January 1, 2011. The unaudited pro forma results of operations have been prepared for comparative purposes only and are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the period or of the results that may occur in the future. Furthermore, the pro forma financial information does not reflect the impact of any reorganization or restructuring expenses or operating efficiencies resulting from combining the two companies (in thousands, except per share data).

	Year Ended December 31,	
	2012	2011
Net revenues	$ 142,355	$ 159,680
Net income (loss)	$ (10,784)	$ (12,631)
Basic earnings (loss) per share	$ (0.41)	$ (0.49)
Diluted earnings (loss) per share	$ (0.41)	$ (0.49)

The unaudited pro forma consolidated results of operations were prepared using the acquisition method of accounting and are based on the historical financial information of the Company and EKR, reflecting the Company s and EKR s results of operations for the years ended December 31, 2012 and 2011. The historical financial information has been adjusted to give effect to the pro forma events that are: (i) directly attributable to the acquisition, (ii) factually supportable and (iii) expected to have a continuing impact on the combined results. The unaudited pro forma consolidated results reflect primarily the following pro forma adjustments:

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Additional interest expense related to the long-term debt used to fund the acquisition;

Additional amortization expense related to the fair value of identifiable intangible assets acquired; and

Removal of acquisition-related transaction costs.

Acquisition of Cardiokine, Inc.

Description of Transaction

On December 30, 2011, the Company acquired Cardiokine, a specialty pharmaceutical company focused on developing hospital products for cardiovascular indications. The Company acquired Cardiokine primarily to obtain Cardiokine s pending new drug application (NDA) for LIXAR to be used, if approved, to treat hyponatremia. In connection with the transaction, Cardiokine s stockholders received Cardiokine s cash on hand at closing, less the amount of a $2.7 million escrow fund established by Cardiokine out of its cash on hand to secure the Company s indemnification rights pursuant to the merger agreement, and the Company assumed approximately $2.0 million of Cardiokine s current liabilities. In addition, the Company agreed to pay consideration consisting of each of the following: (i) $1.0 million paid shortly following closing; (ii) either $7.0 million or $8.5 million (dependent on the scope of the approved label for LIXAR) if Cardiokine s pending NDA for its lixivaptan compound, LIXAR, is approved for sale by the FDA; (iii) up to $147.5 million based on the achievement of certain sales related milestones ($7.5 million at $75 million, $15 million at $150 million, $25 million at $250 million and $100 million at $500 million, each payable at the first time the annual sales reach the relevant milestone); (iv) quarterly earnout payments of 8% or 12% of net sales of the approved product, with such rate being dependent upon the scope of the labeling which the FDA may approve for the product; and (v) one-half of any proceeds realized from the license of the approved product outside the United States (collectively, the Cardiokine Purchase Consideration). The Cardiokine Purchase Consideration will be paid first to a subsidiary of Pfizer Inc. (Pfizer), the licensor of certain rights to the lixivaptan compound, in satisfaction of Cardiokine s payment obligations to Pfizer, until Pfizer has been paid a total of $20 million. Thereafter, any further Cardiokine Purchase Consideration will be paid in accordance with the merger agreement to certain other parties for which obligations existed and then directly to Cardiokine s former stockholders.

Basis of Presentation

The transaction has been accounted for as a business combination under the acquisition method of accounting, which requires, among other things, that the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. Acquisition-related costs are not included as a component of the acquisition accounting, but are recognized as expenses in the periods in which the costs are incurred.

Fair Value of Consideration Transferred

A summary of the purchase price is as follows (in thousands):

Cash consideration paid	$ 1,000
Contingent consideration	8,800
Total fair value of consideration	$ 9,800

Assets Acquired and Liabilities Assumed

The total purchase price was allocated to the acquired tangible and intangible assets and assumed liabilities of Cardiokine based on their estimated fair values as of December 30, 2011. The excess of the purchase price over the estimated fair values of the assets acquired and liabilities assumed was allocated to goodwill.

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The allocation of the total fair value of consideration transferred, as shown above, to the acquired tangible and intangible assets and assumed liabilities of Cardiokine based on their estimated fair values as of the closing date of the transaction is as follows (in thousands):

Prepaid and other assets	5,682
Acquired in-process research and development	11,500
Contingent liability	(8,800)
Assumed liabilities	(9,369)
Total identifiable net assets	$ (987)
Goodwill	1,987
Total cash consideration paid	$ 1,000

Prepaid and other assets consist primarily of an anticipated income tax refund of $5.6 million related to NOL carryback claims and Cardiokine s 2011 final tax return. The refund is classified in acquisition-related current assets offset by a liability to Cardiokine s former stockholders classified in acquisition-related current liabilities on the accompanying consolidated balance sheet as of December 31, 2011.

The estimated fair value of IPR&D related to the development program for LIXAR was determined using the excess-earning method under the income approach. Projected cash flows from the anticipated sales of the product were adjusted for the probabilities of approved labeling and commercialization of the product. A discount rate of 19.0% was used to determine the present value of the projected cash flows.

At the closing of the acquisition, the Company recorded an $8.8 million contingent liability for contingent consideration potentially payable under the merger agreement. The initial fair value of this liability was determined using a discounted cash flow analysis incorporating the estimated future cash flows from potential milestones and royalty payments. These cash flows were then discounted to present value using a discount rate of 21.5%. During the fourth quarter of 2012, the Company received a Complete Response Letter (CRL) from the FDA following the FDA s review of a NDA for LIXAR. Based on the requested additional clinical studies, the Company reassessed the probability of the FDA s approval of LIXAR and the fair value of related contingent payments. The Company reduced the fair value to zero as of December 31, 2012. The Company will continue to periodically re-assess the liability based on events and circumstances related to the underlying milestones including the Company s actions on the LIXAR development program, and any change will be recorded in the Company s consolidated statement of comprehensive (loss) income. The carrying amount of the liability may fluctuate significantly and actual amounts paid to Pfizer may be materially different from the carrying value of the liability.

Goodwill is calculated as the difference between the fair value of the consideration and the provisional values assigned to the assets acquired and liabilities assumed. None of the goodwill is expected to be deductible for tax purposes.

The Company incurred approximately $400,000 of transaction-related costs related to the acquisition of Cardiokine, which include expenses for legal, valuation and accounting services. These costs were expensed as incurred and are included in selling, general and administrative expenses on the accompanying consolidated statements of comprehensive (loss) income.

Pro Forma Impact of the Acquisition of Cardiokine (Unaudited)

The results of operations of Cardiokine are included in the Company s consolidated financial statements from the closing date of December 30, 2011. The following table presents pro forma consolidated results of operations as if the Cardiokine transaction had been consummated on January 1, 2010. The unaudited pro forma results of operations are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the period or of the results that may occur in the future. Furthermore, the pro

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forma financial information does not reflect the impact of any reorganization or restructuring expenses or operating efficiencies resulting from combining the two companies (in thousands, except per share data).

	Year Ended December 31,	
	2011	2010
Net revenues	$ 101,422	$ 224,445
Net (loss) income	$ (16,988)	$ 51,190
Net (loss) income per share, basic	$ (0.66)	$ 2.01
Net (loss) income per share, diluted	$ (0.66)	$ 1.97

NOTE 4: INVENTORY

The following table represents inventories, net as of December 31 (in thousands):

	2012	2011
Raw materials	$ 3,561	$ 2,791
Work in process	2,920	1,663
Finished goods:		
Pharmaceutical products trade	6,991	4,566
Pharmaceutical products samples	25	849
Total	13,497	9,869
Inventory allowances	(2,113)	(450)
Inventories, net	$ 11,384	$ 9,419

The increase in inventories primarily reflects the acquisition of EKR s inventories, which were initially recorded at fair value (as described in Note 3), offset by changes recorded in other operating expenses, net consisting of $11.7 million in CARDENE I.V. charitable inventory donations and a $14.6 million write-off of RETAVASE inventory determined to be no longer saleable based on expected delays in approval and commercial launch. In the year ended December 31, 2012, cost of product sales included $4.2 million of acquisition accounting adjustments related to acquired CARDENE I.V. inventory that was sold during the year.

NOTE 5: PROPERTY AND EQUIPMENT

The following table represents property and equipment as of December 31 (in thousands):

	Useful Life (Years)	2012	2011
Computers and software	3	$ 2,056	$ 1,568
Machinery and equipment	5	289	287
Furniture and fixtures	7	919	919
Leasehold improvements	Lesser of lease term or 5	207	132
Construction in progress	n/a	53	24

Total	3,524	2,930
Less accumulated depreciation	(2,214)	(1,356)
Property and equipment, net	$ 1,310	$ 1,574

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Depreciation expense, including depreciation related to assets acquired by capital lease, for the years ended December 31, 2012, 2011 and 2010 was $732,000, $528,000 and $400,000, respectively, and is included in selling, general and administrative expenses in the accompanying consolidated statements of comprehensive (loss) income.

NOTE 6: GOODWILL AND INTANGIBLE ASSETS

Goodwill

The Company s goodwill balance was $33.4 million and $15.2 million as of December 31, 2012 and 2011, respectively. The increase in goodwill of $18.1 million during 2012 related to the acquisition of EKR in June 2012. As described in Note 3, the allocation of the goodwill balance associated with the EKR acquisition is provisional and subject to the completion of the valuation of the assets acquired and liabilities assumed. No amount of the goodwill balance at December 31, 2012 will be deductible for income tax purposes.

Product Rights and In-Process Research and Development (IPR&D)

The following tables represent product rights, net as of December 31 (in thousands):

	December 31, 2012			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Amortization Period (yrs.)
CUROSURF	$ 107,606	$ 34,740	$ 72,866	15.0
ZYFLO	11,500	6,686	4,814	7.1
CARDENE I.V.	131,556	4,483	127,073	15.0
RETAVASE	26,858		26,858	n/a
Other	575	75	500	n/a
Total	$ 278,095	$ 45,984	$ 232,111	14.6

	December 31, 2011			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Amortization Period (yrs.)
CUROSURF	$ 107,606	$ 25,109	$ 82,497	10.0
Factive®	7,613	3,636	3,977	0.5
Spectracef®	4,505	2,437	2,068	0.5
ZYFLO	11,500	5,082	6,418	7.1
LIXAR	11,500		11,500	n/a
Other	575	75	500	n/a
Total	$ 143,299	$ 36,339	$ 106,960	8.9

The Company amortizes the product rights related to its currently marketed products over their estimated useful lives, which range from six months to fifteen years. As of December 31, 2012, the Company had $27.4 million of product rights related to RETAVASE and its Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product (HP/CP ER Suspension), both of which are expected to be launched in the future. The Company expects to begin amortization upon the commercial launch of these products, which is expected to be shortly after regulatory approval. The rights will be amortized over the product candidates estimated useful lives.

Effective October 1, 2012, the Company changed its estimate of the useful life of the CUROSURF product rights to better reflect the estimated period during which the asset will provide value. The useful life was increased from ten years to 15 years. On December 14, 2012, the Company officially entered into an amendment

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to the CUROSURF license and distribution agreement with Chiesi, which extended the initial term of the original agreement an additional five years to a total of 15 years starting from September 1, 2009. The increase in useful life resulted in a reduction of amortization expense of $1.1 million, an increase in net income of $431,000, and an increase in basic and diluted earnings per share of $0.02 for the year ended December 31, 2012.

On October 31, 2012, the Company received a CRL from the FDA following the FDA s review of an NDA for LIXAR. The FDA has requested the Company complete additional clinical studies to further evaluate the efficacy and safety of lixivaptan in both heart failure patients and syndrome of inappropriate antidiuretic hormone patients. The Company is requesting an End-of-Review meeting with the Division of Cardiovascular and Renal Drug Products of the FDA to better understand the contents of the CRL and the nature and scope of the additional clinical trials requested by the FDA. However, in connection with its annual impairment review of acquired IPR&D, the Company determined the fair value of the IPR&D to be zero using a probability-weighted income approach with a risk adjusted discount rate of 20%. The fair value was compared to its carrying amount resulting in a full impairment loss of $11.5 million, which is included in other operating expenses, net in the accompanying consolidated statements of comprehensive (loss) income.

During 2011, the Company focused its product development projects to align with its strategic direction. This decision resulted in the write-off of $2.5 million of capitalized product rights that no longer aligned with its strategic direction. This write-off is included in other operating expenses, net in the accompanying consolidated statements of comprehensive (loss) income.

Amortization expense for the years ended December 31, 2012, 2011 and 2010 was $17.9 million, $14.4 million and $14.4 million, respectively.

Future estimated amortization expense (excluding the rights related to products expected to be launched) subsequent to December 31, 2012 is as follows (in thousands):

2013	$ 16,621
2014	16,621
2015	16,621
2016	15,016
2017	15,016
Thereafter	124,858
	$ 204,753

Divestiture of Anti-infective Product Rights

In March 2012, the Company entered into asset purchase agreements with each of Merus Labs International Inc. (Merus) and Vansen Pharma Inc. (Vansen) pursuant to which the Company sold all of its rights to the anti-infective drugs Factive and Spectracef. In exchange for cash consideration and the assumption of certain product-related liabilities, Merus acquired all of the Company s rights to Factive, together with all of the Company s Factive product inventory and certain other related assets. In exchange for cash consideration and the assumption of certain product-related liabilities, Vansen acquired all of the Company s rights to the Spectracef family of products, together with all of the Company s Spectracef product inventory and certain other related assets. Vansen also agreed to make offers of employment to certain employees of the Company with responsibility for the distribution and sales of Spectracef. Pursuant to a separate co-promotion agreement, Vansen agreed to co-promote the Company s ZYFLO CR and ZYFLO products to certain physicians for an initial period of 24 months.

In connection with the transaction, the Company divested approximately $3.8 million in product rights, net of accumulated amortization, $2.5 million in inventory and product samples, and other assets of $1.2 million. In addition, Merus and Vansen assumed product-related liabilities of approximately $4.1 million. Total cash consideration for the divestiture was $6.2 million, of which $1.2 million was recorded as a receivable from the buyers. Under the asset purchase agreement for Factive, the Company retained certain royalty obligations to LG Life Sciences, Ltd. and Oscient Pharmaceuticals Corporation through the end of September 30, 2014. The

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Company calculated the fair value of the expected royalty payments and recorded a contingent liability of $1.1 million, which is included in other current and other long-term liabilities. The Company also recognized a gain on the divestiture of $2.0 million which is included in other operating expenses, net in the accompanying consolidated statements of comprehensive (loss) income.

As of December 31, 2012, the Company had $1.6 million of other receivables related to transition services the Company provided to Vansen after the Spectracef divestiture. The receivable is substantially reserved by an offsetting valuation allowance for other receivables of $1.5 million. Both the other receivable and corresponding allowance are included in other current assets in the accompanying consolidated balance sheet.

NOTE 7: ACCRUED EXPENSES

The following table represents accrued expenses as of December 31 (in thousands):

	2012	2011
Accrued product returns	$ 13,629	$ 13,211
Accrued rebates	1,766	2,634
Accrued price adjustments and chargebacks	9,651	9,159
Accrued compensation and benefits	3,022	2,559
Accrued royalties	3,487	3,046
Accrued research and development	1,300	913
Accrued co-promotion	2,330	1,329
Accrued expenses, other	2,194	2,142
Total accrued expenses	$ 37,379	$ 34,993

NOTE 8: LONG TERM DEBT

Term Loans A and B

On June 21, 2012, the Company entered into a credit agreement (the Credit Agreement) with Chiesi Farmaceutici S.p.A. (Chiesi) in connection with its acquisition of EKR. The Credit Agreement governs the senior secured term loan facility with Chiesi (the Term Loan Facility), which is comprised of a five-year Term Loan A of $60.0 million and a five-year Term Loan B of $30.0 million (the Term Loans). The Term Loans were funded on June 25, 2012 and the acquisition of EKR closed on June 26, 2012. The proceeds of the Term Loan Facility were used, together with the Company s cash on hand, to finance the acquisition of EKR and the related fees and expenses incurred by the Company in connection with the acquisition. All obligations under the Term Loan Facility are guaranteed by the Company s domestic subsidiaries, and are secured by a security interest in substantially all of the assets of the Company and its domestic subsidiaries. Under the Credit Agreement, Chiesi is the administrative agent and collateral agent in respect of the Term Loan Facility.

Term Loan A and Term Loan B bear interest at rates of 7.5% and 6.5% per year, respectively, payable quarterly in arrears on the last business day of each fiscal quarter beginning on September 28, 2012. Term Loan A requires quarterly principal payments of $3.5 million commencing on the fiscal quarter ending December 31, 2014 with any remaining balance due at maturity. Term Loan B principal is payable at maturity. The Term Loans are due and payable on June 23, 2017, unless previously prepaid or, in the case of Term Loan B, converted into shares of common stock, prior to such date.

The Company may prepay the Term Loans, in whole or in part without any premium or penalty, provided any prepayments of principal amounts are $5.0 million or whole multiples of $1.0 million in excess thereof, plus any accrued and unpaid interest. The prepayments will be applied first, ratably to the remaining installments of principal of the Term Loan A (excluding the payment due at maturity), second, to any remaining amounts outstanding on Term Loan A, and third, to the outstanding principal on Term Loan B.

The Company is required to prepay all or a portion of the Term Loan Facility under the following conditions: (i) if the Company s ratio of consolidated secured debt to Consolidated EBITDA (as defined in the

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Credit Agreement) is at least 2 to 1 for any fiscal year ending on or after December 31, 2013, by using 50% of the Company s Consolidated Excess Cash (as defined in the Credit Agreement), or (ii) if the Company undertakes certain asset sales or sales of capital stock and does not reinvest the proceeds according to the terms of the Credit Agreement.

Term Loan B contains a conversion option for a two-year period, expiring on June 21, 2014, which provides Chiesi the option, exercisable in its sole discretion, to convert all or a portion of the Term Loan B into shares of common stock at a conversion price equal to $7.098 per share, subject to adjustment under certain conditions. Conversions shall be no less than $5.0 million unless the remaining principal amount of Term Loan B is less than $5.0 million.

The Credit Agreement contains customary representations, covenants and events of default. Upon an Event of Default (as defined in the Credit Agreement), (i) the interest rates for Term Loan A and Term Loan B will each increase by 2% and (ii) Chiesi may declare all outstanding principal and accrued but unpaid interest under the Term Loan Facility to be immediately due and payable. In addition, the Company is subject to covenants prohibiting the payment of any dividends (other than stock dividends) and restricting or limiting other restricted payments, certain corporate activities, transactions with affiliates, incurrence of debt (which debt limit expressly permits, among other things, a secured working capital facility of up to $25 million), liens on properties and asset dispositions. The Company is not subject to any financial covenants other than the mandatory prepayment provisions discussed above.

In connection with the Term Loans, the Company incurred an estimated $511,000 of debt financing costs, which primarily consisted of legal and other professional fees. These costs are being amortized and are recorded as additional interest expense through the maturity of the loans.

The following table summarizes information on the Term Loans as of December 31, 2012 (in thousands):

	Maturity Date	December 31, 2012
Term Loan A (7.5% interest payable quarterly and principal payable in quarterly installments of $3.5 million starting on December 31, 2014)	June 2017	
Principal amount		$ 60,000
Unamortized debt financing costs		(305)
Net carrying amount		59,695
Term Loan B (6.5% interest payable quarterly and principal payable upon maturity, with conversion option through June 21, 2014)	June 2017	
Principal amount		30,000
Unamortized debt financing costs		(155)
Net carrying amount		29,845
Total debt, carrying amount		89,540
Less: current portion		
Total long-term debt, carrying amount		$ 89,540

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Aggregate maturities of our long-term debt for each of the five succeeding years ending December 31 and thereafter are as follows (in thousands):

2013	$
2014	3,500
2015	14,000
2016	14,000
2017	58,500
Thereafter	
	$ 90,000

NOTE 9: STOCK-BASED COMPENSATION

Overview of Stock-Based Compensation Plans

2003 Stock Incentive Plan

The Company assumed, for financial reporting purposes, the Critical Therapeutics, Inc. 2003 Stock Incentive Plan (the 2003 Stock Incentive Plan) at the time of the merger with Cornerstone BioPharma Holdings, Inc. (Cornerstone BioPharma) in October 2008. As of December 31, 2012, there were 159,066 shares of common stock authorized and no shares of common stock available for award under the 2003 Stock Incentive Plan.

2004 Stock Incentive Plan

The Company also assumed, for financial reporting purposes, the Critical Therapeutics, Inc. 2004 Stock Incentive Plan, as amended (the 2004 Stock Incentive Plan). The 2004 Stock Incentive Plan provides for the award to the Company s employees, directors and consultants of shares of common stock to be granted through incentive and nonstatutory stock options, restricted stock and other stock-based awards.

The exercise price of stock options granted under the 2004 Stock Incentive Plan is determined by the Compensation Committee of the Company s Board of Directors and may be equal to or greater than the fair market value of the Company s common stock on the date the option is granted. Equity awards granted under the 2004 Stock Incentive Plan generally become exercisable over a period of four years from the date of grant and expire 10 years after the grant date. As of December 31, 2012, there were 3,367,255 shares of common stock authorized and 801,361 shares available for award, under the 2004 Stock Incentive Plan.

The 2004 Stock Incentive Plan provides for an annual increase in the number of shares authorized for award under the plan, if approved by the Company s Board of Directors. This increase, if approved, is effective on January 1 of each year and may not exceed the lesser of 4% of the Company s outstanding shares on the effective date of the increase or 133,333 shares. The Company s Board of Directors authorized an annual increase to be effective as of January 1, 2013.

2005 Stock Option Plan and 2005 Stock Incentive Plan

In May 2005, the Company adopted the Cornerstone BioPharma Holdings, Inc. 2005 Stock Option Plan (the 2005 Stock Option Plan), which provided for the award to the Company s employees, directors and consultants of up to 2,380,778 shares of common stock through incentive and nonstatutory stock options. In December 2005, the Company adopted the Cornerstone BioPharma Holdings, Inc. 2005 Stock Incentive Plan (the 2005 Stock Incentive Plan, and together with the 2005 Stock Option Plan, the 2005 Plans), which provided for the award to the Company s employees, directors and consultants of up to 2,380,778 shares of common stock through incentive and nonstatutory stock options, restricted stock and other stock-based awards. Following the adoption of the 2005 Stock Incentive Plan, no further awards were made under the 2005 Stock Option Plan.

Cornerstone BioPharma s Board of Directors determined the terms and grant dates of all equity awards issued under the 2005 Plans and the underlying fair market value of Cornerstone BioPharma s common stock

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covered by such awards. Under the 2005 Plans, equity awards generally become exercisable over a period of four years from the date of grant and expire 10 years after the grant date. As of December 31, 2012, there were there were 88,949 shares of common stock authorized and no shares of common stock available for award under the 2005 Stock Option Plan, and 2,380,778 shares of common stock authorized and no shares of common stock available for award under the 2005 Stock Incentive Plan.

Stock Options

The Company uses the Black-Scholes-Merton option pricing model to determine the fair value of its stock options. The determination of the fair value of stock-based payment awards on the date of grant using an option pricing model is affected by the Company s stock price, as well as assumptions regarding a number of complex and subjective variables. These variables include the Company s expected stock price volatility over the term of the awards, actual employee exercise behaviors, risk-free interest rate and expected dividends.

The following table shows the assumptions used to value stock options on the date of grant, as follows:

	Year Ended December 31,		
	2012	2011	2010
Estimated dividend yield	0.0%	0.0%	0.0%
Expected stock price volatility	80%	80%	80-85%
Risk-free interest rate	0.62% - 0.90%	0.79% - 2.24%	1.73% - 2.60%
Expected life of option (in years)	5.00	5.00	5.00
Weighted-average grant date fair value per share	$ 3.60	$ 3.87	$ 3.57

The Company has not paid and does not anticipate paying cash dividends; therefore, the expected dividend rate was assumed to be 0%. The expected stock price volatility was based on the Company s historical volatility for the five year period preceding the grant date. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The expected life was estimated based on historical exercise patterns for previous grants, taking into account employee exercise strategy and cancellation behavior.

The following table summarizes the Company s stock option activity during 2012 under all of the Company s stock-based compensation plans:

	Number of Options	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2012	2,552,847	$ 4.82		
Granted	603,200	5.66		
Exercised	(438,449)	2.64		
Forfeited	(195,807)	6.06		
Expired	(73,437)	6.89		
Outstanding at December 31, 2012	2,448,354	$ 5.26	7.02	$ 1,291
Vested and Exercisable at December 31, 2012	1,529,327	$ 4.94	6.10	$ 1,291

The total intrinsic value of options exercised during 2012, 2011 and 2010 was $1.5 million, $1.6 million and $1.7 million, respectively. As of December 31, 2012, there was approximately $2.9 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.24 years.

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The following table summarizes information about the Company s stock options outstanding as of December 31, 2012:

	Outstanding			Exercisable	
Exercise Price	Number of Options Outstanding	Weighted-Average Contractual Life Outstanding (In Years)	Weighted-Average Exercise Price	Options Exercisable	Weighted-Average Exercise Price
$0.43-$3.90	497,311	4.58	$ 2.13	497,311	$ 2.13
$5.11-$5.26	782,509	7.89	5.24	435,564	5.24
$5.42-$5.97	581,753	7.59	5.77	184,621	5.87
$6.20-$8.92	486,781	7.53	7.06	326,415	7.13
$9.30-$9.30	100,000	6.57	9.30	85,416	9.30
	2,448,354	7.02	5.26	1,529,327	4.94

Restricted Stock

The Company also made restricted stock grants to certain employees under the 2004 Stock Incentive Plan during 2012 and 2011.

The following table summarizes the Company s restricted stock activity during 2012:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested January 1, 2012	219,780	$ 6.42
Granted	50,000	4.85
Vested	(128,370)	6.25
Forfeited		
Unvested December 31, 2012	141,410	$ 6.02

The fair value of restricted stock that vested during the year ended December 31, 2012, 2011 and 2010 was $706,000, $417,000 and $242,000, respectively. As of December 31, 2012, there was approximately $672,000 of total unrecognized compensation cost related to unvested restricted stock issued under the Company s equity compensation plans, which is expected to be recognized over a weighted-average period of 1.55 years.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized based on the total grant date fair value of options and shares vested was approximately $3.0 million, $2.2 million and $1.3 million for the years ended December 31, 2012, 2011 and 2010, respectively. Stock-based compensation expense is included in selling, general and administrative expenses in the accompanying consolidated statements of comprehensive (loss) income.

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NOTE 10: INCOME TAXES

The components of the (benefit from) provision for income taxes are as follows for the years ending December 31, (in thousands):

	2012	2011	2010
Current:			
Federal	$ (3,258)	$ (278)	$ 4,340
State	74	(6)	246
Total	(3,184)	(284)	4,586
Deferred:			
Federal	(14,998)	(398)	(2,793)
State	(1,063)	10	(184)
Total	(16,061)	(388)	(2,977)
Total tax (benefit) provision	$ (19,245)	$ (672)	$ 1,609

The significant components of the Company s deferred tax assets and liabilities consisted of the following as of December 31 (in thousands):

	2012	2011
Current:		
Deferred tax assets:		
Accounts receivable, net	$ 121	$ 216
Inventories, net	1,019	301
Accrued expenses	6,286	5,051
Valuation allowance	(5,190)	(4,959)
Total current deferred tax assets	2,236	609
Deferred tax liabilities:		
Acquired intellectual property	(622)	(607)
Net current deferred tax assets	$ 1,614	$ 2
Noncurrent:		
Deferred tax assets:		
Tax loss carryforwards	$ 63,245	$ 58,806
Tax credits	1,408	1,358
Stock-based compensation	1,431	1,276
Product license rights, net	3,974	359
Valuation allowance	(48,958)	(54,372)
Total noncurrent deferred tax assets	21,100	7,427
Deferred tax liabilities:		
Acquired intellectual property	(36,382)	(6,433)
Property and equipment, net	(401)	(471)
Total noncurrent deferred tax liabilities	(36,783)	(6,904)

Net deferred tax (liability) asset	noncurrent	(15,683)	523
Total net deferred tax (liability) asset		$ (14,069)	$ 525

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The Company has adjusted its deferred tax assets from previous periods, which had a full valuation allowance provided against them. In 2012, the valuation allowance decreased by $5.2 million due to sufficient positive evidence to the realizability of the deferred tax assets.

The amounts recorded as gross deferred tax assets as of December 31, 2012 and 2011 represent the amount of tax benefits of existing deductible temporary differences and carryforwards that are more likely than not to be realized. Significant management judgment is required in determining any valuation allowance recorded against deferred tax assets. Due to uncertainty regarding the Company s ability to fully realize federal net operating loss carryforwards (NOLs), a valuation allowance has been provided. This determination considered the limitations on the utilization of NOLs and tax credits imposed by Sections 382 and 383, respectively, of the U.S. Internal Revenue Code (the Code).

As of December 31, 2012, the Company had federal NOLs available to offset future taxable income of approximately $170.6 million. These NOLs primarily relate to the Company s acquisition of Critical Therapeutics, Inc. The federal NOL s will begin to expire in 2022. At December 31, 2012, the Company also had state NOLs available to offset future taxable income of approximately $664,000. The state NOLs will begin to expire in 2037. The Company also has federal research & development credit carryforwards of $1.4 million.

A reconciliation of the statutory income tax rate to the effective income tax rate is as follows:

	2012	2011	2010
Federal statutory taxes	35.0%	35.0%	35.0%
State income taxes, net of federal benefit	2.9	2.3	2.3
Change in contingent consideration	7.7		
Non-cash contributions	4.7	8.3	(4.7)
Non-deductible transaction costs	(3.0)		
Other permanent differences	(1.8)	(45.6)	6.0
Change in estimated federal and state NOL utilization			(7.4)
Change in valuation allowance	16.9	47.3	(8.3)
Other	(0.6)	1.9	(2.2)
	61.8%	49.2%	20.7%

The 2009 through 2011 tax years of the Company are open to examination by federal and state tax authorities. The Company has not been informed by the tax authorities of any jurisdiction that any of its tax years are under examination.

The Company recognizes a tax benefit from uncertain positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized. During 2012, the Company had a change in judgment related to a tax position taken in a prior period. The change was a result of additional guidance provided by the Internal Revenue Service. The Company reduced its unrecognized tax position by $382,000 during the second quarter, which affected the consolidated statement of comprehensive (loss) income. As of December 31, 2012, the Company had no unrecognized tax benefits.

The Company had no tax-related accrued interest or interest expense in the consolidated financial statements for the years ended December 31, 2012, 2011 and 2010. The Company had no tax-related penalties or accrued penalties included in the consolidated financial statements for the years ending December 31, 2012, 2011 and 2010.

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NOTE 11: NET (LOSS) INCOME PER SHARE

The following table sets forth the computation of basic and diluted net (loss) income per share (in thousands, except share and per share data):

	Year Ended December 31,		
	2012	2011	2010
Numerator:			
Net (loss) income	$ (11,888)	$ (693)	$ 6,169
Denominator:			
Weighted-average common shares, basic	26,115,266	25,684,593	25,412,636
Dilutive effect of stock options, warrants and restricted stock			623,908
Weighted-average common shares, diluted	26,115,266	25,684,593	26,036,544
Net (loss) income per share, basic	$ (0.46)	$ (0.03)	$ 0.24
Net (loss) income per share, diluted	$ (0.46)	$ (0.03)	$ 0.24
Anti-dilutive weighted-average shares	2,784,310	3,000,613	1,489,258

As of December 31, 2012 and 2011, there were 141,410 and 219,780 shares of unvested restricted stock outstanding that contain non-forfeitable rights to dividends. These securities are considered to be participating securities under the two-class method for determining basic and fully diluted net income per share. Because the treasury stock method and the two-class method yield the same result for both basic and diluted net income in each of the periods presented, only the treasury stock method has been disclosed.

NOTE 12: COMMITMENTS AND CONTINGENCIES

Lease Obligations

The Company leases its facilities and certain equipment under non-cancelable operating leases expiring at various dates through 2016. The Company recognizes lease expense on a straight-line basis over the term of the lease, excluding renewal periods, unless renewal of the lease is reasonably assured. Lease expense was $1.5 million, $1.1 million and $1.4 million for the years ended December 31, 2012, 2011 and 2010, respectively.

In connection with the acquisition of EKR, the Company assumed the lease for office space in Bedminster, NJ that was scheduled to extend through December 15, 2015. The lease was subsequently terminated in August 2012, effective September 30, 2012. The Company paid lease termination fees, of which $541,000 was recorded as lease expense during the year ended December 31, 2012.

Future minimum aggregate payments under non-cancelable lease obligations as of December 31, 2012 are as follows (in thousands):

Year Ending	Operating Leases
2013	$ 565
2014	584
2015	599
2016	152
2017	
Thereafter	

Total minimum lease payments	$ 1,900

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Supply Agreements

The Company has entered into various supply agreements with certain vendors and pharmaceutical manufacturers. Financial commitments related to these agreements totaled approximately $56.4 million as of December 31, 2012, which includes any minimum amounts payable and penalties for failure to satisfy purchase commitments that the Company has determined to be probable and that are reasonably estimable. Since many of these commitment amounts are dependent on variable components of the agreements, actual payments and the timing of those payments may differ from management s estimates. As of December 31, 2012, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately $23.7 million.

Royalty Agreements

The Company has contractual obligations to pay royalties to the former owners or current licensors of certain product rights that have been acquired by or licensed to the Company. These royalties are typically based on a percentage of net sales of the particular licensed product and are included in cost of product sales in the consolidated statements of comprehensive (loss) income. For the years ended December 31, 2012, 2011 and 2010, total royalty expenses were $5.4 million, $7.5 million and $12.7 million, respectively.

Other Licensing Agreements

The Company is committed to make potential future milestone payments to third parties as part of licensing, distribution and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. The Company may be required to make $8.4 million in additional payments to various parties if all milestones under the agreements are met. Because the achievement of milestones is neither probable nor reasonably estimable, such contingent payments have not been recorded on the accompanying consolidated balance sheets. The Company is also obligated to pay royalties on net sales or gross profit, if any, of certain product candidates currently in its portfolio following their commercialization.

As of December 31, 2012, the Company had outstanding commitments related to ongoing research and development contracts totaling approximately $1.1 million.

Additional Consideration for the Cardiokine Merger

In addition, in connection with its acquisition of Cardiokine in December 2011, the Company recorded an $8.8 million contingent liability for additional consideration potentially payable under the merger agreement. The Company agreed to pay the Cardiokine Purchase Consideration as described in Note 3. During 2012, the Company determined the fair value of the contingent liability was zero. For more details, refer to Note 6.

Co-Promotion and Marketing Services Agreements

The Company entered into but has now terminated a co-promotion agreement that grants a third party the exclusive right to promote and sell ZYFLO in conjunction with the Company. Under this agreement, the Company pays the third party co-promotion fees equal to the ratio of total prescriptions written by pulmonary specialists to total prescriptions during the applicable period multiplied by a percentage of quarterly net sales of the products covered by the agreement, after third-party royalties. Under this agreement, the Company is obligated to make these payments for a sunset period that lasts until the fourth quarter 2013.

As of December 31, 2012, the Company had outstanding financial commitments related to various marketing and analytical service agreements totaling approximately $4.1 million.

Severance

Selected executive employees of the Company have employment agreements which provide for severance payments of up to two times base salary, bonuses and benefits upon termination, depending on the reasons for the termination. The executive would also be required to execute a release and settlement agreement. As of

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December 31, 2012, the Company had $101,000 recorded as accrued severance related to the departure of one of its executive officers on October 19, 2012.

In connection with the acquisition of EKR, the Company incurred and recorded $1.6 million in accrued severance costs related to former EKR employees and certain EKR employees providing services for a stated transition period. As of December 31, 2012, $48,000 of these costs remain recorded as accrued severance and are included in accrued expenses on the consolidated balance sheet.

Legal Proceedings

The Company is involved in lawsuits, claims, investigations and proceedings related to its business. There are no matters pending that the Company currently believes are reasonably possible of having a material impact to our business, consolidated financial condition, results of operations or cash flows.

NOTE 13: SIGNIFICANT CONCENTRATIONS

The financial instruments that potentially subject the Company to concentrations of credit risk are cash, cash equivalents and accounts receivable. The Company s cash and cash equivalents are maintained with two financial institutions.

The Company relies on certain materials used in its development and third-party manufacturing processes, most of which are procured from Chiesi. The Company purchases its pharmaceutical ingredients pursuant to long-term supply agreements with a limited number of suppliers. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development or commercialization process and thereby adversely affect the Company s operating results. In addition, a disruption in the commercial supply of or a significant increase in the cost of the API from any of these sources could have a material adverse effect on the Company s business, financial position and results of operations. Chiesi individually represented 74% and 78% of the Company s total inventory purchases for the years ended December 31, 2012 and 2011, respectively. Amounts due to Chiesi represented approximately 39% and 26% of total accounts payable as of December 31, 2012 and 2011, respectively.

The Company sells its products primarily to large national wholesalers, which in turn may resell the products to smaller or regional wholesalers, hospitals, retail pharmacies, chain drug stores, government agencies and other third parties. The following tables list the Company s customers that individually comprise greater than 10% of total gross product sales for the years ended December 31, 2012, 2011 and 2010 or 10% of total accounts receivable as of December 31, 2012 and 2011:

	Year Ended December 31,			December 31,	
	2012 Gross Product Sales	2011 Gross Product Sales	2010 Gross Product Sales	2012 Accounts Receivable	2011 Accounts Receivable
Cardinal Health	33%	39%	43%	31%	52%
McKesson Corporation	32%	34%	29%	33%	22%
Amerisource Bergen Corporation	28%	21%	22%	29%	21%
Total	93%	94%	94%	93%	95%

NOTE 14: RELATED PARTY TRANSACTIONS

Chiesi, the Company s majority stockholder, manufactures all of the Company s requirements for CUROSURF pursuant to a license and distribution agreement that became effective on July 28, 2009, as amended on September 28, 2010 and December 14, 2012. The Company began promoting and selling CUROSURF in September 2009. Inventory purchases from Chiesi aggregated $23.6 million for the year ended December 31, 2012. As of December 31, 2012, the Company had accounts payable of $4.9 million due to Chiesi.

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As discussed in Note 8, on June 21, 2012, the Company entered into the Term Loan Facility with Chiesi in connection with its acquisition of EKR. The Term Loan Facility, which is governed by the Credit Agreement, includes a Term Loan A of $60.0 million and Term Loan B of $30.0 million. The Term Loans were funded on June 25, 2012 and the acquisition of EKR closed on June 26, 2012. As of December 31, 2012, the net carrying value of the Term Loans was $89.5 million, net of capitalized unamortized debt financing costs. During the year ended December 31, 2012, the Company paid $3.4 million of interest expense less withholding tax to Chiesi related to the Term Loans. There was no accrued interest payable due to Chiesi as of December 31, 2012.

On November 6, 2012, the Company and Chiesi entered into a License and Distribution Agreement pursuant to which Chiesi granted the Company an exclusive license to market and sell Chiesi s BETHKIS® product in the United States. BETHKIS is an FDA-approved inhaled tobramycin-based product indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa. In consideration for the grant of the license, the Company made an initial payment of $1.0 million and will make a milestone payment of $2.5 million upon the first commercial sale of the product in the United States. The Company will also be required to pay certain costs related to a Phase IV clinical trial with respect to the product and quarterly royalties based on a percentage of net sales.

The BETHKIS license transfer between the Company and Chiesi was recorded by the Company as an equity transaction between entities under common control. As such, the Company did not record an asset for the license acquired, since there were no historical carrying amounts recorded by Chiesi. No liabilities were transferred.

NOTE 15: EMPLOYEE BENEFIT PLANS

The Company established a qualified 401(k) plan (the 401(k) Plan), effective January 1, 2005, covering all employees who are at least 21 years of age. The Company s employees may elect to make contributions to the plan within statutory and plan limits, and the Company may elect to make matching or voluntary contributions. The Company began contributing to the 401(k) Plan during 2011 and made a total of $233,000 and $85,000 in contributions for the years ended December 31, 2012 and 2011, respectively. The Company s contributions vest in four equal installments on each of the four anniversaries following the later of the start date of the match or the employee s date of participation in the 401(k) Plan. Expenses related to the plan were insignificant during the years ended December 31, 2012, 2011 and 2010.

NOTE 16: SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred after December 31, 2012. The Company did not have any material subsequent events that require adjustment or disclosure in these financial statements, other than the going-private proposal discussed in Note 1 above.

NOTE 17: RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

Fair Value Disclosures

In May 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-04 Amendments to Achieve Common Fair Value Measurement and disclosure Requirements in U.S. GAAP and IFRSs which amended standards requiring additional fair value disclosures. The amended standards require disclosures of transfers in and out of Levels 1 and 2 of the fair value hierarchy, sensitivity of a fair value measurement categorized within Level 3 of the fair value hierarchy to changes in unobservable inputs and any interrelationships between those unobservable inputs and the categorization by level of the fair value hierarchy for items that are not measured at fair value in the statement of financial position, but for which the fair value of such items is required to be disclosed. The Company adopted the new guidance on January 1, 2012. Because this new standard is related primarily to disclosures, its adoption has not had a significant impact on the Company s consolidated financial statements.

Presentation of Comprehensive Income

In June 2011, the FASB issued ASU 2011-05 Presentation of Comprehensive Income, new guidance concerning the presentation of total comprehensive income and its components. Under this guidance an entity has

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the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income, either in a single continuous statement of comprehensive income, or in two separate but consecutive statements. This guidance also requires an entity to present on the face of the financial statements reclassification adjustments from other comprehensive income to net income. In December 2011, the FASB issued ASU 2011-12 Deferral of the Effective Date for Amendments to the Presentation of Reclassification of the Items out of Accumulated Other Comprehensive Income, an accounting standards update that deferred this presentation requirement for other comprehensive income reclassifications on the face of the financial statements. The Company adopted the new guidance on January 1, 2012. The Company has no adjustments between net income and comprehensive income. The adoption of this guidance is not material to the Company or its presentation of its consolidated financial statements.

NOTE 18: QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

The following is a summary of the Company s consolidated quarterly results of operations for each of the years ended December 31, 2012 and 2011 (in thousands, except per share data):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
2012					
Net product sales	$ 22,157	$ 21,471	$ 37,525	$ 34,927	$ 116,080
Cost of product sales (exclusive of amortization of product rights)	8,686	8,901	14,397	10,595	42,579
(Loss) income from operations	(3,043)	(5,633)	2,723	(21,385)	(27,338)
Net (loss) income	(1,825)	(4,353)	1,249	(6,959)	(11,888)
Net (loss) income per share, basic	(0.07)	(0.17)	0.05	(0.26)	(0.46)
Net (loss) income per share, diluted	(0.07)	(0.17)	0.05	(0.26)	(0.46)
2011					
Net product sales	$ 29,975	$ 27,964	$ 25,178	$ 18,184	$ 101,301
Cost of product sales (exclusive of amortization of product rights)	10,034	9,189	9,960	8,640	37,823
Income (loss) from operations	2,540	540	191	(4,508)	(1,237)
Net income (loss)	1,742	197	117	(2,749)	(693)
Net income (loss) per share, basic	0.07	0.01	0.00	(0.11)	(0.03)
Net income (loss) per share, diluted	0.07	0.01	0.00	(0.11)	(0.03)

The sum of the quarterly earnings per share amounts will not necessarily equal the annual earnings per share amount due to the weighting of common shares outstanding during each of the respective periods.

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CORNERSTONE THERAPEUTICS INC.

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

(In thousands)

	Beginning Balance	Additions Charged to Costs and Expenses	Additions Charged to Other Accounts(1)	Deductions	Ending Balance
Year Ended December 31, 2012					
Reserves:					
Accrued product returns	$ 13,211	$	$ 12,365(2)	$ 11,947	$ 13,629
Accrued rebates	2,634		4,262(3)	5,130	1,766
Accrued price adjustments and chargebacks	9,159		46,427(4)	45,935	9,651
Deducted from asset accounts:					
Allowance for prompt payment discounts	585		3,617(5)	3,882	320
Inventory allowance	450	2,540(6)		877	2,113
Year Ended December 31, 2011					
Reserves:					
Accrued product returns	$ 15,025	$	$ 42,021(7)	$ 43,835	$ 13,211
Accrued rebates	3,034		4,067(8)	4,467	2,634
Accrued price adjustments and chargebacks	21,520		24,266(9)	36,627	9,159
Deducted from asset accounts:					
Allowance for prompt payment discounts	2,015		2,153	3,583	585
Inventory allowance	1,845	209		1,604	450
Year Ended December 31, 2010					
Reserves:					
Accrued product returns	$ 10,962	$	$ 20,131(10)	$ 16,068	$ 15,025
Accrued rebates	1,013		5,230(11)	3,209	3,034
Accrued price adjustments and chargebacks	3,503		51,235(12)	33,218	21,520
Deducted from asset accounts:					
Allowance for prompt payment discounts	384		5,665(13)	4,034	2,015
Inventory allowance	1,802	1,340		1,297	1,845

(1) All activity is netted against gross product sales unless otherwise stated.

(2) Includes a provision of $1,503 relating to sales made in prior periods and $4,389 for acquired liabilities related to our acquisition of EKR, offset by reductions of $2,230 primarily due to the divestiture of our anti-infective product rights.

(3) Includes $140 primarily relating to sales made in 2010 for which revenue had been previously deferred.

(4) Includes $5,614 for acquired liabilities related to our acquisition of EKR, offset by reductions of $2,062 relating primarily to the divestiture of our anti-infective product rights.

(5) Includes $145 for acquired liabilities related to our acquisition of EKR.

(6) Includes $1,168 for acquired inventory allowances related to our acquisition of EKR.

(7) Includes a provision of $7,291 relating to sales made in prior periods and $26,632 for anticipated returns of product for which revenue had been previously deferred.

(8) Includes $82 relating to sales made during 2010 for which revenue had been previously deferred.

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(9) Includes $884 relating to sales made during 2010 for which revenue had been previously deferred.

(10) Includes a provision of $8,865 relating to sales made in prior periods.

(11) Includes a deferred provision of $493 relating to sales made during 2010 for which revenue has been deferred.

(12) Includes a deferred provision of $16,731 relating to sales made during 2010 for which revenue has been deferred.

(13) Includes a deferred provision of $1,763 relating to sales made during 2010 for which revenue has been deferred.

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ITEM 9. ***CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE***
Not applicable.

ITEM 9A. ***CONTROLS AND PROCEDURES***
Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2012, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of December 31, 2012, our disclosure controls and procedures were effective in ensuring that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, including ensuring that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Our internal control system is designed to provide reasonable assurance to our management and the Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework (the COSO criteria). Based on its assessment, our management determined that, as of December 31, 2012, our internal control over financial reporting was effective.

ITEM 9B. ***OTHER INFORMATION***
Not applicable.

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PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

Directors and Executive Officers

Information regarding our directors may be found under the captions Proposal One Election of Directors and Corporate Governance Board Committees in the Proxy Statement for our 2013 Annual Meeting of Stockholders, or will be provided in an amendment to this Annual Report on Form 10-K. Information regarding our executive officers and directors may be found under the caption Executive Officers of the Registrant and Non-Employee Directors of the Registrant, respectively, in Part I of this annual report on Form 10-K. Such information is incorporated herein by reference.

Compliance With Section 16(a) of the Exchange Act

Information regarding compliance with Section 16(a) of the Exchange Act by our directors, officers and beneficial owners of more than 10% of our common stock may be found under the caption Stock Ownership Information Section 16(a) Beneficial Ownership Reporting Compliance in the Proxy Statement for our 2013 Annual Meeting of Stockholders, or will be provided in an amendment to this Annual Report on Form 10-K. Such information is incorporated herein by reference.

Code of Ethics

We have adopted a code of business conduct and ethics that applies to our directors, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) and other employees. A copy of our code of business conduct and ethics is available on our website at www.crtx.com under Investors Corporate Governance. We intend to post on our website and file on Form 8-K, if required, all disclosures that are required by applicable law, the rules of the SEC or NASDAQ listing standards concerning any amendment to, or waiver from, our code of business conduct and ethics.

Director Nominees

Information regarding procedures for recommending nominees to the Board of Directors may be found under the caption Corporate Governance Director Nomination Process in the Proxy Statement for our 2013 Annual Meeting of Stockholders, or will be provided in an amendment to this Annual Report on Form 10-K. Such information is incorporated herein by reference.

Audit Committee

We have a separately designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Additional information regarding the Audit Committee, including our audit committee financial expert, may be found under the captions Corporate Governance Board Committees Audit Committee and Proposal Two Ratification of Selection of Independent Registered Public Accounting Firm Audit Committee Report in the Proxy Statement for our 2013 Annual Meeting of Stockholders, or will be provided in an amendment to this Annual Report on Form 10-K. Such information is incorporated herein by reference.

ITEM 11. *EXECUTIVE COMPENSATION*

Information with respect to this item may be found under the caption Information About Executive and Director Compensation in the Proxy Statement for our 2013 Annual Meeting of Stockholders, or will be provided in an amendment to this Annual Report on Form 10-K. Such information is incorporated herein by reference.

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ITEM 12. ***SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS***

Information with respect to this item may be found under the captions Stock Ownership Information and Information About Executive and Director Compensation Securities Authorized for Issuance Under Equity Compensation Plans in the Proxy Statement for our 2013 Annual Meeting of Stockholders, or will be provided in an amendment to this Annual Report on Form 10-K. Such information is incorporated herein by reference.

ITEM 13. ***CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE***

Information with respect to this item may be found under the captions Chiesi Transaction and Corporate Governance in the Proxy Statement for our 2013 Annual Meeting of Stockholders, or will be provided in an amendment to this Annual Report on Form 10-K. Such information is incorporated herein by reference.

ITEM 14. ***PRINCIPAL ACCOUNTANT FEES AND SERVICES***

Information with respect to this item may be found under the captions Proposal Two Ratification of Selection of Independent Registered Public Accounting Firm Independent Registered Public Accounting Firm s Fees and Corporate Governance Pre-Approval Policy and Procedures in the Proxy Statement for our 2013 Annual Meeting of Stockholders, or will be provided in an amendment to this Annual Report on Form 10-K. Such information is incorporated herein by reference.

PART IV

ITEM 15. ***EXHIBITS AND FINANCIAL STATEMENT SCHEDULES***

(a) (1) *Financial Statements.*

For a list of the financial information included herein, see Index to Consolidated Financial Statements on page 80 of this annual report on Form 10-K.

(a) (2) *Financial Statement Schedules*

Schedule II Valuation and Qualifying Accounts is included in Item 8 of this Annual Report on Form 10-K. All other schedules are omitted because they are not applicable or the required information is shown in our consolidated financial statements or the related notes thereto.

(a) (3) *Exhibits.*

The list of exhibits filed as a part of this annual report on Form 10-K is set forth on the Exhibit Index immediately preceding the exhibits hereto and is incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CORNERSTONE THERAPEUTICS INC.

By: /s/ Craig A. Collard
Craig A. Collard
Chief Executive Officer
March 14, 2013

Date: March 14, 2013

We, the undersigned officers and directors of Cornerstone Therapeutics Inc., hereby severally constitute and appoint Craig A. Collard and Alastair McEwan, and each of them singly, our true and lawful attorneys, with full power to them and each of them singly, to sign for us in our names in the capacities indicated below, all amendments to this report, and generally to do all things in our names and on our behalf in such capacities to enable Cornerstone Therapeutics Inc. to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all requirements of the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Craig A. Collard	Chief Executive Officer and	March 14, 2013
Craig A. Collard	Director (Principal Executive Officer)	
/s/ Alastair McEwan	Chief Financial Officer and Treasurer	March 14, 2013
Alastair McEwan	(Principal Financial Officer)	
/s/ Ira Duarte	Director, Accounting and Financial Planning and Analysis (Principal Accounting Officer)	March 14, 2013
Ira Duarte		
/s/ Christopher Codeanne	Director	March 14, 2013
Christopher Codeanne		
/s/ Michael Enright	Director	March 14, 2013
Michael Enright		
/s/ Anton Giorgio Failla	Director	March 14, 2013
Anton Giorgio Failla		
/s/ James Harper	Director	March 14, 2013

James Harper		
/s/ Michael Heffernan	Director	March 14, 2013
Michael Heffernan		

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Signature	Title	Date
/s/ Laura Shawver	Director	March 14, 2013
Laura Shawver		
/s/ Robert Stephan	Director	March 14, 2013
Robert Stephan		
/s/ Marco Vecchia	Director	March 14, 2013
Marco Vecchia		

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Exhibit Index

Exhibit No	Description
2.1	Agreement and Plan of Merger among the Registrant, Neptune Acquisition Corp. and Cornerstone BioPharma Holdings, Inc. dated May 1, 2008 (incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K dated May 1, 2008).
2.2	Amendment No. 1, dated August 7, 2008, to Agreement and Plan of Merger among the Registrant, Neptune Acquisition Corp. and Cornerstone BioPharma Holdings, Inc. dated May 1, 2008 (incorporated by reference to Exhibit 2.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008).
2.3	Agreement and Plan of Merger among the Registrant, Cohesion Merger Sub, Inc., Cardiokine, Inc. and Shareholder Representative Services LLC dated December 28, 2011 (incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K dated December 28, 2011).
2.4+**	Asset Purchase Agreement between the Registrant and Vansen Pharma, Inc. dated March 7, 2012 (incorporated by reference to Exhibit 2.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2012).
2.5+**	Asset Purchase Agreement between the Registrant and Merus Labs International Inc. dated March 7, 2012 (incorporated by reference to Exhibit 2.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2012).
2.6**	Agreement and Plan of Merger among the Registrant, Stone Acquisition Sub, Inc., EKR Holdings, Inc. and EKR Therapeutics, Inc. dated May 14, 2012 (incorporated by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K dated May 14, 2012).
2.7	Amendment No. 1, dated June 26, 2012, to Agreement and Plan of Merger among the Registrant, Stone Acquisition Sub, Inc., EKR Holdings, Inc. and EKR Therapeutics, Inc. dated May 14, 2012 (incorporated by reference to Exhibit 2.2 to the Registrant s Current Report on Form 8-K dated June 21, 2012).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004).
3.2	Amendment to the Registrant s Certificate of Incorporation, effecting a 10-to-1 reverse stock split of the Registrant s common stock (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
3.3	Amendment to the Registrant s Certificate of Incorporation, changing the name of the corporation from Critical Therapeutics, Inc. to Cornerstone Therapeutics Inc. (incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
3.4	Amendment to the Registrant s Certificate of Incorporation, effecting certain changes pursuant to the Governance Agreement among Chiesi Farmaceutici S.p.A., the Registrant and certain other stockholders of the Registrant dated May 6, 2009 (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K dated August 27, 2009).
3.5	Fourth Amended and Restated Bylaws of the Registrant dated July 28, 2009 (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K dated July 27, 2009).
4.1	Form of the Registrant s Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.1+	Co-Promotion and Marketing Services Agreement between the Registrant and Dey, L.P. dated March 13, 2007 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007).
10.2+	Amendment No. 1, dated June 25, 2007, to Co-Promotion and Marketing Services Agreement between the Registrant and Dey, L.P. dated March 13, 2007 (incorporated by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007).

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10.3+	Amendment No. 2, dated May 4, 2009, to Co-Promotion and Marketing Services Agreement between the Registrant and Dey, L.P. dated March 13, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2009).
10.4	Consent and Waiver, dated March 7, 2012, with respect to Co-Promotion and Marketing Services Agreement between the Registrant and Dey, L.P. dated March 13, 2007 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2012).
10.5+	Agreement for Manufacturing and Supply of Zileuton between Shasun Pharma Solutions Limited (formerly known as Rhodia Pharma Solutions Ltd.) and the Registrant dated February 8, 2005 (incorporated by reference to Exhibit 10.41 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2004).
10.6+	Amendment No. 1, dated May 9, 2007, to Agreement for Manufacturing and Supply of Zileuton, between Shasun Pharma Solutions Limited (formerly known as Rhodia Pharma Solutions Ltd.) and the Registrant dated February 8, 2005 (incorporated by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the period ended March 31, 2007).
10.7+	Manufacturing and Supply Agreement among the Registrant, Jagotec AG and SkyePharma PLC dated August 20, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007).
10.8+	Letter Amendment, dated June 12, 2009, to Manufacturing and Supply Agreement among the Registrant, Jagotec AG and SkyePharma PLC dated August 20, 2007 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated June 12, 2009).
10.9+	License Agreement between the Registrant and Abbott Laboratories dated December 18, 2003 (incorporated by reference to Exhibit 10.10 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.10	Amendment No. 1, dated April 13, 2005, to License Agreement between the Registrant and Abbott Laboratories dated December 18, 2003 (incorporated by reference to Exhibit 10.14 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2006).
10.11+	Amendment No. 2, dated January 28, 2010, to License Agreement between the Registrant and Abbott Laboratories dated December 18, 2003 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2010).
10.12+	License Agreement between the Registrant and Abbott Laboratories dated March 19, 2004 (incorporated by reference to Exhibit 10.11 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.13	Amendment No. 1, dated September 15, 2004, to License Agreement between the Registrant and Abbott Laboratories dated March 19, 2004 (incorporated by reference to Exhibit 10.16 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2006).
10.14+	Agreement between the Registrant and Jagotec AG dated December 3, 2003 (incorporated by reference to Exhibit 10.13 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.15+	Development and Scale-Up Agreement between the Registrant and Jagotec AG dated May 5, 2004 (incorporated by reference to Exhibit 10.25 to Amendment No. 2 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-113727)).
10.16+	Development and Manufacturing Agreement among Neos Therapeutics, L.P., Coating Place, Inc. and Cornerstone BioPharma, Inc. dated February 27, 2008 (incorporated by reference to Exhibit 10.16 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.17+	Amendment No. 1, dated June 16, 2009, to Development and Manufacturing Agreement among Neos Therapeutics, L.P., Coating Place, Inc. and Cornerstone BioPharma, Inc. dated February 27, 2008 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated June 16, 2009).

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10.18+	Copromotion Agreement between the Registrant and Vansen Pharma, Inc. dated March 7, 2012 (included as Exhibit F in Exhibit 2.4 hereto).
10.19+	Amended and Restated Development and Manufacturing Agreement between EKR Therapeutics, Inc. and Baxter Healthcare Corporation dated November 6, 2009 (incorporated by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012).
10.20	Stock Purchase Agreement between Chiesi Farmaceutici S.p.A. and the Registrant dated May 6, 2009 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated May 6, 2009; Exhibits A, B, C, D and E thereto incorporated by reference to Exhibits 10.9-10.14, 10.4, 10.3, 10.5 and 10.6, respectively, to the Registrant s Current Report on Form 8-K dated May 6, 2009; and Exhibit H thereto incorporated by reference to Exhibit 10.2 to the Registrant s Amendment No. 1 on Form 8-K/A to Current Report on Form 8-K dated May 6, 2009).
10.21+	License and Distribution Agreement between Chiesi Farmaceutici S.p.A. and the Registrant dated May 6, 2009 (incorporated by reference to Exhibit 10.2 to the Registrant s Amendment No. 1 on Form 8-K/A to Current Report on Form 8-K dated May 6, 2009).
10.22	Amendment No. 1, dated September 28, 2010, to License and Distribution Agreement between Chiesi Farmaceutici S.p.A. and the Registrant dated May 6, 2009.
10.23+	Amendment No. 2, dated December 14, 2012, to License and Distribution Agreement between Chiesi Farmaceutici S.p.A. and the Registrant dated May 6, 2009.
10.24	Commitment Letter between the Registrant and Chiesi Farmaceutici S.p.A. dated May 14, 2012 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated May 14, 2012).
10.25	Credit Agreement among the Registrant, Chiesi Farmaceutici S.p.A., as administrative agent and the initial lender, and the other lenders from time to time party thereto dated June 21, 2012 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated June 21, 2012).
10.26	License and Distribution Agreement between Chiesi Farmaceutici S.p.A. and the Registrant dated November 6, 2012 (incorporated by reference to Exhibit 10.1 to the Registrant s Form 8-K dated November 6, 2012).
10.27	Governance Agreement among the Registrant, Chiesi Farmaceutici S.p.A. and, solely with respect to the sections identified therein, Cornerstone BioPharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.3 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.28	Stockholders Agreement among the Registrant, Chiesi Farmaceutici S.p.A., Craig A. Collard, Steven M. Lutz, Cornerstone BioPharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.4 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.29	Amendment, dated June 26, 2009, to Stockholders Agreement among the Registrant, Chiesi Farmaceutici S.p.A., Craig A. Collard, Steven M. Lutz, Cornerstone BioPharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K dated June 26, 2009).
10.30	Registration Rights Agreement between the Registrant and Chiesi Farmaceutici S.p.A. dated May 6, 2009 (incorporated by reference to Exhibit 10.5 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.31	Registration Rights Agreement among the Registrant, Craig A. Collard, Steven M. Lutz, Cornerstone BioPharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership dated May 6, 2009 (incorporated by reference to Exhibit 10.6 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.32	Stock Purchase Agreement among the Registrant, Chiesi Farmaceutici S.p.A., Craig A. Collard, Steven M. Lutz, Cornerstone BioPharma Holdings, Ltd. and Lutz Family Limited Partnership dated December 16, 2010 (incorporated by reference to Exhibit 10.45 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2010).

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10.33	Lease Agreement between Crescent Lakeside, LLC and the Registrant (as assignee of Cornerstone BioPharma Holdings, Inc.) dated May 1, 2008 (incorporated by reference to Exhibit 10.26 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.34	Lease Modification Agreement No. 1, dated October 31, 2008, to Lease Agreement between Crescent Lakeside, LLC and the Registrant (as assignee of Cornerstone BioPharma Holdings, Inc.) dated May 1, 2008 (incorporated by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009).
10.35	Lease Modification Agreement No. 2, dated October 2, 2009, to Lease Agreement between Crescent Lakeside, LLC and the Registrant (as assignee of Cornerstone BioPharma Holdings, Inc.) dated May 1, 2008 (incorporated by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009).
10.36#	2004 Stock Incentive Plan of the Registrant (as Amended and Restated May 20, 2010) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated May 20, 2010).
10.37#	Form of Incentive Stock Option Agreement granted under the 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.68 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008).
10.38#	Form of Nonstatutory Stock Option Agreement granted under the 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.70 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008).
10.39#	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan (for awards granted before May 20, 2010) (incorporated by reference to Exhibit 10.72 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008).
10.40#	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan (for awards granted from May 20, 2010 to May 18, 2011) (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010).
10.41#	Form of Nonstatutory Stock Option Agreement for a Non-Employee Director granted under the 2004 Stock Incentive Plan (for awards granted on or after May 19, 2011) (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011).
10.42#	Form of Restricted Stock Agreement granted under the 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.75 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2009).
10.43#	Cornerstone BioPharma Holdings, Inc. 2005 Stock Incentive Plan (as Amended and Restated effective October 31, 2008) (incorporated by reference to Exhibit 10.37 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.44#	Form of Nonstatutory Stock Option Agreement granted under the Cornerstone BioPharma Holdings, Inc. 2005 Stock Incentive Plan (incorporated by reference to Exhibit 10.39 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.45#	Cornerstone BioPharma Holdings, Inc. 2005 Stock Option Plan (as Amended and Restated effective October 31, 2008) (incorporated by reference to Exhibit 10.38 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.46#	Form of Nonstatutory Employee Stock Option Agreement granted under the Cornerstone BioPharma Holdings, Inc. 2005 Stock Option Plan (incorporated by reference to Exhibit 10.40 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
10.47#	Amended and Restated Non-Employee Director Compensation and Reimbursement Policy of the Registrant effective May 18, 2011 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011).

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10.48#	Amended and Restated Executive Employment Agreement between the Registrant and Craig A. Collard dated May 6, 2009 (incorporated by reference to Exhibit 10.9 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.49#	Amended and Restated Executive Employment Agreement between the Registrant and Joshua B. Franklin dated May 6, 2009 (incorporated by reference to Exhibit 10.13 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.50#	Executive Employment Agreement between the Registrant and Kenneth R. McBean dated September 6, 2011 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated August 30, 2011).
10.51#	Executive Employment Agreement between the Registrant and Alastair McEwan dated November 6, 2012 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated November 5, 2012).
10.52#	Letter Agreement between the Registrant and Alastair McEwan dated November 6, 2012 (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K dated November 5, 2012).
10.53#	Executive Employment Agreement between the Registrant and Vincent T. Morgus dated February 1, 2011 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated February 1, 2011).
10.54#	Separation Letter Agreement and General Release between the Registrant and Vincent T. Morgus dated October 19, 2012 (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K dated October 19, 2012).
10.55#	Executive Employment Agreement between the Registrant and Andrew K. W. Powell dated October 30, 2009 (incorporated by reference to Exhibit 10.96 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2009).
10.56#	Executive Employment Agreement between the Registrant and Alan Roberts dated May 6, 2009 (incorporated by reference to Exhibit 10.14 to the Registrant s Current Report on Form 8-K dated May 6, 2009).
10.57#	Form of Indemnification Agreement, entered into between Cornerstone BioPharma Holdings, Inc. and each of Craig A. Collard and Alastair McEwan (incorporated by reference to Exhibit 10.36 to the Registrant s Current Report on Form 8-K dated October 30, 2008).
21.1	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP.
23.2	Consent of Grant Thornton LLP.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from Cornerstone Therapeutics Inc. s Annual Report on Form 10-K for the year ended December 31, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Comprehensive (Loss) Income, (iii) Consolidated Statements of Stockholders Equity, (iv) the Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements.

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* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

** Pursuant to Regulation S-K, Item 601(b)(2), certain schedules to this exhibit have not been filed herewith. A list of omitted schedules is included in the agreement. The Registrant agrees to furnish supplementally a copy of any such schedule to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.

\# Management contract or compensatory plan or arrangement.

\+ Portions of the exhibit have been omitted pursuant to a request for confidential treatment, which portions have been separately filed with the Securities and Exchange Commission.