

CAMBREX CORP
Form 10-K
February 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2015

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 1-10638

CAMBREX CORPORATION

(Exact name of registrant as specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

22-2476135
(I.R.S. Employer
Identification No.)

One Meadowlands Plaza,
East Rutherford, New Jersey **07073**
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(201) 804-3000**

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$.10 par value	New York Stock Exchange

Securities registered pursuant to Section 12 (g) of the Act: (None)

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

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

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 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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 the 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.

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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 Smaller reporting company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$1,353,570,294 as of June 30, 2015.

As of January 29, 2016, there were 31,799,188 shares outstanding of the registrant's Common Stock, \$.10 par value.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s definitive Proxy Statement for the 2016 Annual Meeting are incorporated by reference into Part III of this Report.

CAMBREX CORPORATION AND SUBSIDIARIES**INDEX TO ANNUAL REPORT ON FORM 10-K****For the Year Ended December 31, 2015**

Item		Page
No.		No.
PART I		
1	Business	4
1A	Risk Factors	9
1B	Unresolved Staff Comments	18
2	Properties	19
3	Legal Proceedings	19
4	Mine Safety Disclosures	19
PART II		
5	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	19
6	Selected Financial Data	22
7	Management's Discussion and Analysis of Financial Condition and Results of Operations	23
7A	Quantitative and Qualitative Disclosures about Market Risk	36
8	Financial Statements and Supplementary Data	36
9	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	75
9A	Controls and Procedures	75
9B	Other Information	76
PART III		
10	Directors, Executive Officers and Corporate Governance	77
11	Executive Compensation	78
12	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	78
13	Certain Relationships and Related Transactions, and Director Independence	78
14	Principal Accountant Fees and Services	78

PART IV

15

Exhibits and Financial Statement Schedules

79

2

Forward-Looking Statements

This document contains and incorporates by reference forward-looking statements including statements regarding expected performance, including, but not limited to, the Company's belief that cash flows from operations, along with funds available from the revolving line of credit, will be adequate to meet the operational and debt servicing needs of the Company, as well as other statements relating to expectations with respect to sales, the timing of orders, research and development expenditures, earnings per share, capital expenditures, the outcome of pending litigation (including environmental proceedings and remediation investigations) and related estimates of potential liability, acquisitions, divestitures, collaborations or other expansion opportunities. These statements may be identified by the fact that they use words such as "may," "will," "could," "should," "would," "expect," "anticipate," "intend," "estimate," "believe" or similar. Any forward-looking statements contained herein are based on current plans and expectations and involve risks and uncertainties that could cause actual outcomes and results to differ materially from current expectations. The factors described in Item 1A of Part I of this Annual Report on Form 10-K, captioned "Risk Factors," or otherwise described in the Company's filings with the Securities and Exchange Commission, provide examples of such risks and uncertainties that may cause the Company's actual results to differ materially from the expectations the Company describes in its forward-looking statements, including, but not limited to, pharmaceutical outsourcing trends, competitive pricing or product developments, government legislation and regulations (particularly environmental issues), tax rates, interest rates, technology, manufacturing and legal issues, including the outcome of outstanding litigation, changes in foreign exchange rates, uncollectible receivables, the timing of orders, loss on disposition of assets, cancellation or delays in renewal of contracts, lack of suitable raw materials or packaging materials, the Company's ability to receive regulatory approvals for its products and continued demand in the U.S. for late stage clinical products or the successful outcome of the Company's investment in new products.

The forward-looking statements are based on the beliefs and assumptions of Company management and the information available to Company management as of the date of this report. The Company cautions investors not to place significant reliance on expectations regarding future results, levels of activity, performance, achievements or other forward-looking statements. The information contained in this Annual Report on Form 10-K is provided by the Company as of the date hereof, and, unless required by law, the Company does not undertake and specifically disclaims any obligation to update these forward-looking statements contained in this Annual Report on Form 10-K as a result of new information, future events or otherwise.

(dollars in thousands, except per share data)

PART I

Item 1 Business.

General

Cambrex Corporation (the "Company" or "Cambrex"), a Delaware corporation, began business in December 1981. Cambrex is a life sciences company that provides products and services that accelerate and improve the development and commercialization of new and generic therapeutics. The Company primarily supplies its products and services worldwide to innovator and generic pharmaceutical companies. The Company's overall strategy is to: grow its portfolio of custom development projects, especially those in the later stages of the clinical trial process; secure long-term supply agreements to produce active pharmaceutical ingredients ("APIs") and intermediates for newly approved drug products; expand sales of products and projects based on its proprietary technologies; partner with generic drug companies to grow the Company's extensive portfolio of generic APIs; and develop, or co-develop, with partners a portfolio of niche generic drug products in finished dosage form. The Company also seeks to demonstrate excellence in regulatory compliance, environmental, health and safety, and customer service. Cambrex has three operating segments, which are manufacturing facilities that have been aggregated as one reportable segment.

The Company uses a consistent business approach:

Niche Market Focus: The Company participates in niche markets where significant technical expertise provides a competitive advantage and market differentiation.

Market Leadership: The Company secures leading market positions through excellent customer service, proprietary technologies, specialized capabilities and an outstanding regulatory record and leverages these capabilities across the market segments in which it participates.

New Products and Services: The Company continues to invest in research and development ("R&D") in order to introduce new generic and controlled substance APIs, a portfolio of niche generic drug products in finished dosage form, and optimize manufacturing processes to accelerate revenue growth, provide a competitive advantage and maintain its leading market positions.

Operational Excellence: The Company maintains its commitment to continually improve productivity and customer service levels and maintains excellent quality and regulatory compliance systems.

Acquisition and Licensing: The Company may drive growth in strategic business segments through the prudent acquisition of businesses, products, product lines, technologies and capabilities to enhance the Company's position in its niche markets.

Market Overview and Growth Drivers

The Company participates in markets that serve the healthcare industry. Customers include generic drug companies and companies that discover and commercialize small molecule human therapeutics using organic chemistry.

The aging western population, continued investment in healthcare research and drug development, growth in the world's developing markets, and the necessity to develop therapeutics to address unmet needs drives business growth in life sciences companies. Aging "baby boomers" in the United States, Europe and Japan may provide an enormous healthcare opportunity. This group typically has more education, a higher socio-economic level and higher demands for healthcare services than previous generations.

(dollars in thousands, except per share data)

Demand for Cambrex products and services is dependent upon some of its customers' continuing access to financial resources to advance their R&D projects for therapeutic candidates from the laboratory to the clinic, and eventually, to the patient. Healthcare investment comes from a variety of sources. Large pharmaceutical and biotechnology companies spend billions on drug discovery and development and billions more are spent by numerous smaller emerging pharmaceutical companies. Macro-economic conditions can have an impact on the availability of funding for the Company's customers, especially many of the smaller companies that are often dependent upon venture capital and other private sources of funding.

Cambrex assists companies in developing robust processes for the manufacture of clinical and commercial quantities. Product testing, analytical methods and quality processes are integrated into the manufacturing process. Cambrex excels in the manufacture and testing of APIs and drug substances at laboratory, clinical and commercial scale and specializes in optimizing manufacturing processes.

Demand for outsourced services from pharmaceutical companies continues to grow. Large pharmaceutical companies outsource a portion of the development and manufacturing of intermediates and APIs to manage multiple internal priorities, access new technologies or additional capacity, preserve needed capital or ensure multiple sources of supply. Many emerging pharmaceutical and generic drug companies outsource all process development and manufacturing, and larger pharmaceutical companies typically outsource development and manufacturing. With large plants and product development resources in both Europe and the U.S., and large teams of professionals with substantial experience in the development, scale-up and operation of pharmaceutical manufacturing processes, Cambrex is particularly well positioned to assist drug companies with these much needed services for APIs.

New drugs are typically patented. When the patent expires, the drug may be manufactured and marketed in its generic form. Growth in the generic drug market is driven by the continuing stream of drug patents that will expire in the future and favorable market forces that encourage the use of generic pharmaceuticals as a more cost effective alternative to higher-priced branded drugs. In the United States, and many countries in Europe, governments and prescription benefit management companies provide incentives for generic substitution to reduce costs. Cambrex manufactures approximately 100 generic APIs, typically in relatively small quantities for use in niche therapeutics. The Company also continuously develops a portfolio of APIs for eventual commercial sale to generic drug companies upon future patent expiration.

The Company recently began developing a portfolio of finished dosage form generic drug products and expects to eventually file abbreviated New Drug Applications ("ANDAs") in the U.S. and may make equivalent filings in other countries to market these products. Cambrex will work with formulation development, manufacturing and marketing partners and may fund all or a portion of the expenses necessary to bring these products to market. Given expected development and approval times, the Company does not expect to realize revenues from this initiative until 2018 at the earliest, although this could be sooner if the Company acquires products already being sold commercially.

The market for human therapeutics is regulated by the Food and Drug Administration (“FDA”) in the United States and other similar regulatory agencies throughout the world. These agencies oversee and regulate the development, manufacturing and commercialization processes for APIs and regulated intermediates. Excellent regulatory and quality systems as well as extensive experience in pharmaceutical fine chemical scale-up and manufacturing are essential to serve the industry and serve as a barrier to entry for potential new competitors.

Competitors from developing markets continually increase their capabilities in drug substance manufacturing and finished dosage form drugs. While overall global demand has been lifted by the rapid growth in certain developing markets, the presence of competitors within these markets, who have lower cost structures and competition in general, have resulted in downward pricing pressure throughout the pharmaceutical supply chain, and especially on generic APIs and early stage development services for clinical phase products. Pricing pressures, due to developing market competitors, on later stage clinical projects and supply arrangements for patented products has been limited to date, although these pressures may increase as competitors in developing markets improve their quality, regulatory and manufacturing systems to become more acceptable as suppliers to larger pharmaceutical companies. Cambrex regularly sources R&D services, raw materials and certain intermediates from developing market companies.

(dollars in thousands, except per share data)

Products

The Company uses its technical expertise in a wide range of chemical processes to meet the needs of its customers for high quality products and services for specialized applications.

The Company's business is primarily comprised of the custom development and manufacture of pharmaceutical ingredients derived from organic chemistry. Products and services are supplied globally to innovator and generic drug companies. Products include APIs, pharmaceutical intermediates and, to a lesser extent, other fine chemicals.

The Company's products and services are sold to a diverse group of several hundred customers, with one customer, Gilead Sciences, Inc., accounting for 34.5% of 2015 consolidated sales and 24.0% of 2014 consolidated sales. The Company's products are sold through a combination of direct sales and independent agents. One API, an antiviral product, represented 32.1% and 22.9% of 2015 and 2014 consolidated sales, respectively.

The following table shows gross sales by geographic area:

	2015	2014	2013
Europe	\$280,593	\$232,894	\$210,463
North America	127,024	117,477	86,974
Asia	14,024	12,865	13,800
Other	12,215	10,914	5,975
Total	\$433,856	\$374,150	\$317,212

Marketing and Distribution

Marketing generally requires significant cooperative effort among a highly trained sales and marketing staff, a scientific staff that can assess the technical fit and estimate manufacturing economics, manufacturing and engineering staff to scale up the chemical process and business unit management to determine the strategic and operational fit. The process to take a client's project from the clinical trial stage to a commercial, approved therapeutic may take from two to ten years. The Company uses sales agents in those areas where they are deemed to be more effective or economical than direct sales efforts, primarily to access generic API customers in markets outside the U.S. and Western Europe.

Raw Materials

The Company uses a wide array of raw materials in its businesses. For its products, the Company generally will attempt to have a primary and secondary supplier for its critical raw materials. Prices for these raw materials are generally stable, except for the petroleum-based solvents and certain other commodity materials, where prices can vary with market conditions.

Research and Development

The Company's R&D program is designed to increase the Company's competitiveness by improving its technology and developing processes for the manufacture of new products to meet customer requirements. The goals are to grow our portfolio of generic APIs, establish a portfolio of finished dosage form generic drug products, introduce innovative and proprietary products, improve manufacturing processes to reduce costs, improve quality and increase our capabilities to compete for business requiring significant technical expertise. R&D activities are performed at all of the Company's manufacturing facilities. As of December 31, 2015, 166 employees are at least partially involved in R&D activities worldwide.

(dollars in thousands, except per share data)

The Company spent \$12,540, \$13,075 and \$10,387 in 2015, 2014 and 2013, respectively, on R&D efforts.

Patents and Trademarks

The Company has patent protection covering certain products, processes and services. In addition, the Company also relies on know-how and trade secrets (related to many of its manufacturing processes and techniques not generally known to other companies) for developing and maintaining its market position. The Company currently owns 22 issued patents and has 3 patent applications pending in the United States and owns over 190 patents and has over 100 patent applications pending in foreign countries covering various technologies. The Company seeks to protect its proprietary technology and prepares new patent applications as it develops new inventions.

The patent rights the Company considers most significant to its business are U.S. Patent Nos. 6,828,336 and 6,586,449 and 26 foreign counterparts which relate to its nicotine polacrilex resin products and methods of manufacturing, and expire on May 28, 2022.

The Company's products and services are sold around the world under trademarks that are owned by the Company. This includes Profarmaco, which is registered around the world as a word and design mark. Rights in this trademark will exist at least as long as the Company or its majority owned subsidiaries continue to use the trademark.

The Company has entered into a worldwide perpetual license agreement with Celgene Corporation and Celgro Corporation that gives the Company the exclusive rights to certain intellectual property, including know-how and technology, relating to the development and manufacture of chirally pure bulk APIs. This intellectual property is related to amphetamine salts currently sold by the Company. Under the terms of this agreement, the Company pays no royalties or fees related to its use of this intellectual property.

Competition

The Company has numerous primary API and advanced intermediate competitors throughout Western Europe and the United States and many more competitors within various product categories the Company serves, including a growing number of competitors in Asia, Eastern Europe and other low-cost areas. The Company believes that low cost providers have had the impact of driving prices down for many products and services for which the Company competes to provide, especially within the generic API market, and the Company anticipates that it will face increased competition from these providers in the future. It is expected that regulatory compliance, product quality, pricing, and logistics will determine the extent of the long term impact of these competitors in the primary markets that the

Company serves. If the Company perceives significant competitive risk and a need for technical or financial commitment, it generally attempts to negotiate long term contracts or guarantees from its customers.

Environmental and Safety Regulations and Proceedings

Certain products manufactured by the Company involve the use, storage and transportation of toxic and hazardous materials. The Company's operations are subject to extensive laws and regulations relating to the storage, handling, emission, transportation and discharge of materials into the environment and the maintenance of safe working conditions. The Company maintains environmental and industrial safety and health compliance programs and training at its plants and believes that its manufacturing operations are in compliance with all applicable safety, health and environmental laws.

Prevailing legislation tends to hold companies primarily responsible for the proper disposal of its waste even after transfer to third party waste disposal facilities. Other future developments, such as increasingly strict environmental, safety and health laws and regulations, and enforcement policies, could result in substantial costs and liabilities to the Company and could subject the Company's handling, manufacture, use, reuse or disposal of substances or pollutants at its plants to more rigorous scrutiny than at present.

Known environmental matters that may result in liabilities to the Company and the related estimates and accruals are summarized in Note 20 to the Company's consolidated financial statements.

(dollars in thousands, except per share data)

The Company's policy is to comply with all legal requirements of applicable environmental, health and safety laws and regulations. The Company believes it is in compliance with such requirements and has adequate professional staff and systems in place to remain in compliance. In some cases, compliance can only be achieved by capital expenditures, and the Company made capital expenditures of \$2,739, \$3,733 and \$3,554 in 2015, 2014 and 2013, respectively, for environmental projects. As the environmental proceedings in which the Company is involved progress from the remedial investigation and feasibility study stage to implementation of remedial measures, related capital and other expenditures may increase. The Company considers costs for environmental compliance to be a normal cost of doing business and includes such costs in pricing decisions.

Employees

At December 31, 2015, the Company had 1,228 employees worldwide (852 of whom were from international operations) compared with 1,117 employees at December 31, 2014 and 936 at December 31, 2013.

Non-U.S. production, administration, scientific and technical employees are represented by various local and national unions. The Company believes its labor relations are satisfactory.

Seasonality

The Company experiences some seasonality primarily due to planned plant shutdowns by the Company and certain customers in the third quarter. Operating results for any quarter, however, are not necessarily indicative of results for any future period. In particular, as a result of various factors including, but not limited to, acquisitions, plant shutdowns, and the timing of large contract revenue streams, the Company believes that period-to-period comparisons of its operating results should not be relied upon as an indication of future performance.

Export and International Sales

Export sales from the Company's domestic operations in 2015, 2014 and 2013 amounted to \$159,048, \$101,101 and \$86,850, respectively. Sales from international operations were \$196,710, \$187,415, and \$164,010 in 2015, 2014 and 2013, respectively. Refer to Note 18 to the Company's consolidated financial statements.

Additional Information

Cambrex Corporation was incorporated as a Delaware corporation in 1981. The Company's principal office is located at One Meadowlands Plaza, East Rutherford, NJ 07073 and its telephone number is (201) 804-3000.

This Annual Report on Form 10-K, the Company's Quarterly Reports on Form 10-Q, the Company's Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are made available free of charge on the Company's website www.cambrex.com as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The most recent certifications by the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 are filed as exhibits to this Annual Report on Form 10-K. The Company also files with the New York Stock Exchange ("NYSE") the Annual Chief Executive Officer Certification as required by Section 303A.12.(a) of the NYSE Listed Company Manual.

The following corporate governance documents are available free of charge on the Company's website: the charters of its Audit, Regulatory Affairs, Compensation and Governance Committees, Corporate Governance Guidelines, Code of Business Conduct and Ethics and Independence Standards for Directors. These corporate governance documents are also available in print to any stockholder requesting a copy from the corporate secretary at the principal executive offices. Information contained on the website is not part of this report. The Company will also post on its website any amendments to or waivers of its Code of Business Conduct and Ethics that relate to its Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer.

(dollars in thousands, except per share data)

Item 1A Risk Factors.

Factors That May Affect Future Results

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered, including the cautionary note under the heading “Forward-Looking Statements.” If any of the following risks manifests, the Company’s business, financial condition, operating results, cash flows and reputation could be materially adversely affected. The risks and uncertainties described below are not the only ones the Company faces. Additionally, risks and uncertainties not presently known to the Company or that it currently deems immaterial may also impair its business, financial condition, operating results and cash flows in the future.

Certain of the Company’s customers and suppliers comprise a significant percentage of the Company’s business and the loss of one or more of these customers or suppliers could have a material adverse effect on the Company’s financial position, results of operations and cash flows.

Sales to a relatively small number of customers have historically accounted for a significant percentage of the Company’s business. For example, one customer accounted for 34.5% of 2015 consolidated sales. Should this, or any other significant customer renegotiate on terms more favorable to them, or discontinue or decrease their usage of the Company’s products, the loss could have a material adverse effect on the Company’s financial position, results of operations and cash flow. The Company’s customers routinely attempt to reduce costs, including the costs of the Company’s products, as a result of macro-economic trends and various market dynamics specifically affecting the pharmaceuticals industry.

New technologies, competition or a reduction in demand for the Company’s products could reduce sales.

The markets for the Company’s products are competitive and price sensitive. The Company has numerous primary API and advanced intermediate competitors throughout Western Europe and the United States and many more competitors within various segments of the markets the Company serves, including a growing number of competitors in Asia, Eastern Europe and other low-cost areas. The Company’s competitors may lower prices on products in the future and the Company may, in certain cases, respond by lowering its prices. Conversely, failure to anticipate and respond to price competition may adversely impact the Company’s market share. In general, innovator pharmaceutical companies expect price declines over time and especially upon contract renewals. These price declines could have a significant negative impact on future profits. Competitors may develop new technologies or products, negatively impacting the Company. Several of the Company’s customers, especially those that buy its generic APIs and larger pharmaceutical companies that primarily sell patented products, have internal capabilities similar to the Company’s. If one or more of these customers replace the Company’s products with their own internal capabilities, demand for the Company’s products may decrease. In addition, demand for the Company’s products may weaken due to a reduction in R&D

budgets, loss of distributors or other factors. A reduction in demand for the Company's products, particularly the one product that represented 32.1% of sales in 2015, could impair profit margins and may have a material adverse effect on the Company's financial position, results of operations and cash flow.

The Company's failure to obtain new customer contracts or renew existing contracts may adversely affect its business.

The Company must continually renew existing customer contracts and win new contracts, which subjects the Company to potentially significant pricing pressures. In the event the Company is unable to replace these contracts timely or at all, or is forced to accept terms, including pricing terms, less favorable to the Company, the Company's revenue may not be able to be sustained or may decline. In addition, certain of the Company's long-term contracts may be cancelled or delayed by customers for any reason upon notice. Multiple cancellations, non-renewals, or renewals on less favorable terms to the Company of significant contracts could materially impact the Company's business. While the Company's preferred practice is to renegotiate new or extended agreements prior to expiration, if these contracts cannot be renewed or extended on terms acceptable to the Company or at all, the Company's business, results of operations and financial condition could be materially adversely affected.

(dollars in thousands, except per share data)

Failure to obtain raw materials from third-party manufacturers could affect the Company's ability to manufacture and deliver its products.

The Company relies on third-party manufacturers to supply many of its raw materials and intermediates. In addition, the Company has a single source for supplies of some raw materials to its products. Manufacturing problems may occur with these and other outside sources. Prolonged disruptions in the supply of any of the Company's key raw materials, difficulty implementing replacement materials or new sources of supply, or a significant increase in the prices of raw materials could have a material adverse effect on the Company's operating results, financial condition or cash flows. If a supplier provides the Company raw materials or other supplies that are deficient or defective or if a supplier fails to provide the Company such materials or supplies in a timely manner, the Company may have limited ability to find appropriate substitutes or otherwise meet required specifications and deadlines. Moreover, the Company could experience inventory shortages if it is required to use an alternative supplier on short notice, which also could lead to raw materials being purchased on less favorable terms than the Company has with its regular suppliers. If such problems occur, the Company may not be able to manufacture its products profitably or on time, which could harm the Company's reputation and have a material adverse effect on the Company's business.

Failure to obtain sufficient quota from the Drug Enforcement Administration ("DEA") could affect the Company's ability to manufacture and deliver certain products.

The starting materials used in several of the Company's products and many of the Company's finished products are controlled substances and are regulated by the DEA. Consequently, their manufacture, shipment (including import and export), storage, sale and use are subject to a high degree of regulation. In particular, the DEA limits the manufacturing and distribution of certain starting materials and APIs manufactured by the Company and it must regularly apply for quota to obtain and manufacture these substances. As a result of these limitations, the Company may not be able to meet commercial demand for these substances, which could harm its relationship with customers and its reputation. If the Company's DEA registration were revoked or suspended, or if any of the Company's quota applications were rejected, the Company could no longer lawfully possess, manufacture or distribute controlled substances, which could have a material adverse effect on the Company's business.

Disruptions to the Company's or its customers' manufacturing operations or supply chain could adversely affect its results.

Due to heavy reliance on manufacturing and related operations to produce and distribute the products the Company sells, the Company could be adversely affected by disruptions to these operations or its customers' operations. The Company and its suppliers and customers operate in a highly regulated industry. Any violation of applicable regulations, failure to meet applicable manufacturing standards, or other actions by regulatory agencies, including, but not limited to, plant shutdowns or the removal of products from the market that eliminates or reduces the Company's and its customer's sales of products could negatively impact the Company's business and reputation. In addition, a

number of factors could cause production interruptions at the Company's facilities, including equipment malfunctions, disruptions in the supply chain, facility contamination, labor problems, raw material shortages, natural disasters, disruption in utility services, fire, terrorist activities, human error or disruptions in the operations of the Company's suppliers. Any significant disruption to those operations for these or any other reasons could adversely affect the Company's sales and customer relationships. Any sustained reduction in the Company's ability to provide products would negatively impact its sales growth expectations, cash flows and profitability.

Litigation may harm the Company or otherwise negatively impact its management and financial resources.

The Company's business is subject to the risk of litigation by employees, customers, consumers, suppliers, stockholders or others through private actions, class actions, administrative proceedings, regulatory actions or other litigation. The outcome of litigation, particularly class action lawsuits and regulatory actions, is difficult to assess or quantify. Plaintiffs in these types of lawsuits may seek recovery of very large or indeterminate amounts, and the magnitude of the potential loss relating to such lawsuits may remain unknown for substantial periods of time. Complex or extended litigation could cause the Company to incur large expenditures and distract its management. The cost to defend current and future litigation may be significant. There may also be adverse publicity associated with litigation that could decrease customer acceptance of the Company's products, regardless of whether the allegations are valid or whether the Company is ultimately found liable. Disputes from time to time with such companies or individuals are not uncommon, and the Company cannot be assured that it will always be able to resolve such disputes on terms favorable to the Company. As a result, litigation may adversely affect its business, financial condition and results of operations. In addition, certain contracts with our suppliers and customers contain provisions whereby the Company indemnifies, subject to certain limitations, the counterparty for damages suffered as a result of claims related to use of the Company's products or facilities and other matters. Claims made under these provisions could be expensive to litigate and could result in significant payments.

(dollars in thousands, except per share data)

Refer to Note 20 to the Company's consolidated financial statements for a discussion of the Company's environmental and legal matters.

Incidents related to hazardous materials could adversely affect the Company.

Portions of the Company's operations require the controlled use of hazardous materials. Although the Company designs and implements safety procedures to comply with the standards prescribed by federal, state, and local regulations, the risk of accidental contamination of property, or injury to individuals from these materials, cannot be completely eliminated. In the event of accidental contamination of property or injury to individuals caused by these materials, the Company could be liable for damages which could adversely affect its business. Additionally, any incident could shut down the Company's operations, which could have a material adverse effect on the business and results of operations of the Company.

The Company generates waste that must be transported to approved storage, treatment and disposal facilities. The transportation and disposal of such waste are required to meet applicable state and federal statutes and regulations. The handling of such waste potentially exposes the Company to environmental liability if, in the future, it is determined that the violation of statutes or regulations occurred.

The Company is also a party to several environmental remediation investigations and activities and, along with other companies, has been named a potentially responsible party ("PRP") for certain waste disposal sites. The Company's estimated reserve for environmental remediation is based on information currently available to it and may be subject to material adjustment in future periods as new facts or circumstances may indicate. Moreover, despite its efforts to comply with environmental laws, the Company may face significant remediation liabilities and additional legal proceedings concerning environmental matters, which could have a material adverse effect on the Company's business.