CAMBREX CORP
Form 10-K
February 07, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

x 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
o 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	22-2476135
(State or other jurisdiction of incorporation or organization)	(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:

Title of each class	Name of each exchange on which registered
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 o. No x.

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 o. No x.

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 x. No o.

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 x. No o.

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. x

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 o Accelerated filer x Non-accelerated filer o Smaller reporting company o

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $273,334,679 as of June 30, 2012.

As of January 31, 2013, there were 29,938,601 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 2013 Annual Meeting are incorporated by reference into Part III of this Report.

CAMBREX CORPORATION AND SUBSIDIARIES

INDEX TO ANNUAL REPORT ON
FORM 10-K FILED WITH THE
SECURITIES AND EXCHANGE COMMISSION

For the Year Ended December 31, 2012

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Forward-Looking Statements

This document contains and incorporates by reference forward-looking statements including statements regarding expected performance, especially the Company's estimate relating to the amount and timing of required capital expenditures under its new large Phase III supply agreement, 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, 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," "believ expressions. 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, as well as any cautionary language in this Annual Report on Form 10-K, 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 rate, interest rate, technology, manufacturing and legal issues, including the outcome of outstanding litigation disclosed in the Company's public filings, changes in foreign exchange rates, uncollectible receivables, loss on disposition of assets, cancellation or delays in renewal of contracts, lack of suitable raw materials or packaging materials, and the Company's ability to receive regulatory approvals for its products, as well as risks relating to the Company's new large Phase III supply agreement including that the Company will expend significant resources to expand its manufacturing facilities without any assurance that the new agreement will generate any revenue beyond that would be earned under termination provisions within the agreement, that the customer's product candidate will be successful in Phase III trials or obtain the necessary regulatory approvals to commercialize the product candidate, that the customer's Phase III program will not be terminated early, that anticipated quantities will not be meaningfully reduced, that the planned Phase III and pre-launch activities will proceed on the timeline anticipated, if at all, that the Company's expansion will proceed on the anticipated timeline without disruption to existing customers or our new customer and without disruption to the Company's and its customers' ability to meet key product delivery milestones.

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.

PART I

Item 1Business.

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. Cambrex has three operating segments, which are manufacturing facilities that have been aggregated as one reportable segment. 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; and partner with generic drug companies to grow the Company’s extensive portfolio of generic APIs. The Company’s acquisition of a 51% equity stake in Zenara Pharma (“Zenara”) also gives the Company the additional capability of producing final dosage form products as well as establishing it as one of the leading global suppliers to the nicotine replacement therapy (“NRT”) market. The Company also seeks to demonstrate excellence in regulatory compliance, environmental, health and safety performance, and customer service.

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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 product development ("R&D") in order to introduce innovative products and services 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 new 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 life saving 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.

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. Macro-economic conditions can have an impact on the availability of funding for the Company's customers, especially those customers dependent upon venture capital and other private sources of funding.

Once a drug is identified, companies develop a robust process for the manufacture of clinical and commercial quantities. Product testing, analytical methods and quality processes are integrated into the manufacturing process. This is a critical step to getting a commercially viable drug to market. Cambrex excels in the manufacture and testing of APIs and drug substances at laboratory, clinical and commercial scale and specializes in optimizing manufacturing processes.

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Demand for outsourced services from pharmaceutical companies continues to grow. Large pharmaceutical and biotechnology companies may outsource the development and manufacturing of a drug substance 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 many larger pharmaceutical companies have publicly stated that they will increasingly outsource the manufacturing of drug products. Cambrex is particularly well positioned to assist drug companies with these much needed services for traditional 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 health care 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 over 70 generic APIs, typically in relatively small quantities for use in niche therapeutics.

The market for human therapeutics is regulated by the Food and Drug Administration ("FDA") in the United States and other regulatory agencies throughout the world. These agencies oversee and regulate the development, manufacturing and commercialization process for APIs and regulated intermediates. Excellent regulatory and quality systems are essential to serve the industry and serve as a barrier to entry for potential new competitors.

Competitors from developing markets have increased their capabilities in drug substance manufacturing and finished dosage form drugs in recent years. 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, have resulted in downward pricing pressure throughout the pharmaceutical supply chain, and especially on generic APIs and certain 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 developing markets become more acceptable as suppliers to larger pharmaceutical companies. The Company owns a 51% equity stake in Zenara, a Hyderabad, India based pharmaceutical company focused on the formulation of final dosage form products. Cambrex also sources R&D services, raw materials and certain intermediates from developing market companies and will continue to do so. The Company will also continue to assess additional opportunities to invest in, or partner with, companies with capabilities in these geographies.

Development of the Business

The discussion below provides insight into the general development of the Company's business, including recent acquisitions and dispositions of assets.

In November 2010, the Company acquired a 51% equity stake in Zenara for approximately $18,900. Zenara is a Hyderabad, India based pharmaceutical company focused on the formulation of final dosage form products. Pursuant to the stock purchase agreement, Cambrex will acquire the remaining 49% in early 2016 at a value to be determined using a weighted combination of a multiple of 2015 earnings before interest, taxes, depreciation and amortization ("EBITDA") and cumulative EBITDA for the years 2011 through 2015, adjusted for Zenara's net debt or net cash position. Cambrex accounts for its investment in Zenara using the equity method of accounting. See Notes 2 and 7 to the Company's consolidated financial statements for additional information.

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.

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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 acquisition of a 51% equity stake in Zenara also gives the Company the additional capability of producing final dosage form products and establishes it as one of the leading global suppliers to the NRT market.

The Company's products and services are sold to a diverse group of several hundred customers, with one customer, Gyma Laboratories of America, Inc. ("Gyma"), a distributor representing multiple customers, accounting for 12.5% of 2012 consolidated sales. The Company's products are sold through a combination of direct sales and independent agents. One API, sold to multiple customers, accounted for 11.9% of 2012 consolidated sales. The Company currently has a supply agreement related to this API that accounted for 6.0% of 2012 consolidated sales and a supply agreement for another API that accounted for 8.0% of 2012 consolidated sales, both of which are scheduled to expire on December 31, 2013. The Company intends to seek to renegotiate new or extended agreements prior to expiration, but there is no guarantee that these contracts will be renewed or extended.

The following table shows gross sales to geographic area:

	2012	2011	2010
Europe	$ 150,678	$ 156,814	$ 127,009
North America	105,439	75,979	78,497
Asia	12,827	10,448	12,554
Other	8,987	11,234	8,376
Total	$ 277,931	$ 254,475	$ 226,436

Marketing and Distribution

The Company's products generally include higher value, low-to-medium volume niche products requiring significant technical expertise to develop and manufacture. 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 and independent distributors in those areas where they are deemed to be more effective or economical than direct sales efforts.

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 introduce innovative and proprietary products, improve manufacturing processes to reduce costs, improve quality and increase capacity to identify market opportunities that warrant significant technical expertise, and offer the prospects of a long-term, profitable business relationship. R&D activities are performed at all of the Company's manufacturing

facilities in both the United States and Europe. Approximately 120 employees are at least partially involved in R&D activities worldwide.

The Company spent $9,544, $11,037 and $10,305 in 2012, 2011 and 2010, respectively, on R&D efforts.

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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 15 issued patents and has 26 patent applications pending in the United States and owns 159 patents and has 97 patent applications pending in foreign countries covering various technologies. The Company seeks to protect its proprietary technology and prepares new patent applications as decisions are made to patent 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 5-MAT and 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 over 25 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 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, 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

General: 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 19 to the Company's consolidated financial statements.

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Present and Future Environmental Expenditures: 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 $3,757, $3,088 and $2,321 in 2012, 2011 and 2010, 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 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, 2012, the Company had 891 employees worldwide (627 of whom were from international operations) compared with 833 employees at December 31, 2011 and 829 at December 31, 2010.

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

The Company exports numerous products to various areas, principally Western Europe and Asia. Export sales from the Company's domestic operations in 2012, 2011 and 2010 amounted to $32,872, $31,605 and $18,529, respectively. Sales from international operations were $168,202, $171,068, and $155,073 in 2012, 2011 and 2010, respectively. Refer to Note 17 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 Internet 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, its Corporate Governance Guidelines, its Code of Business Conduct and Ethics and its Independence Standards for Directors. These corporate governance

documents are also available in print to any stockholder requesting a copy from its corporate secretary at its principal executive offices. Information contained on its 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.

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Item 1ARisk 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 and cash flows 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 also may 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.

Gyma, a distributor representing multiple customers, accounted for 12.5% of sales during 2012 and an additional 14% of sales were derived from two contracts scheduled to expire at the end of 2013. In addition, one API, sold to multiple customers, accounted for 11.9% of sales in 2012 and included one customer representing 6.0% of 2012 sales that is covered under a contract expiring at the end of 2013. The Company has also observed increasing pressure on the part of its customers to reduce costs, including the use of its services and products, as a result of macro-economic trends and various market dynamics specifically affecting the pharmaceuticals industry. Should one or more of the Company's customers renegotiate on terms more favorable to them, or discontinue or decrease their usage of the Company's services and products, the loss could have a material adverse effect on the Company's financial position, results of operations and cash flow.

New technologies, competition or a reduction in demand for Cambrex's products could reduce sales.

The markets for the Company's products are competitive and price sensitive. 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 Cambrex's market share. Companies may develop new technologies that would negatively impact the Company's ability to competitively provide certain products and services. Several of Cambrex's customers, especially those that buy its generic APIs, have internal capabilities similar to Cambrex's. If one or more of these customers replace the Company's products or services 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 could impair profit margins and may have a material adverse effect on the Company's financial position, results of operation and cash flow.

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

Many of Cambrex's contracts with its customers are short term in duration. As a result, the Company must continually replace its contracts with 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 clients 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. The Company currently has two supply agreements that account for approximately 14.0% of 2012 consolidated sales that are scheduled to expire on December 31, 2013. While the Company intends to seek 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 operation and financial condition could be materially adversely affected.

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Failure to obtain products and 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 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 its 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 the starting materials and APIs manufactured by the Company and it must apply for quota annually 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, the removal of a product from the market, or product recalls that eliminate or reduce the Company's and its customer's sales of products or services could negatively impact the Company's business. 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 or contamination, 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.

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