

CAMBREX CORP
Form 10-K
February 13, 2019

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, 2018

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 22 2476135
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) 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:

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| | |
|-------------------------------|---|
| 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 if 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 every Interactive Data File required to be submitted 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 such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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.

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

| | |
|-------------------------|---------------------------|
| Large accelerated filer | Accelerated filer |
| Non-accelerated filer | Smaller reporting company |
| | Emerging growth company |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The aggregate market value of the voting and non-voting common equity held by non affiliates of the registrant computed by reference to the closing price of the common stock on June 30, 2018 was approximately \$1,718,362,472.

As of January 31, 2019, there were 33,608,765 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 2019 Annual Meeting are incorporated by reference into Part III of this Report.

CAMBREX CORPORATION AND SUBSIDIARIES

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For the Year Ended December 31, 2018

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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 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, 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, customer and product concentration, the Company's ability to secure new customer contracts and renew existing contracts on favorable terms, pharmaceutical outsourcing trends, competitive pricing, product developments, government legislation and regulations (particularly environmental issues), the ability to successfully integrate acquisitions, 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, 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 undue 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 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. With the acquisition of Halo Pharma ("Halo"), the Company has added capabilities as a finished dosage form Contract Development and Manufacturing Organization. The Company also seeks to demonstrate excellence in regulatory compliance, environmental, health and safety, and customer service. Cambrex has six manufacturing facilities that have been aggregated as two reportable segments, Active Pharmaceutical Ingredients ("APIs") and Finished Dosage Form ("FDF").

The Company uses a consistent business approach:

- **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, and optimize manufacturing processes to accelerate revenue growth, provide a competitive advantage and maintain its leading market positions.
- **Broad Dosage Form Manufacturing Capabilities:** The Company manufactures oral solids, liquids and sterile ointments and gels. Specialty offerings include modified release, pediatric dosage forms and oral dissolving tablets.
- **Niche Market Focus:** The Company participates in niche markets where significant technical expertise provides a competitive advantage and market differentiation. This includes differentiated drug delivery, controlled substances and complex formulation.
- **Integrated Product Development and Manufacturing:** The Company's product development business feeds clinical and commercial manufacturing opportunities.
- **Investment in Manufacturing Capacity:** The Company commits significant capital to improving and expanding its manufacturing facilities to meet the ongoing growth in pharmaceutical outsourcing.
- **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

(dollars in thousands, except per share data)

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 annually 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 FDFs at laboratory, clinical and commercial scale and specializes in scaling up and 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 APIs and FDF 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 and FDF.

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 70 generic APIs, typically in relatively small quantities for use in niche therapeutics. The Company also continuously maintains a portfolio of APIs in development for eventual commercial sale to generic drug companies upon future patent expiration.

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, regulated intermediates and FDF. Continuous significant investment in facilities, people and training, along with excellent regulatory and quality systems and 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 for 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)

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Development of the Business

In September 2018, the Company completed the acquisition of 100% of Halo Pharma (“Halo”), a finished dosage form Contract Development and Manufacturing Organization. The deal was structured as a stock purchase for consideration of approximately \$425,000. The Company utilized cash on hand and borrowings under the credit facility to pay the purchase price. Cambrex acquired two GMP compliant facilities, one in Whippany, NJ, and the other in Mirabel, Quebec, Canada.

In October 2016, Cambrex purchased 100% of PharmaCore, Inc. a privately-held company located in High Point, NC for \$24,275, net of cash. The transaction was structured as a stock purchase. PharmaCore, which was renamed Cambrex High Point, Inc. (“CHP”), specializes in developing, manufacturing and scaling up small molecule APIs for projects in early clinical phases. With the acquisition of CHP, Cambrex enhanced its capabilities and expertise to efficiently develop early clinical phase products and new technologies, and increased the number of potential late stage and commercial products that could be manufactured at Cambrex’s larger manufacturing sites.

In late 2015, Cambrex committed to a plan to sell Zenara. On January 30, 2017, the Company transferred the assets and liabilities of Zenara to the buyer for consideration of approximately \$2,800, which was held in escrow until approval by Indian regulatory authorities was obtained several months later. Accordingly, as of January 30, 2017, the Company no longer includes Zenara in its reported results. Refer to Note 9 to the Company’s consolidated financial statements for further explanation of the sale of Zenara.

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 and finished dosage form products and services. Products and services are supplied globally to innovator and generic drug companies. Products include APIs, pharmaceutical intermediates and FDF.

The Company’s products and services are sold to a diverse group of several hundred customers, with one customer, Gilead Sciences, Inc., accounting for 24.8%, 35.1% and 36.9% of 2018, 2017, and 2016 consolidated sales, respectively. Substantially all of the sales to this customer are within the API segment. The Company’s products are sold through a combination of direct sales and independent agents. One API, an antiviral product, represented 23.5%, 32.8% and 31.6% of 2018, 2017 and 2016 consolidated sales, respectively.

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 or the finished dosage form, 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. The Company has recently experienced difficulties sourcing certain raw materials from China due to increased regulatory requirements in that country.

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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, 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, 2018, 181 employees were at least partially involved in R&D activities worldwide.

Patents and Trademarks

The Company has patent protection covering processes for manufacturing certain products. 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. As of December 31, 2018, the Company owned 23 issued patents and had one patent application pending in the United States, and owned over 200 patents and had over 23 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 right the Company considers most significant to our business is U.S. Patent No. 7,705,184, which relates to methods of manufacturing amphetamines, expires on May 15, 2029.

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 FDF and API competitors throughout Western Europe and the United States and many more competitors within various product categories the Company serves, including numerous competitors in Asia, Eastern Europe and other low-cost areas. 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, health and safety 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 21 to the Company's consolidated financial statements.

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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 \$10,791, \$9,872 and \$6,081 in 2018, 2017 and 2016, respectively, for environmental, health and safety compliance 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, 2018, the Company had 1,732 employees worldwide (987 of whom were from international operations) compared with 1,228 employees at December 31, 2017 and 1,295 at December 31, 2016.

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 2018, 2017 and 2016 amounted to \$138,613, \$195,193 and \$182,215, respectively. Sales from international operations were \$239,628, \$213,041 and \$220,765 in 2018, 2017 and 2016, respectively. Refer to Note 19 to the Company's consolidated financial statements.

Available Information

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 SEC maintains an internet site, www.sec.gov, containing reports, proxy and information statements, and other information regarding issuers that file electronically with 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.

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 and cash flows could be materially and

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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 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 24.8% of 2018 consolidated sales. This customer uses the Company's largest product for an anti-viral drug that has experienced decreasing sales and, accordingly, the Company expects sales of this product to decline in 2019, and again in 2020, the final year of the 5-year supply agreement. Decreased sales to this customer, or any other significant customer, or any future contract renegotiations with this customer or any other significant customer in an attempt to acquire terms more favorable to them, could have a material adverse effect on the Company's financial position, results of operations and cash flows. For certain large customers and products, the Company invests significant resources to increase production capacity. If we fail to contract for new projects as existing projects approach completion, we will experience excess production capacity, which could have a material adverse effect on profit margins.

Attempts by the Company's customers to reduce costs could have a material adverse effect on the Company's financial position, results of operations and cash flows.

The Company's customers routinely attempt to reduce costs, including the costs of the Company's products, as a result of various market dynamics specifically affecting the pharmaceuticals industry. Moreover, pricing for pharmaceutical products has come under scrutiny by governments, legislative bodies and enforcement agencies. Such pricing pressures, if passed on to the Company, could have a material adverse effect on the Company's financial position, results of operations and cash flows.

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 API and FDF 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 or services 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 have internal capabilities similar to the Company's. If one or more of these customers replace the Company with their own internal capabilities, demand for the Company's products or services may decrease. In addition, demand for the Company's products or services 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 or services could impair profit margins and may have a material adverse effect on the Company's financial position, results of operations and cash flow.

The overall level of late-stage clinical phase projects could decline and the outsourcing trends may decline, either of which could slow the Company's growth.

The Company primarily supplies its products and services worldwide to innovator and generic pharmaceutical companies. As a result, the success of the Company depends, in part, on the demand for such pharmaceutical companies' finished drug product. Any decrease in the number of such companies' clinical-phase projects could result

in a decrease in the number and size of the Company's supply contracts and have an adverse effect on its financial condition and results of operations. The Company's success also depends on the continued reliance by such pharmaceutical companies on third-party manufacturers for the APIs and finished dosage formulation used in their drug products. To the extent the Company's customers, particularly large pharmaceutical companies with established manufacturing expertise, shift to direct manufacturing and finished dosage formulation for certain APIs used in their drug products, the Company's sales could be materially and adversely affected.

(dollars in thousands, except per share data)

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

The Company seeks to continually renew existing customer contracts and secure new contracts, which subjects the Company to potentially significant pricing pressures. While the Company's preferred practice is to renegotiate new or extended agreements prior to expiration, in the event the Company is unable to replace contracts timely or at all, or is forced to accept terms, including pricing terms, less favorable to the Company, the Company's business, results of operations and financial condition could be materially and adversely affected. In addition, certain of the Company's long-term contracts may be cancelled or delayed by customers for any reason upon notice. Multiple cancellations of significant contracts could have a material adverse effect on the Company's business.

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, which in some instances are supplied from a single source. 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. In particular, manufacturing problems may occur with these suppliers, and if a supplier provides the Company with raw materials or other supplies that are deficient or defective or if a supplier fails to provide the Company with 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. The Company has also encountered issues in sourcing from China due to increased regulatory requirements. 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") or an inability to renew other licenses, certificate approvals, or permits necessary for the Company's operations could affect the Company's ability to manufacture and deliver certain products.

The Company's operations are subject to various licenses, certificates, approvals and permits in domestic and foreign jurisdictions. There is no assurance that the Company will be able to renew all licenses, certificates, approvals, and permits upon their expiration or that it will satisfy new requirements for such licenses, certificates, approvals, and permits in the future. Any such event may have an adverse effect on the Company's business.

In particular, 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. The DEA limits the manufacturing and distribution of certain starting materials and APIs manufactured by the Company and the Company 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. In addition, if the Company's DEA registration were revoked or suspended, 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,

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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. In addition, any future shutdown of the federal government may harm or delay our ability to manufacture and supply products or cause disruptions in the supply chain. 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 provide assurance 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 the Company's suppliers and customers contain provisions whereby the Company indemnifies, subject to certain limitations, its 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.

Refer to Note 21 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 caused by 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 and/or be forced to shut down its operations, which could have a material adverse effect on its business and results of operations.

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. For example, the Company is currently a party to several environmental proceedings and remediation activities and, along with other companies, has been named a potentially responsible party ("PRP") for certain waste disposal sites. Despite its efforts to comply with applicable 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.

It is the Company's policy to record appropriate liabilities for environmental matters where remedial efforts are probable and the costs can be reasonably estimated. Such liabilities are based on the Company's best estimate of the undiscounted future costs required to complete the remedial work. Environmental matters often span several years and frequently involve regulatory oversight or adjudication. Additionally, many remediation requirements are fluid

and are likely to be affected by future technological, site and regulatory developments. Each of these matters is subject to various uncertainties, and it is possible that some of these liabilities will be materially higher than the Company has estimated.

In matters where the Company has been able to reasonably estimate its liability, the Company has accrued for the estimated costs associated with the study or remediation of applicable sites not owned by the Company and the

(dollars in thousands, except per share data)

Company's current and former operating sites. Reserves are adjusted periodically as remediation efforts progress or as additional technical, regulatory or legal information become available. Given the uncertainties regarding the outcome of investigative and study activities, the status of laws, regulations, enforcement, policies, the impact of other PRPs, technology and information related to individual sites, the Company does not believe it is possible to currently develop an estimate of the range of reasonably possible environmental losses in excess of its reserves.

Refer to Note 21 to the Company's consolidated financial statements for a discussion of the Company's environmental and legal matters.

Potential product liability claims, errors and omissions claims in connection with services the Company performs and potential liability under indemnification agreements between the Company and its officers and directors could adversely affect the Company.

The Company manufactures products intended for use by the public. These activities could expose the Company to risk of liability for personal injury or death to persons using such products. The Company seeks to reduce its potential liability through measures such as contractual indemnification provisions with customers (the scope of which may vary by customer, and the performances of which are not secured) and insurance maintained by the customer and its customers. The Company could be materially adversely affected if it were required to pay damages or incur defense costs in connection with a claim that is outside the scope of the indemnification agreements, if the indemnity, although applicable, is not performed in accordance with its terms or if the Company's liability exceeds the amount of applicable insurance or indemnity. In addition, the Company could be held liable for errors and omissions in connection with the services it performs. The Company currently maintains product liability and errors and omissions insurance with respect to these risks. There can be no assurance, however, that the Company's insurance coverage will be adequate or that insurance coverage will continue to be available on terms acceptable to the Company.

The Company also indemnifies its officers and directors for certain events or occurrences while the officer or director is serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Although the Company has a director and officer insurance policy that covers a portion of any potential exposure, the Company could be materially and adversely affected if it were required to pay damages or incur legal costs in connection with a claim above such insurance limits.

Any claims beyond the Company's insurance coverage limits, or that are otherwise not covered by the Company's insurance, may result in substantial costs and a reduction in its available capital resources.

The Company maintains property insurance, employer's liability insurance, product liability insurance, general liability insurance, business interruption insurance, and directors and officers' liability insurance, among others. Although the Company maintains what it believes to be adequate insurance coverage, potential claims may exceed the amount of insurance coverage or may be excluded under the terms of the policy, which could cause an adverse effect on the Company's business, financial condition and results from operations. Generally, the Company would be at risk for the loss of inventory that is not within customer specifications. These amounts could be significant. In addition, in the future the Company may not be able to obtain adequate insurance coverage or the Company may be required to pay higher premiums and accept higher deductibles in order to secure adequate insurance coverage.

The Company depends on key personnel and the loss of key personnel could harm the Company's business and results of operations.

The Company depends on its ability to attract and retain qualified scientific and technical employees as well as a number of key executives. These employees may voluntarily terminate their employment with the Company at any time. There can be no assurance that the Company will be able to retain key personnel, or to attract and retain additional qualified employees. The Company does not maintain key-man or similar policies covering any of its

senior management or key personnel. The Company's inability to attract and retain key personnel would have a material adverse effect on the Company's business.

(dollars in thousands, except per share data)

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The Company has made and continues to make significant capital investments in its facilities to meet its potential future needs and, as a result, the Company depends on the success of attracting new and retaining existing customers' business.

The Company has made and continues to make substantial investments in all of its manufacturing facilities. As a result, the Company's fixed costs have increased and may continue to increase. If the Company is not able to utilize the facilities to capacity, its margins could be adversely affected.

The Company continues to expand its large-scale API manufacturing capacity to support expected growth in the business. There can be no assurance that sales volumes will be sufficient to ensure the economical operation of this expanded capacity, in which case, the Company's results of operations could be adversely affected.

Disruption or instability in global capital markets could have a material adverse effect on the Company's business, financial condition and results of operations.

The U.S. and global capital markets have experienced periods of disruption during which general economic conditions have deteriorated with adverse consequences for the broader financial and credit markets and during which the availability of debt and equity capital for the market as a whole was reduced significantly. Any future reduction in the availability of debt or equity capital could adversely affect the ability of the Company's customers to obtain financing for product development and could result in a decrease in, or cancellation of, orders for the Company's products as well as impact the ability of the Company's customers to make payments. While the Company believes that cash flows from operations and funds available under its revolving credit facility will be adequate to meet the operational and debt servicing needs of the Company for the foreseeable future, such disruptions could impact the Company's cash flows and the availability of funds under its revolving credit facility, if, for instance, one or more of the participant banks were to fail, in which case the Company's business may be materially and adversely affected.

Indebtedness from the Credit Agreement could adversely affect the Company's financial condition or restrict the Company's future operations.

On January 2, 2019, the Company and certain of its subsidiaries entered into a credit agreement (the "Credit Agreement") relating to a five-year \$600,000 revolving credit facility and \$200,000 term loan. The Credit Agreement imposes certain limitations on the Company, including:

- requiring the Company to dedicate a portion of its cash flows from operations to payments on its indebtedness, thereby reducing funds available for working capital, capital expenditures, research and development efforts, acquisitions, selling and marketing efforts and other purposes;
- increasing the Company's vulnerability to adverse economic and industry conditions, which could place the Company at a competitive disadvantage to its competitors that have relatively less indebtedness;
- restricting the Company from making strategic acquisitions or causing the Company to make non-strategic divestitures;
- limiting the Company's flexibility in planning for, or reacting to, changes in its business or industry; and
- limiting the Company's ability to borrow additional amounts for working capital, capital expenditures, research and development efforts, acquisitions, selling and marketing efforts and other purposes.

Any of these factors could materially adversely affect the Company's business, financial condition, and results of operations.

If the Company acquires other businesses, it may be harmed by difficulties in integration and employee retention, unidentified liabilities of the acquired businesses, or obligations incurred in connection with financing the acquisition.

In the course of the Company's business, the Company selectively pursues complementary acquisitions that involve known and unknown risks that could adversely affect the Company's future revenues and operating results. For

example:

(dollars in thousands, except per share data)

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- The Company may fail to successfully integrate its acquisitions in accordance with its business strategy.
 - The initial rationale for the acquisition may not remain viable due to a variety of factors, including unforeseen regulatory changes and market dynamics after the acquisition, and this may result in a significant delay or reduction in the profitability of the acquisition.
 - Integration of acquisitions may divert management's attention away from the Company's primary product offerings, resulting in the loss of key customers or personnel, and may expose the Company to unanticipated liabilities.
 - The Company may not be able to retain the skilled employees and experienced management that may be necessary to operate the businesses it acquires. If the Company cannot retain such personnel, it may not be able to locate or hire new skilled employees and experienced management to replace them.
 - The Company may purchase a business that has contingent liabilities that include, among others, known or unknown environmental, patent or product liability claims.
 - The Company's acquisition strategy may require it to obtain additional debt or equity financing, potentially resulting in a high level of debt obligations or significant dilution of ownership, or both.
 - The Company may purchase businesses located in jurisdictions where it does not have operations and as a result it may not be able to anticipate local regulations and the impact such regulations have on its business.
- Any indemnities or warranties or insurance obtained in connection with such acquisitions may not fully cover the actual liabilities the Company incurs due to limitations in scope, amount or duration, financial limitations of the indemnitor or warrantor or other reasons.

As a result of acquiring businesses or entering into other significant transactions, the Company may experience significant charges to earnings for merger related expenses. If the Company is not able to successfully integrate the acquired business, it may affect the Company's results of operations and the market price of its common stock. Furthermore, if the Company is unable to improve the operating margins of acquired businesses or operate them profitably, it may be unable to achieve its growth strategy.

In addition, if the Company makes one or more significant acquisitions in which the consideration includes equity shares or other securities or additional capital is raised through equity financings, equity interests in the Company may be significantly diluted and may result in a dilution of earnings per share. If the Company makes one or more significant acquisitions in which the consideration includes cash, it may be required to use a substantial portion of its available cash or incur a significant amount of debt or otherwise arrange additional funds to complete the acquisition, which may result in reduced liquidity, a decrease in its net income and a consequential reduction in its earnings per share.

The Company's liquidity, business, financial condition, results of operations and cash flows could be materially and adversely affected if the financial institutions which hold its funds fail.

The Company has significant funds held in bank deposits, money market funds and other accounts at certain financial institutions. A significant portion of the funds held in these accounts exceed insurable limits. In the normal course of business, the Company maintains cash balances with European Union banks up to the equivalent of \$20,000 and slightly larger balances in U.S. banks. The Company routinely monitors the risks associated with these institutions and diversifies its exposure by maintaining balances with multiple financial institutions. If any of the financial institutions where the Company has deposited funds were to fail, the Company may lose some or all of its deposited funds. Such a loss could have a material adverse effect on the Company's liquidity, business, financial condition, results of operations and cash flows.

The Company has significant inventories on hand.

The Company maintains significant inventories and has an allowance for slow-moving and obsolete inventory. Any significant unanticipated changes in future product demand or market conditions, including obsolescence or the

(dollars in thousands, except per share data)

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uncertainty in the global market, could also have an impact on the value of inventory and adversely impact the Company's results of operations.

International unrest could adversely affect the Company's results.

The Company's international revenues, which include revenues from its non-U.S. subsidiaries and export sales from the U.S., represent the majority of its product revenues. The Company's operations extend to numerous countries outside of the U.S.

There are a number of significant risks arising from the Company's international operations, including:

- the possibility that nations or groups could boycott its products;
- inflation, foreign currency exchange rates and the impact of shifts in the U.S. and local economies on those rates;
- general economic decline or political unrest in the markets in which it operates;
- effects from the voter-approved exit of the United Kingdom from the European Union (commonly referred to as "Brexit"), including any resulting deterioration in economic conditions, volatility in currency exchange rates or adverse regulatory changes;
- geopolitical risks, terrorism, or acts of war or hostility;
- compliance with local laws and regulations including laws restricting the inflow of capital or cash and unexpected changes in regulatory requirements;
- difficulties and expenses of compliance with a wide variety of foreign laws and regulations;
- longer accounts receivable cycles in certain foreign countries;
- import and export licensing requirements;
- government sanctions that may reduce or eliminate the Company's ability to sell its products in certain countries; and
- the protection of the Company's intellectual property and that of its customers.

If the Company is unable to effectively manage these risks, it may not produce the revenues, earnings, or strategic benefits that it anticipates which could have a material adverse effect on the Company's business.

As a result of the Company's substantial international operations, a significant portion of the Company's business is conducted in currencies other than the U.S. dollar, which is its reporting currency. The Company recognizes foreign currency gains or losses arising from its operations in the period incurred. As a result, currency fluctuations between the U.S. dollar and the currencies in which the Company does business, primarily the euro and the Swedish krona, have caused, and will continue to cause, foreign currency gains and losses. The Company cannot predict the effects of exchange rate fluctuations upon its future operating results because of the number of currencies involved, the variability of currency exposures, and the potential volatility of currency exchange rates. The Company periodically purchases foreign exchange contracts to mitigate the impact of this volatility on its operations, but its strategies are short-term in nature and may not adequately protect its operating results from the full effects of exchange rate fluctuations.

Certain jurisdictions have experienced governmental corruption to some degree and, in some circumstances, anti-bribery laws may conflict with some local customs and practices. As a result of the Company's policy to comply with the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws, the Company may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws. Furthermore, while employees and agents must comply with these laws, the Company cannot be certain that internal policies and procedures will always prevent violations of these laws, despite a commitment to legal compliance and corporate ethics. Violations or mere allegations of such violations could have a material adverse effect on the Company's business and reputation.

(dollars in thousands, except per share data)

The Company's operating results may unexpectedly fluctuate in future periods.

The Company's revenue and operating results can fluctuate on a quarterly basis. The operating results for a particular quarter may be higher or lower than expected as a result of a number of factors, including, but not limited to, the timing of contracts; the delay, cancellation or acceleration of a contract; seasonal slowdowns in different parts of the world; the timing of accounts receivable collections; pension contributions; changes in government regulations; and changes in exchange rates against the U.S. dollar. Because a high percentage of the Company's costs are relatively fixed in the short term, such as the cost of maintaining facilities and compensating employees, any one of these factors could have a significant impact on the Company's quarterly results. In some quarters, the Company's revenue and operating results may be significantly lower than or higher than the expectations of securities analysts and investors due to any of the factors described above. Because of these fluctuations, results for any one quarter are not necessarily indicative of the results that may be achieved for any other quarter or for the full fiscal year.

The possibility the Company will be unable to protect its technologies could affect its ability to compete.

The Company's success depends to some degree upon its ability to develop proprietary products and technologies. However, the Company cannot be assured that patents will be granted on any of its patent applications. The Company also cannot be assured that the scope of any of its issued patents will be sufficiently broad to offer meaningful protection. The Company has patents issued in selected countries; therefore, third parties can make, use, and sell products covered by its patents in any country in which the Company does not have patent protection. In addition, the Company may be involved in patent litigation in the future. Issued patents or patents the Company licenses could be successfully challenged, invalidated or circumvented so that its patent rights would not create an effective competitive barrier. Although the Company intends to defend the validity of owned patents and use all appropriate methods to prevent their infringement, such efforts are expensive and time consuming, with no assurance of success. The ability to enforce patents depends on the laws of individual countries and each country's practices regarding enforcement of intellectual property rights. The Company provides its customers the right to use its products under label licenses that are for research purposes only. These licenses could be contested, and the Company cannot be assured that it would either be aware of an unauthorized use or be able to enforce the restrictions in a cost-effective manner.

If a third party makes a claim to an intellectual property right to technology the Company uses, the Company may need to discontinue an important product or product line, alter its products and processes, defend its right to use such technology in court or pay license fees. Although the Company may, under these circumstances, attempt to obtain a license to such intellectual property, it may not be able to do so on favorable terms, or at all. Additionally, if the Company's products are found to infringe on a third party's intellectual property, the Company may be required to pay damages for past infringement, and lose the ability to sell certain products or receive licensing revenues.

The Company also relies on trade secrets, unpatented proprietary know-how and continuing technological innovation that it seeks to protect, in part by confidentiality agreements with licensees, suppliers, employees and consultants. It is possible that these agreements will be breached and the Company will not have adequate remedies for any such breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, the Company's trade secrets and proprietary technology may otherwise become known or be independently developed by its competitors or the Company may not be able to maintain the confidentiality of information relating to such products.

Information technology systems could fail to perform adequately or the Company may fail to adequately protect such systems against data corruption, cyber-based attacks, or network security breaches.

The Company utilizes information technology networks and systems to process, transmit, and store electronic information. In particular, the Company depends on information technology infrastructure to effectively manage its business data, supply chain, logistics, accounting, and other business processes and electronic communications

between employees, customers and suppliers. Ineffective allocation and management of the resources necessary to build and sustain an appropriate technology infrastructure could adversely affect the Company's business. In addition, security breaches or system failures of this infrastructure can create system disruptions, shutdowns, or unauthorized access to confidential information. Inability to prevent such breaches or failures could disrupt the Company's operations or cause financial damage or loss because of lost or misappropriated information.

(dollars in thousands, except per share data)

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The Company could be subject to impairment charges in the future.

Under U.S. GAAP, the Company is required to evaluate goodwill for impairment at least annually. If the Company determines that the fair value is less than the carrying value, an impairment loss will be recorded in the Company's statement of operations. The determination of fair value is a highly subjective exercise and can produce significantly different results based on the assumptions used and methodologies employed. If the Company's projected long-term sales growth rate, profit margins or terminal rate are considerably lower or the assumed weighted average cost of capital is considerably higher, future testing may indicate impairment and the Company would have to record a non-cash goodwill impairment loss in its statement of operations.

Assessments by various tax authorities may be materially different than the Company has provided for and it may experience significant volatility in its annual and quarterly effective tax rate.

As a matter of course, the Company is audited by federal, state, and foreign tax authorities. From time to time, these audits result in proposed assessments. In recent years, the Company utilized significant tax attributes such as domestic federal foreign tax credits to reduce U.S. cash taxes. While the Company believes that it has adequately provided for any taxes related to these items, and taxes related to all other aspects of its business, any such assessments or future settlements may be materially different than it has provided. Refer to Note 11 of the Company's consolidated financial statements for a discussion of the Company's income taxes.

The Company has deferred tax assets that it may not be able to use under certain circumstances.

If the Company is unable to generate future taxable income of sufficient amounts and type in certain jurisdictions, or if there is a significant change in tax rates or the time period within which taxable income is recognized, the Company could be required to increase its valuation allowances against its deferred tax assets resulting in an increase in its recorded tax expense and a potential adverse impact on future results. Future changes in corporate income tax rates could require the Company to revalue its deferred tax balances, potentially resulting in significant non-cash charges.

Low investment performance by the Company's defined benefit pension plan assets or other events including changes in regulations or actuarial assumptions may increase the Company's pension expense, and may require the Company to fund a larger portion of its pension obligations, thus diverting funds from other potential uses.

The Company sponsors a defined benefit pension plan, frozen in 2007, that covers certain eligible employees. The Company's pension expense and required contributions to the pension plan are directly affected by changes in interest rates, the value of plan assets, the projected rate of return on plan assets, the actual rate of return on plan assets, and the actuarial assumptions used to measure the defined benefit pension plan obligations. If plan assets perform below the assumed rate of return used to determine pension expense, future pension expense will increase. The proportion of pension assets to liabilities, which is called the funded status, determines the level of contribution to the plan that is required by law. Changes in the plan's funded status related to the value of assets or liabilities could increase the amount required to be funded. The Company cannot predict whether changing market or economic conditions, regulatory changes or other factors will further increase the Company's pension funding obligations, diverting funds from other potential uses.

Any significant change in government regulation of the drug development process could have a material adverse effect on the Company.

The manufacturing of pharmaceutical products is subject to extensive regulation by governmental authorities, including the FDA, the European Medicines Agency and comparable regulatory authorities in other countries. The process of obtaining regulatory approval to produce and market pharmaceutical products is rigorous, time-consuming, costly, and often unpredictable. Any modifications to these regulations could have a material adverse effect on the Company's business. If regulations become more stringent, the Company may be unable to obtain requisite regulatory

approvals on a timely basis for marketing and production of products. Conversely, any significant reduction in the scope of regulatory requirements or the introduction of simplified drug approval procedures could reduce barriers to entry and increase competition for the Company's products.

(dollars in thousands, except per share data)

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Healthcare legislative reform measures could have a material adverse effect on the Company.

The continuing increase in expenditures for healthcare has been the subject of considerable government attention almost everywhere the Company does business. The potential repeal or repeal and replacement of the Affordable Care Act could have a material adverse effect on the Company's industry generally and on the Company's ability to maintain or increase sales. In addition, there has been heightened public scrutiny in the United States recently over the manner in which drug manufacturers set prices for their marketed products. Such cost containment measures in the United States, or similar measures in the other countries in which the Company does business, could result in more rigorous coverage criteria and lower reimbursement, placing additional downward pressure on the prices that the Company receives for its products and adversely affecting the Company's ability to sell its products.

Failure to comply with current Good Manufacturing Practices ("cGMP") and other government regulations, as well as delays in obtaining regulatory approval by the Company or its customers could have a material adverse effect on the Company.

All facilities and manufacturing techniques used for manufacturing products for clinical use or for commercial sale in the U.S. must be operated in conformity with cGMP regulations as required by the FDA and other comparable regulatory authorities in other countries, and for certain products, the DEA. The Company's facilities are subject to periodic regulatory and customer inspections to ensure compliance with cGMP and other requirements applicable to such products. A finding that the Company has materially violated these requirements could result in regulatory sanctions including, but not limited to, the regulatory agencies withholding approval of new drug applications or supplements and the denial of product entry into the U.S., or other countries, of products manufactured at non-compliant facilities, the loss of a customer contract, the disqualification of data for client submissions to regulatory authorities and a mandated closing of the Company's facilities. Any such violations would have a material adverse effect on the Company's business. The Company's customers are typically subject to the same, or similar regulations and any such violations or other actions by regulatory agencies, including, but not limited to, plant shutdowns or product recalls that eliminate or reduce the Company's sale of its products or services could negatively impact the Company's business. In addition, the submission of new products to regulatory authorities for approval by the Company or its customers does not guarantee that approval to market the product will be granted. Each authority may impose its own requirements or delay or refuse to grant approval to the Company or customer even when the product has already been approved in another country. Products that have already been approved can be removed from the market by regulatory agencies for numerous reasons.

Item 1B Unresolved Staff Comments.

None.

(dollars in thousands, except per share data)

Item 2 Properties.

Set forth below is information relating to manufacturing facilities owned by the Company as of December 31, 2018:

| Location | Acreage | Operating Subsidiary | Segment |
|----------------------------|----------|-------------------------------------|-----------------------------------|
| Charles City, Iowa | 57 acres | Cambrex Charles City, Inc. | Active Pharmaceutical Ingredients |
| Karlskoga, Sweden | 42 acres | Cambrex Karlskoga AB | Active Pharmaceutical Ingredients |
| Paullo (Milan), Italy | 12 acres | Cambrex Profarmaco Milano S.r.l. | Active Pharmaceutical Ingredients |
| High Point, North Carolina | 7 acres | Cambrex High Point | Active Pharmaceutical Ingredients |
| Whippany, New Jersey | 21 acres | Cambrex Whippany | Finished Dosage Form |
| Mirabel, Canada | 23 acres | Cambrex Mirabel | Finished Dosage Form |

Item 3 Legal Proceedings.

See "Environmental and Safety Regulations and Proceedings" under Item 1 and Note 21 to the Company's consolidated financial statements with respect to various proceedings involving the Company in connection with environmental matters. The Company is party to a number of other proceedings also discussed in Note 21 to the Company's consolidated financial statements.

Item 4 Mine Safety Disclosures.

None.

(dollars in thousands, except per share data)

PART II

Item 5 Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

The Company's common stock, \$0.10 par value, is listed on the NYSE under the symbol CBM.

As of February 1, 2019, there were approximately 22,572 beneficial holders of the outstanding common stock of the Company.

The Company does not anticipate paying cash dividends in the foreseeable future. There were no cash dividends paid on our common stock during the past three fiscal years.

Equity Compensation Table

The following table provides information as of December 31, 2018 with respect to shares of common stock that may be issued under the Company's existing equity compensation plans, all of which have been approved by security holders.

| | | Number of securities |
|---|---|---|
| Number of securities to be issued upon exercise of outstanding options, warrants and rights | Weighted average exercise price of outstanding options, warrants and rights | Number of securities remaining for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
| 1,051,623 | \$ 41.41 | 662,671 |

(dollars in thousands, except per share data)

Comparison of Five-Year Cumulative Total Returns

The comparative stock performance graph below compares the five-year cumulative total stockholder return (assuming reinvestment of dividends, if any) from investing \$100 on December 31, 2013, to the close of the last trading day of 2018, in each of (i) Cambrex common stock, (ii) the S&P 500 Index and (iii) an index of the Company's peer group. The stock price performance reflected in the graph below is not necessarily indicative of future price performance.

The Company's commercial activities are focused on manufacturing and marketing to customers concentrated in the Life Sciences Industry (including pharmaceutical chemicals and intermediates). Although the Company's products are diverse, the Company believes that an index of its peer group based on its GICS code is a reasonable comparison group for the commercial activities on which it currently focuses. The peer group is for S&P GICS code 352030, Life Sciences Tools & Services, and is comprised of 47 companies as of December 31, 2018.

(dollars in thousands, except per share data)

Item 6 Selected Financial Data.

The following selected consolidated financial data of the Company for each of the five years in the period through December 31, 2018 are derived from the audited financial statements. The consolidated financial statements of the Company as of December 31, 2018 and 2017 and for each of the years in the three year period ended December 31, 2018 and the reports of the independent registered public accounting firm are included elsewhere in this annual report. The data presented below should be read in conjunction with the financial statements of the Company, the notes to the financial statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere. The Company adopted ASC 606 – Revenue from Contracts with Customers on January 1, 2018 using the modified retrospective method which does not require comparative periods reported under ASC 605 to be restated, therefore years 2014 through 2017 are under ASC 605.

| | Years Ended December 31, | | | | |
|--|--------------------------|---------------------|---------------------|---------------------|---------------------|
| | 2018 ⁽¹⁾ | 2017 ⁽²⁾ | 2016 ⁽³⁾ | 2015 ⁽⁴⁾ | 2014 ⁽⁵⁾ |
| INCOME DATA: | | | | | |
| Gross sales | \$514,997 | \$525,936 | \$491,538 | \$433,856 | \$374,150 |
| Net revenue | 532,093 | 534,456 | 490,644 | 433,326 | 374,613 |
| Gross profit | 196,688 | 230,303 | 204,388 | 176,965 | 123,798 |
| Selling, general and administrative expenses | 68,506 | 68,984 | 58,042 | 57,867 | 52,489 |
| Research and development expenses | 15,547 | 16,901 | 14,292 | 12,540 | 13,075 |
| Acquisition and integration expenses | 11,139 | - | 840 | - | - |
| Restructuring expenses | - | - | 1,158 | 15,573 | - |
| Loss on voluntary pension settlement | - | - | - | - | 7,170 |
| Gain on sale of asset | - | - | - | - | (1,234) |
| Operating profit | 101,496 | 144,418 | 130,056 | 90,985 | 52,298 |
| Interest expense, net | 3,967 | 1,253 | 717 | 1,699 | 2,174 |
| Unrealized gain on investment in equity securities | (13,023) | - | - | - | - |
| Equity in losses of partially-owned affiliates | - | - | - | - | 4,623 |
| Other expenses/(income), net | 747 | 1,340 | 1,800 | (279) | (5) |
| Income before income taxes | 109,805 | 141,825 | 127,539 | 89,565 | 45,506 |
| Provision/(benefit) for income taxes | 16,596 | 38,061 | 40,214 | 32,389 | (12,627) |
| Income from continuing operations | 93,209 | 103,764 | 87,325 | 57,176 | 58,133 |
| (Loss)/income from discontinued operations, | | | | | |
| net of tax | (791) | (1,314) | (5,647) | 41 | (830) |
| Net income | 92,418 | 102,450 | 81,678 | 57,217 | 57,303 |
| EARNINGS PER SHARE DATA: | | | | | |
| Earnings/(loss) per common share (basic): | | | | | |
| Income from continuing operations | \$2.80 | \$3.18 | \$2.72 | \$1.82 | \$1.89 |
| (Loss)/income from discontinued operations, | | | | | |
| net of tax | \$(0.02) | \$(0.04) | \$(0.17) | \$- | \$(0.03) |
| Net income | \$2.78 | \$3.14 | \$2.55 | \$1.82 | \$1.86 |
| Earnings/(loss) per common share (diluted): | | | | | |
| Income from continuing operations | \$2.77 | \$3.10 | \$2.65 | \$1.76 | \$1.84 |
| (Loss)/income from discontinued operations, | | | | | |
| net of tax | \$(0.02) | \$(0.04) | \$(0.17) | \$- | \$(0.03) |
| Net income | \$2.75 | \$3.06 | \$2.48 | \$1.76 | \$1.81 |
| Weighted average shares outstanding | | | | | |

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(in thousands):

| | | | | | |
|---|-----------|-----------|-----------|-----------|-----------|
| Basic | 33,243 | 32,662 | 32,086 | 31,420 | 30,763 |
| Diluted | 33,665 | 33,486 | 32,969 | 32,555 | 31,643 |
| BALANCE SHEET DATA: (at end of period) | | | | | |
| Working capital | \$305,680 | \$339,537 | \$227,193 | \$129,477 | \$125,172 |
| Total assets | 1,223,428 | 740,565 | 611,865 | 505,539 | 486,587 |
| Long-term debt | 300,000 | - | - | - | 60,000 |
| Total stockholders' equity | 653,727 | 544,864 | 405,427 | 310,835 | 251,226 |

(1) Income from continuing operations includes the results of Halo since the date acquired and tax benefits for the finalization of the Tax Cuts and Jobs Act (“TCJA”) toll charge and for New Jersey tax reform. Loss from

(dollars in thousands, except per share data)

- discontinued operations includes pre-tax expense of \$971, reduced by a tax benefit of \$180, for environmental remediation related to sites of divested businesses. The cumulative effect of initially applying the new revenue standard was \$16,219 and has been recorded as an adjustment to increase the opening balance of retained earnings.
- (2) Income from continuing operations includes a tax benefit of \$5,236 as a result of applying Accounting Standards Update (“ASU”) 2016-09 and tax expense of \$117 as a result of the changes in enacted tax rates in the U.S. and the toll charge. Loss from discontinued operations includes pre-tax expense of \$2,020, reduced by a tax benefit of \$706, for environmental remediation related to sites of divested businesses.
- (3) Income from continuing operations includes restructuring expenses related to the decision to sell the finished dosage form facility in Hyderabad, India and acquisition and integration expenses related to the acquisition of CHP. Loss from discontinued operations includes pre-tax expense of \$8,777, reduced by a tax benefit of \$3,130, for environmental remediation related to sites of divested businesses.
- (4) Income from continuing operations includes restructuring expenses and a tax benefit related to the decision to sell the finished dosage form facility in Hyderabad, India. Income from discontinued operations includes pre-tax income of \$63, reduced by tax expense of \$22, for environmental reimbursements related to sites of divested businesses.
- (5) Income from continuing operations includes a gain on the sale of land, net of tax, a charge related to a voluntary lump sum pension settlement, a loss related to the purchase of the remaining shares in Zenara, a benefit for the release of a valuation allowance and a benefit for the settlement of tax disputes. Loss from discontinued operations includes pre-tax expense of \$1,277, reduced by a tax benefit of \$447, for environmental remediation related to sites of divested businesses.

(dollars in thousands, except per share data)

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

In September 2018, the Company purchased Halo Pharma (“Halo”), a finished dosage form contract development and manufacturing company. As a result, and to be in alignment with how the business is managed, the Company’s operating segments were aggregated to form two reportable segments, Active Pharmaceutical Ingredients (“APIs”) and Finished Dosage Form (“FDF”). The API segment consists of four operating segments which manufactures APIs. The FDF segment consists of one operating segment which manufactures and develops finished dosage form products. The Company adopted ASC 606 effective January 1, 2018 electing the modified retrospective method. Prior periods were not restated to conform to this new accounting standard. As such, year over year comparisons are not presented on a comparable basis. The Company has included a discussion of certain Income Statement accounts that compare 2018 on an ASC 605 basis (previous guidance) to 2017 to enhance comparability.

The following significant events, which are explained in detail on the following pages, occurred during 2018:

- The Company acquired Halo in September for approximately \$425,000. Halo’s Net revenue for the period from the acquisition date, September 12, 2018 through December 31, 2018 was \$28,600.
- The Company adopted ASC 606 – Revenue from Contracts with Customers (“ASC 606”) on January 1, 2018 using the modified retrospective method. The cumulative effect adjustment recorded to retained earnings as of January 1, 2018 was \$16,219, net of tax.
- Net revenue was \$532,093 under current U.S. GAAP, ASC 606. Under ASC 605, the previous revenue recognition standard, and the standard under which 2017 results were reported, 2018 net revenue was \$551,874 compared to \$534,456 in 2017, a 3.3% increase. Foreign currency exchange favorably impacted revenue by 0.9%.
- Operating profit was \$101,496 under ASC 606. Under ASC 605, operating profit was \$115,524 compared to \$144,418 in 2017.
- The 2018 net debt balance was \$204,148, an increase of \$387,432, compared to net cash of \$183,284 in 2017. Net revenue in 2018 was \$532,093 under ASC 606, a 0.4% decrease compared to 2017. Under ASC 605, net revenue was \$551,874 compared to \$534,456 in 2017, a 3.3% increase. Excluding the impact of applying ASC 606 of \$19,781 and the impact of foreign currency exchange, net revenue increased 2.4%. The increase is a result of higher volumes (2.7%) partially offset by lower pricing (-0.3%). The volume increase was primarily due to sales from Halo, the Company’s new finished dosage form business, higher controlled substances and clinical phase products partially offset by lower sales of certain branded APIs. The price decline was due to a combination of contractual agreements and negotiated market based price adjustments for certain products.

Gross margins decreased to 37.0% in 2018 compared to 43.1% in 2017. Foreign currency favorably impacted margins by 0.6%. Margins were negatively impacted by lower production volumes, unfavorable product mix, lower pricing, the inclusion of Halo and purchase accounting.

The Company reported income from continuing operations of \$93,209, or \$2.77 per diluted share in 2018, compared to \$103,764, or \$3.10 per diluted share in 2017.

Critical Accounting Estimates

The Company’s critical accounting estimates are those that require the most subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. The Company bases its estimates on historical experience and on other assumptions that are deemed reasonable by management under each applicable circumstance. Actual results or amounts could differ from estimates and the differences could have a material impact on the consolidated financial statements. A discussion of the Company’s critical accounting

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policies, the underlying judgments and uncertainties affecting their application and the likelihood that materially different amounts would be reported under different conditions or using different assumptions, is as follows:

Revenue Recognition

2018 results are accounted for under the following new policy:

The Company adopted ASC 606 Revenue from Contracts with Customers on January 1, 2018 using the modified retrospective method. As a result, the Company has changed its accounting policy for revenue recognition as detailed below. The cumulative effect of initially applying the new revenue standard was recorded as an adjustment to the opening balance of retained earnings. The comparative information has not been restated and continues to be reported under accounting standard ASC 605 which was in effect for those periods.

Revenue is recognized when control over a product or service is transferred to a customer. Revenue is measured as the amount of consideration expected in exchange for transferring goods or providing services.

Sales terms to certain customers include rebates if certain conditions are met. Additionally, sales are generally made with a limited right of return under certain conditions. The Company estimates these rebates and returns at the time of sale based on the terms of agreements with customers and historical experience and estimated orders. The Company recognizes revenue net of these estimated costs which are classified as allowances and rebates.

Shipping and handling costs are treated as fulfillment costs and estimates for the portion of revenue recognized on performance obligations recognized over time are accrued.

For variable consideration arrangements where the transaction price fluctuates based on quantity, the most likely estimated quantity is assumed using forecasts provided by the customer.

Single-use products

In most single-use product sales, a quantity is ordered and manufactured according to the customer's specifications and is typically only one performance obligation. The Company also manufactures early phase product that can be included in a contract with services. These services are distinct and separated from the product performance obligations and are shown as a service revenue stream. The products are manufactured exclusively for a specific customer and have no alternative use. Generally, under these customer agreements, the Company is entitled to consideration for progress to date that includes an element of profit margin. To the extent an agreement does not include an element of profit margin for progress to date, it is recognized at a point in time. Revenues that are recognized over time utilize a measure of progress toward satisfaction of the performance obligations. The Company measures progress using an input method which compares the cost of cumulative work in process to date to the most current estimates for the entire performance obligation. The raw materials are excluded from this measurement due to the high value and inclusion in the early stages of the project that would otherwise overstate progress to date.

Multi-use products

The Company's multi-use product sales can be sold to multiple customers and have an alternative use. Both the transaction sales price and shipping terms are agreed upon in the contract. For these products, all revenue is recognized at a point in time, generally when title to products and risk of loss is transferred to the customers based upon shipping terms. These arrangements typically include only one performance obligation.

Service revenue

The service revenue stream represents services provided to a customer to assist with early stages of the regulatory approval process. The customer owns the drug details and process. The Company works with its customers to develop, validate and document the production process in order to comply with the regulatory approval process. These custom development projects could have one or more performance obligations with no alternative use. The contracts are structured to ensure the Company is paid for in-process work, including a profit margin. Revenues related to this stream are recognized over time by allocating to each performance obligation the best estimate of the standalone selling price of each service. Standalone selling prices are generally based on the prices charged to customers or based on an expected cost-plus margin. The Company measures progress using an input method which

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compares the cost of cumulative work in process to date to the most current cost estimates for the entire performance obligation.

Contract balances

The timing of revenue recognition, billings and cash collections results in billed trade receivables, contract assets (unbilled receivables), and contract liabilities (customer advances and deferred revenue). For each reporting period presented, the Company reports contract balances in a net contract asset or liability position on a contract-by-contract basis. Contract assets are recorded when the right to consideration is conditioned on something other than the passage of time. When an entity's right to consideration is unconditional, the receivable is recorded within Trade Receivables on the balance sheet. Contract liabilities represent advance payments from customers, and deferred revenue. Contract assets will convert to trade receivables or cash and current contract liabilities will convert into revenue within a one-year period.

Payment terms can vary by the type and location of the customer and the products or services offered. The term between invoicing and when payment is due is not significant. For certain products or services and customer types, payment prior to satisfaction of a performance obligation can be required, and results in recording a contract liability.

All prior periods presented are accounted for under the following policy:

Revenues are generally recognized when title to products and risk of loss are transferred to customers. Additional conditions for recognition of revenue are that collection of sales proceeds is reasonably assured and the Company has no further performance obligations.

Amounts billed in advance are recorded as contract liabilities on the balance sheet. Since payments received are sometimes non-refundable, the termination of a contract by a customer prior to its completion could result in an immediate recognition of deferred revenue relating to payments already received but not previously recognized as revenue.

Sales terms to certain customers include rebates if certain conditions are met. Additionally, sales are generally made with a limited right of return under certain conditions. The Company estimates these rebates and returns at the time of sale based on the terms of agreements with customers and historical experience and estimated orders. The Company recognizes revenue net of these estimated costs which are classified as allowances and rebates.

The Company bills a portion of freight cost incurred on shipments to customers. Amounts billed to customers are recorded within net revenues. Freight costs are reflected in cost of goods sold.

Asset Valuations and Review for Potential Impairments

The review of long-lived assets, principally fixed assets and other amortizable intangibles, requires the Company to estimate the undiscounted future cash flows generated from these assets whenever events or changes in circumstances indicate that the carrying value may not be fully recoverable. If undiscounted cash flows are less than the carrying value, the long-lived assets are written down to fair value.

The review of the carrying value of goodwill is conducted annually or whenever events or changes in circumstances indicate that the carrying value may not be fully recoverable. The Company first performs a qualitative assessment to test goodwill for impairment. If, after performing the qualitative assessment, the Company concludes that it is more likely than not that the fair value of the reporting units is less than its carrying value, the two-step process would be utilized. In the first step, the fair value of the reporting units is determined using a discounted cash flow model and compared to the carrying value. If such analysis indicates that impairment may exist, the Company then estimates the fair value of the other assets and liabilities utilizing appraisals and discounted cash flow analyses to calculate an

impairment charge.

The determination of fair value is judgmental and involves the use of significant estimates and assumptions, including projected future cash flows primarily based on operating plans, discount rates, determination of appropriate market comparables and perpetual growth rates. These estimates and assumptions could have a significant impact on whether or not an impairment charge is recognized and the magnitude of any such charge.

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Income Taxes

The Company applies the asset and liability method to accounting for income taxes. Deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial statement carrying amounts and tax bases of assets and liabilities, and net operating loss (“NOL”) and tax credit carryovers, on a taxing jurisdiction basis using enacted tax rates in effect for the year in which the differences are expected to reverse or the NOLs or tax credit carryforwards are expected to be realized. The recoverability of deferred tax assets is dependent upon the Company’s assessment that it is more likely than not, considering both positive and negative evidence, that sufficient future taxable income of the appropriate type and in the appropriate taxable years will be generated in the relevant tax jurisdictions to utilize the deferred tax assets. This assessment takes into account the nature, frequency, and severity of any financial reporting losses, sources of future taxable income, and available prudent and feasible tax planning strategies. If, based on the weight of available evidence, it is more likely than not that the deferred tax assets will not be realized, the Company records a valuation allowance against all or a portion of the deferred tax assets to adjust the balance to the amount considered more likely than not to be realized.

The Company has provided a valuation allowance against state NOLs, state tax credits, and foreign NOLs. It is possible that changes in the Company’s assessment could result in the release of valuation allowance attributable to these items in the future, or the establishment of a valuation allowance against certain deferred tax assets for which the Company has no current reserves. The Company’s accounting for deferred taxes represents management’s best estimate of those future events. Changes in current estimates, due to unanticipated events, could have a material impact on the Company’s financial condition and results of operations.

Assumptions and Approach Used in Assessing the Need for a Valuation Allowance

The Company considers both positive and negative evidence related to the likelihood of realization of deferred tax assets. If, based on the weight of available evidence, it is more likely than not the deferred tax assets will not be realized, the Company records a valuation allowance against all or a portion of the deferred tax assets to adjust the balance to the amount considered more likely than not to be realized. The weight given to the positive and negative evidence is commensurate with the extent to which the evidence may be objectively verified.

This assessment, which is completed on a taxing jurisdiction basis, takes into account a number of types of evidence, including the following:

- Nature, frequency, and severity of current and cumulative financial reporting losses. A pattern of objectively-measured recent financial reporting losses is heavily weighted as a source of negative evidence. The Company generally considers cumulative pre-tax losses in the current three-year period to be significant negative evidence regarding future profitability. The Company also considers the strength and trend of earnings, as well as other relevant factors. In certain circumstances, historical information may not be as relevant due to changes in the Company’s business operations;
- Sources of future taxable income. Future reversals of existing taxable temporary differences are heavily-weighted sources of objectively verifiable evidence. Projections of future taxable income exclusive of reversing temporary differences are a source of positive evidence only when the projections are combined with a history of recent profits and can be reasonably estimated; and
 - Tax planning strategies. Prudent and feasible tax planning strategies that would be implemented to maximize utilization of expiring tax credit carryforwards are evaluated as a source of additional positive evidence.

The Company accounts for uncertain tax positions by applying the more likely than not threshold to recognition and de-recognition. Tax benefits from uncertain tax positions are recognized if it is more likely than not that the tax position will be sustained upon examination by taxing authorities with full knowledge of all relevant information, based on the technical merits of the position. The calculation of uncertain tax positions involves significant judgment in applying complex tax laws, and resolution of these matters in a manner inconsistent with management’s

expectations could have a material impact on the Company's financial condition and results of operations.

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In December 2017, the U.S. enacted TCJA tax reform legislation that imposed a one-time toll charge on undistributed foreign earnings, reduced the U.S. corporate income tax rate to 21%, transitioned the U.S. to a modified territorial tax system whereby future repatriations of foreign earnings will generally be exempt from U.S. tax, and altered the deductibility or tax treatment of certain items, among other changes. During the third quarter of 2018 the Company finalized the calculation of the toll charge, which had previously been recorded on a provisional basis, resulting in a \$2,105 tax benefit.

Environmental and Litigation Contingencies

The Company periodically assesses the potential liabilities related to any lawsuits or claims brought against it. See Note 21 to the Company's consolidated financial statements for a discussion of the Company's current environmental and litigation matters, reserves recorded and its position with respect to any related uncertainties. While it is typically very difficult to determine the timing and ultimate outcome of these actions, the Company uses its best judgment to determine if it is probable that the Company will incur an expense related to a settlement for such matters and whether a reasonable estimation of such probable loss, if any, can be made. If probable and estimable, the Company accrues for the costs of investigation, remediation, settlements and legal fees. Given the inherent uncertainty related to the eventual outcome of litigation and environmental matters, it is possible that all or some of these matters may be resolved for amounts materially different from any provisions that the Company may have made with respect to their resolution from time to time.

Employee Benefit Plans

The Company provides a range of benefits to certain employees and retired employees, including pension benefits under a plan that was frozen in 2007. The Company records annual amounts relating to these plans based on calculations, which include various actuarial assumptions, including discount rates, assumed rates of return and turnover rates. The Company reviews its actuarial assumptions on an annual basis and makes modifications to the assumptions based on current rates and trends when it is deemed appropriate to do so. The effect of the modifications is generally recorded and amortized over future periods. The Company believes that the assumptions utilized for recording obligations under its plans are reasonable.

The discount rate used to measure pension liabilities and costs is selected by projecting cash flows associated with plan obligations which are matched to a yield curve of high quality bonds. The Company then selects the single rate that produces the same present value as if each cash flow were discounted by the corresponding spot rate on the yield curve.

(dollars in thousands, except per share data)

Results of Operations

2018 Compared to 2017

APIs

Net revenue was \$503,493 under ASC 606, a 5.8% decrease compared to 2017. Under ASC 605, net revenue was \$522,361 compared to \$534,456 in 2017, a 2.3% decrease. Excluding the impact of applying ASC 606 of \$18,868 and a 0.8% favorable impact of foreign exchange compared to 2017, net revenue decreased 3.1% primarily due to lower volumes (2.8%) and lower pricing (0.3%). The decrease in volumes was driven by lower sales of certain branded APIs partially offset by an increase in controlled substances and clinical phase products.

Gross profit in 2018 was \$189,305 compared to \$230,303 in 2017. Gross margins in 2018 decreased to 37.6% from 43.1% in 2017. Excluding the impact of the new revenue recognition standard, gross margins would have been 38.9%. Margins were negatively impacted by lower production volumes, unfavorable product mix and lower pricing.

Selling, general and administrative (“SG&A”) expenses of \$45,477 in 2018 decreased compared to \$49,081 in 2017. The decrease was mainly due to lower personnel related costs (approximately \$2,800), an accounts receivable write-off in the third quarter of 2017 (approximately \$700) and lower ERP support fees (approximately \$500) partially offset by the impact of foreign currency (approximately \$300). Sales and marketing expenses were flat compared to 2017. SG&A, as a percentage of net revenue, was 9.0% in 2018 and 9.2% in 2017.

Research and development (“R&D”) expenses were \$13,107, or 2.6% of net revenue in 2018, compared to \$12,892, or 2.4%, of net revenue in 2017.

Operating profit in 2018 was \$130,721 compared to \$168,330 in 2017. The decrease in operating profit was due to lower gross profit partially offset by lower operating expenses as described above.

Excluding the impact of the new revenue recognition standard, operating profit in 2018 was \$144,827.

FDF

Net revenue was \$28,600 for the period from the acquisition date, September 12, 2018, through December 31, 2018.

Gross margins were 25.8% and gross profit was \$7,383 in 2018.

SG&A expenses were \$6,438 in 2018. SG&A, as a percentage of net revenue, was 22.5%.

R&D expenses were \$79 for the period from acquisition to December 31, 2018.

Acquisition and integration expenses were \$1,471 in 2018. Included in these expenses is a charge for severance of \$900.

FDF operating loss for the period September 12, 2018 through December 31, 2018 was \$605 which includes integration and severance expenses of \$1,471.

Results on an ASC 605 basis were not materially different than the reported results under ASC 606.

Corporate

The Company's Corporate headquarters provides management and administrative services to support the Company, and consists of certain aspects of the Company's executive management, legal, compliance, human resources, information technology and finance departments. The Company allocates certain corporate expenses to each of its segments. SG&A expenses of \$16,591 in 2018 decreased compared to \$19,903 in 2017. The decrease was mainly due to lower personnel related costs (approximately \$1,000), M&A due diligence expenses (approximately \$800) and medical expenses (approximately \$700).

R&D expenses of \$2,361 in 2018 decreased compared to \$4,009 in 2017. The decrease is due to the timing of spending on the development of generic drug products.

(dollars in thousands, except per share data)

Acquisition and integration expenses were \$9,668 in 2018 and primarily consisted of professional fees and transaction costs related to the Halo and Avista acquisitions.

Operating losses were \$28,620 in 2018 compared to \$23,912 in 2017.

During the second quarter of 2018, the Company acquired a 19.9% equity investment in a European company (“Investee”). The Investee completed an initial public offering on a foreign exchange late in the quarter, which reduced the Company’s ownership share to 16.3%. The Company’s investment is subject to a prohibition on selling the shares for one year following the acquisition. The Company has one seat on the Board of Directors of the Investee and concluded it is able to exercise significant influence and that equity accounting would be appropriate. In accordance with ASC 825, the Company has elected to record this investment at fair value. The Company selected an appropriate valuation methodology to compute a discount for the lack of marketability to be applied to the closing market price of the shares as of December 31, 2018. The fair value of the Company’s shares was \$13,023 at December 31, 2018 resulting in an unrealized gain that was recorded as “Unrealized gain on investment in equity securities” on the Company’s income statement and “Prepaid expenses and other current assets” on the Company’s balance sheet. Since the shares owned by the Company are substantially in excess of the daily trade volumes of the stock, it could be difficult to sell the shares in a timely manner when the restrictions lapse and it is possible the ultimate value to be realized by the Company could be significantly less upon a sale of the securities.

Net interest expense was \$3,967 in 2018 compared to \$1,253 in 2017. The increase is due to interest expense on borrowings to fund the Halo acquisition partially offset by higher interest income generated from higher cash balances. There was \$300,000 outstanding on the Credit Facility at December 31, 2018. The average interest rate on debt was 3.8% in 2018. The Company did not have any debt outstanding as of December 31, 2017.

Income tax expense from continuing operations was \$16,596 in 2018 compared to \$38,061 in 2017. Excluding the impacts of immediately recognizing certain effects of share-based compensation, acquisition and integration expenses, amortization of purchased intangibles, unrealized gain on investment in equity securities, adjusted income and related interest expense from the Halo acquisition, a \$2,105 benefit for finalizing the TCJA toll charge expensed in 2017, and a \$736 benefit for New Jersey tax reform enacted in 2018, the effective tax rate would have been 21.4% in 2018, compared to 30.5% in 2017.

Income from continuing operations in 2018 was \$93,209, or \$2.77 per diluted share, versus \$103,764 or \$3.10 per diluted share in 2017.

Excluding the impact of the new revenue recognition standard, income from continuing operations in 2018 was \$104,309 or \$3.10 per diluted share.

2017 Compared to 2016

APIs

Net revenue in 2017 of \$534,456 was \$43,812 or 8.9% higher than 2016. Excluding the impact of foreign currency net revenue increased 8.7%. The increase is a result of higher volumes (10.6%) partially offset by lower pricing (1.9%). The volume increase was primarily due to higher sales of branded APIs and clinical phase products, controlled substances, and generic APIs. The price decline was due to a combination of contractual agreements and negotiated market based price adjustments for certain products. The acquisition of CHP contributed approximately \$18,000 to net revenue while the disposition of Zenara reduced net revenue by \$4,065.

A take-or-pay payment of approximately \$6,200 and royalties of \$1,000 recorded as “Other revenues, net” in the Company’s income statement also contributed to higher revenue.

The Company's products and services are sold to a diverse group of several hundred customers, with one customer accounting for 35.1% and 36.9% of 2017 and 2016 consolidated sales, respectively. The Company's products are sold through a combination of direct sales and independent agents. One API, an antiviral product, represented 32.8% and 31.6% of 2017 and 2016 consolidated sales, respectively.

Gross profit in 2017 was \$230,303 compared to \$204,388 in 2016. Gross margins increased to 43.1% in 2017 compared to 41.7% in 2016. The 2017 gross margins included a 0.2% unfavorable impact from foreign currency

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versus 2016. Margins were positively impacted by higher production volumes that drove plant efficiencies, a take-or-pay payment and higher royalties partially offset by lower pricing.

Selling, general and administrative (“SG&A”) expenses were \$49,081, or 9.2% of net revenue in 2017, compared to \$43,693, or 8.9%, in 2016. The increase in administrative expenses is mainly due to the addition of CHP (approximately \$2,000), consulting costs associated with an operational excellence initiative (approximately \$1,400), and higher sales and marketing expenses (approximately \$1,000).

Research and development (“R&D”) expenses were \$12,892, or 2.4% of net revenue in 2017, compared to \$11,406, or 2.3%, of net revenue in 2016. The increase is primarily due to higher personnel expenses (approximately \$1,000).

Acquisition and integration expenses were \$200 in 2016 related to the acquisition of CHP.

Restructuring expenses relate to the decision to sell Zenara, which was classified as held for sale at December 31, 2015. Charges include the write off of goodwill and an amortizable intangible asset as well as adjusting Zenara’s assets and liabilities to reflect fair value. These charges totaled \$1,016 in 2016, the majority of which are non-cash expenses. See Note 9 to the Company’s consolidated financial statements for an explanation of the sale of Zenara.

Operating profit was \$168,330 in 2017 compared to \$148,073 in 2016. The increase in operating profit is primarily due to higher gross profit and lower restructuring expenses partially offset by higher operating expenses.

Corporate

SG&A expenses of \$19,903 in 2017 increased compared to \$14,349 in 2016. The increase was mainly due to higher medical expenses (approximately \$2,000), higher personnel related costs (approximately \$1,700) and M&A expenses (approximately \$400).

R&D expenses of \$4,009 in 2017 decreased compared to \$2,886 in 2016. The increase is due to the timing of spending on the development of generic drug products.

Acquisition and integration expenses of \$640 in 2016 relate to the addition of CHP. Restructuring expenses of \$142 in 2016 relate to the decision to sell Zenara.

Operating losses were \$23,912 in 2017 compared to \$18,017 in 2016.

Net interest expense was \$1,253 in 2017 compared to \$717 in 2016. Higher interest expense was the result of higher amortization of debt issuance costs, higher commitment fees related to the new credit facility entered into during the second quarter of 2016 and lower capitalized interest as a result of the completion of several large projects in 2016. These increases were partially offset by higher interest income generated from higher cash balances. The Company did not have any debt outstanding as of December 31, 2017 and 2016.

Tax expense was \$38,061 in 2017, resulting in an effective tax rate of 26.8%, compared to \$40,214 and 31.5% in 2016. Tax expense in 2017 was favorably impacted by \$5,236 as a result of applying ASU 2016-09, which requires recognition immediately in the tax provision of certain effects of share-based payments that were possibly deferred under the previous guidance. As a result of TCJA, tax expense in 2017 was also increased by \$2,105 for the estimate of the toll charge on the deemed repatriation of foreign earnings, increased \$1,611 for the revaluation of domestic federal deferred tax balances, and decreased \$3,599 to write off the deferred tax liability that the Company had previously provided on certain undistributed foreign earnings. Excluding the effects of applying the new share-based payment standard and TCJA, the effective tax rate for 2017 was 30.5%.

Income from continuing operations in 2017 was \$103,764 or \$3.10 per diluted share, versus \$87,325, or \$2.65 per diluted share in 2016.

Liquidity and Capital Resources

During 2018, cash flows from operations provided \$86,982, compared to \$149,015 in the same period a year ago. The decrease in cash flows from operations in 2018 compared to 2017 was largely due to lower net income after adjusting for non-cash items and higher accounts receivable partially offset by higher accounts payable.

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Cash flows used in investing activities of \$486,842 in 2018 reflects the purchase of Halo of \$424,244 and capital expenditures of \$62,598. Capital expenditures in 2018 and 2017 primarily expanded the Company's manufacturing capacity to support expected growth.

Cash flows provided by financing activities in 2018 of \$314,041 reflects borrowings to fund the Halo acquisition and proceeds from stock options exercised. Cash flows provided by financing activities in 2017 represents proceeds from stock options exercised. Net debt increased \$387,432 during 2018 to a net debt balance of \$204,148.

The Company has a \$500,000 Senior Credit Facility ("Credit Facility") which expires in May 2021. The Company pays interest on this Credit Facility at LIBOR plus 1.25% - 2.00% based upon certain financial measurements. The Credit Facility also includes financial covenants regarding interest coverage and leverage ratios. The Credit Facility has \$300,000 debt outstanding at December 31, 2018 and was undrawn in 2017.

On January 2, 2019, the Company amended and restated its Credit Facility to an \$800,000 five-year Syndicated Senior Credit Facility expiring January 2, 2024, comprising of a \$600,000 Revolving Credit Facility and \$200,000 Term Loan A ("New Credit Facility"). The Company pays interest on the New Credit Facility at LIBOR plus 1.25% - 2.00% based upon certain financial measurements. The New Credit Facility also includes financial covenants regarding interest coverage and leverage ratios.

For 2019, capital expenditures are expected to be approximately \$60,000 to \$70,000.

The Company's products and services are sold to a diverse group of several hundred customers, with one customer accounting for 24.8% and 35.1% of 2018 and 2017 consolidated sales, respectively. The Company's products are sold through a combination of direct sales and independent agents. One API, an antiviral product, represented 23.5% and 32.8% of 2018 and 2017 consolidated sales, respectively.

The Company's forecasted cash flow from future operations may be adversely affected by various factors including, but not limited to, declines in customer demand, increased competition, the deterioration in general economic and business conditions, increased environmental remediation, interest rates, returns on assets within the Company's domestic pension plans, tax payments, as well as other factors. Our largest product (23.5% of 2018 sales) is used by our customer to produce an anti-viral drug. Our sales of this product declined significantly in 2018 and we expect significant declines in sales in 2019, and again in 2020, the final year of the 5-year supply agreement.

As discussed more fully in Note 21 to the Consolidated Financial Statements, the Company continually receives additional information to develop estimates to record reserves for remediation activities at Berry's Creek and other environmental sites. These matters, either individually or in the aggregate, could result in actual costs that are significantly higher than the Company's current assessment and could have a material adverse effect on the Company's cash flows in future reporting periods. Based upon past experience, the Company believes that payments significantly in excess of current reserves, if required, would be made over an extended number of years.

Contractual Obligations

At December 31, 2018, the Company's contractual obligations with initial or remaining terms in excess of one year were as follows:

| | Total | 2019 | 2020 | 2021 | 2022 | 2023 | 2024+ |
|----------------------|---------|---------|-------|------|------|------|-------|
| Purchase obligations | \$9,067 | \$8,777 | \$256 | \$27 | \$7 | \$- | \$- |

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| | | | | | | | |
|------------------------------|----------|---------|---------|---------|-------|-------|---------|
| Operating leases | 8,465 | 1,004 | 1,204 | 1,126 | 974 | 937 | 3,220 |
| Contractual cash obligations | \$17,532 | \$9,781 | \$1,460 | \$1,153 | \$981 | \$937 | \$3,220 |

In addition to the contractual obligations listed above, the Company expects to contribute \$255 in cash to its U.S. defined-benefit pension plan in 2019. It is possible that higher pension contributions could be required in 2020 and beyond. For the unfunded international pension plan, the Company expects to make annual benefit payments of approximately \$800 in 2019 and approximately \$900 for years 2020 through 2023. See Note 18 to the Company's consolidated financial statements for details on the Company's unfunded balance related to its pension plans. Also not included in the table above is \$2,398 of uncertain tax positions due to uncertainties surrounding the timing of the obligation. See Note 11 to the Company's consolidated financial statements for details on the Company's tax

(dollars in thousands, except per share data)

positions. The Company may be required to make cash payments to remediate certain environmental sites at unknown future periods as discussed in Note 21 to the Company's consolidated financial statements.

See Notes 12, 18, 20 and 21 to the Company's consolidated financial statements for additional information regarding the Company's debt, pension plans, commitments and contingencies.

The Company's forecasted cash flow from future operations may be adversely affected by various factors including, but not limited to, declines in customer demand, increased competition, the deterioration in general economic and business conditions, increased environmental remediation, interest rates, returns on assets within the Company's domestic pension plans, tax payments, as well as other factors. See the Risk Factors section of this document for further explanation of factors that may negatively impact the Company's cash flows. Any change in the current status of these factors could adversely impact the Company's ability to fund operating cash flow requirements.

Market Risks

Currency Risk Management

The Company's primary market risk relates to exposure to foreign currency exchange rate fluctuations on transactions entered into by international operations which are primarily denominated in the U.S. dollar, euro and Swedish krona. The Company may use foreign currency exchange forward contracts to mitigate the effect of short-term foreign exchange rate movements on the Company's operating results. The notional amount of the contracts outstanding as of December 31, 2018 was \$35,734. The foreign exchange contracts have varying maturities with none exceeding twelve months.

With respect to the contracts outstanding at December 31, 2018, a 10% fluctuation of the currency rates over a one-year period would cause approximately \$3,530 pre-tax earnings to be at risk. These calculations do not include the impact of exchange gains or losses on the underlying positions that would offset the gains and losses of the derivative instrument.

Contingencies

The Company is subject to various investigations, claims and legal proceedings covering a wide range of matters that arise in the ordinary course of its business activities. The Company continually assesses known facts and circumstances as they pertain to applicable legal and environmental matters and evaluates the need for reserves and disclosures as deemed necessary based on these facts and circumstances. These matters, either individually or in the aggregate, could result in actual costs that are significantly higher than the Company's current assessment and could have a material adverse effect on the Company's operating results and cash flows in future reporting periods. Based upon past experience, the Company believes that payments significantly in excess of current reserves, if required, would be made over an extended number of years.

Environmental

In connection with laws and regulations pertaining to the protection of the environment, the Company and its subsidiaries are a party to several environmental proceedings and remediation activities and along with other companies, have been named a potentially responsible party ("PRP") for certain waste disposal sites ("Superfund sites"). All of the liabilities currently recorded on the Company's balance sheet for environmental proceedings are associated with discontinued operations. The Company had insurance policies in place at certain of the discontinued operations for certain years that the Company believes should cover some portion of the recorded liabilities or potential future liabilities and the Company expects the net cash impact related to the contingencies described below to be reduced by the applicable income tax rate.

It is the Company's policy to record appropriate liabilities for environmental matters where remedial efforts are probable and the costs can be reasonably estimated. Such liabilities are based on the Company's estimate of the undiscounted future costs required to complete the remedial work. Each of these matters is subject to various uncertainties, and it is possible that some of these matters will be decided against the Company. The resolution of such matters often spans several years and frequently involves regulatory oversight or adjudication. Additionally, many remediation requirements are fluid and are likely to be affected by future technological, site and regulatory

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developments. It is not possible at this time for the Company to determine fully the effect of all asserted and unasserted claims on its consolidated financial condition, results of operations or liquidity; however, to the extent possible, where asserted and unasserted claims can be estimated and where such claims are considered probable, the Company would record a liability. Consequently, the ultimate liability with respect to such matters, as well as the timing of cash disbursements, is uncertain.

In matters where the Company is able to reasonably estimate the probable and estimable costs associated with environmental proceedings, the Company accrues for the estimated costs associated with the study and remediation of applicable sites. At December 31, 2018, these reserves were \$17,411, of which \$16,599 is included in "Other non-current liabilities" on the Company's balance sheet. At December 31, 2017, the reserves were \$17,511, of which \$16,976 is included in "Other non-current liabilities" on the Company's balance sheet. The increase in the reserves includes adjustments to reserves of \$1,055, partially offset by payments of \$1,155. The reserves are adjusted periodically as remediation efforts progress or as additional technical, regulatory or legal information becomes available. Given the uncertainties regarding the outcome of investigative and study activities, the status of laws, regulations, enforcement, policies, the impact of other PRPs, technology and information related to individual sites, the Company does not believe it is possible to currently develop an estimate of the range of reasonably possible environmental loss in excess of its reserves.

Bayonne

As a result of the sale of a Bayonne, New Jersey facility, the Company became obligated to investigate site conditions and conduct required remediation under the New Jersey Industrial Site Recovery Act. The Company is completing an investigation and sampling plan at the property pursuant to the New Jersey Department of Environmental Protection's ("NJDEP") private oversight program. The results will be used to develop a proposed remedial action work plan for the site. Among other things, the remedial plan is anticipated to set forth further details of the proposed cleanup, including the removal and/or encapsulation of certain impacted soils and implementation of engineering controls and deed restrictions. As of December 31, 2018, the Company's reserve was \$608.

Clifton and Carlstadt

The Company has implemented a sampling and pilot program in Clifton and Carlstadt, New Jersey pursuant to the NJDEP private oversight program. The results of the sampling and pilot program to date have been used to develop an estimate of the Company's future liability for remediation costs, and the Company continues to move forward with the projects at each site in accordance with the established schedules and work plans. As of December 31, 2018, the Company's reserve was \$1,827.

Berry's Creek

The Company received a notice from the United States Environmental Protection Agency ("USEPA") that two subsidiaries of the Company are considered PRPs at the Berry's Creek Study Area in New Jersey. These subsidiaries are among many other PRPs that were listed in the notice. Pursuant to the notice, the PRPs have been asked to perform a remedial investigation ("RI") and feasibility study ("FS") of the Berry's Creek site. The Company has joined the group of PRPs and entered into an Administrative Settlement Agreement ("Agreement") and Order on Consent with the USEPA agreeing to jointly conduct or fund an appropriate remedial investigation and feasibility study of the Berry's Creek site with the other PRPs in the Agreement. The PRPs have engaged consultants to perform the work specified in the Agreement and develop a method to allocate related costs among the PRPs.

In June 2016, the PRPs received a request from USEPA to amend the RI/FS Work Plan to accommodate a phased, iterative approach to the Berry's Creek remediation. USEPA requested an initial Phase I remedy that focuses on a portion of the site, namely, sediments in Upper and Middle Berry's Creek and the marsh in Upper Peach Island Creek. Any subsequent remedial action will occur after the implementation and performance monitoring of this Phase

I remedy and the extent of future action is expected to be at least partially determined by the outcome of this initial phase. In April 2017, USEPA approved the requested addendum to the RI/FS Work Plan, which included the description of the phased and adaptive management approach to the Berry's Creek remedy.

In September 2018, USEPA issued its Record of Decision ("ROD") for an interim remedy at Berry's Creek. The interim remedy calls for, among other things, dredging and capping of contaminated sediments. The next step

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in the process is to design the remedy (“Remedial Design”). USEPA issued a letter to the Berry’s Creek PRP Group in September 2018 that provided notice of potential liability and a request that the PRP Group agree to perform the Remedial Design. USEPA provided a draft settlement agreement and statement of work to implement the Remedial Design. As a member of the Berry’s Creek PRP Group, the Company will participate in the PRP Group’s engagement with USEPA on Remedial Design, and is coordinating with PRP Group members and PRP Group common counsel accordingly.

The estimated costs for the interim remedy may be further developed and the Company’s accrual may change based upon revisions to cost estimates. As of December 31, 2018, the Company’s reserve was \$9,647. At this time it is not known when the costs for the complete remediation plan will be estimable, and as such, no accrual beyond the interim remedy has been recorded. The Company’s share has been preliminarily estimated by the PRP group at 2.4%. While the Company will defend its position that its share should be reduced from the current level, its share could be increased or decreased depending on the outcome of the final allocation process that will take place in future periods.

While any resolution of this matter is not expected to materially impact the Company’s operations or financial position, it could be material to the financial statements in the period recorded.

In July 2014, the Company received a notice from the U.S. Department of the Interior, U.S. Fish & Wildlife Service, regarding the Company’s potential liability for natural resource damages at the Berry’s Creek site and inviting the Company to participate in a cooperative assessment of natural resource damages. Most members of the Berry’s Creek PRP group received such notice letters, and the PRP Group coordinated a joint response, which was to decline participation in a cooperative assessment at this time, given existing investigation work at the site. The cost of any future assessment and the ultimate scope of natural resource damage liability are not yet known.

Maybrook Site

A subsidiary of Cambrex is named a PRP of a site in Hamptonburgh, New York by the USEPA in connection with the discharge, under appropriate permits, of wastewater at that site prior to Cambrex’s acquisition in 1986. The PRPs implemented soil remediation which was completed in 2012 pending approval by the USEPA. The PRPs will continue implementing the ground water remediation at the site. USEPA completed its 5-year review report in August 2018, and USEPA’s review of the site remedy is on-going. It is unclear if such review, together with an agreed proposed modification to the USEPA Consent Decree, will result in any additional site work. In November 2018, under a statewide initiative, the New York State Department of Environmental Conservation (“NYSDEC”) requested that the PRPs perform additional sampling for certain “emerging contaminants.” NYSDEC approved the PRPs work plan in December 2018, and the sampling is anticipated to be performed during the first quarter of 2019. As of December 31, 2018, the Company’s reserve was \$329, to cover long-term ground water monitoring and related costs.

Harriman Site

Subsidiaries of Cambrex and Pfizer are named as responsible parties for the Company’s former Harriman, New York production facility by the New York State Department of Environmental Conservation (“NYSDEC”). A final Record of Decision (“ROD”) describing the Harriman site remediation responsibilities for Pfizer and the Company was issued in 1997 (the “1997 ROD”) and incorporated into a federal court Consent Decree in 1998 (the “Consent Decree”). In December 2013, the Company, Pfizer and the NYSDEC entered into a federal court stipulation, which the court subsequently endorsed as a court order, resolving certain disputes with the NYSDEC about the scope of the obligations under the Consent Decree and the 1997 ROD, and requiring the Company and Pfizer to carry out an environmental investigation and study of certain areas of the Harriman Site.

Site clean-up work under the 1997 ROD, the Consent Decree and the 2013 stipulation is ongoing and is being jointly performed by Pfizer and the Company, with NYSDEC oversight. Since 2014, Pfizer and the Company have performed supplemental remedial investigation measures requested by the NYSDEC, and the findings have been

submitted to NYSDEC in various reports, including a study evaluating the feasibility of certain remedial alternatives in August 2016. By letter dated January 5, 2017, NYSDEC disapproved such feasibility study report and requested certain revisions to the report. The Company and Pfizer engaged in further discussions with NYSDEC and have agreed to submit a revised version of the August 2016 feasibility study to address certain of NYSDEC's requests. In September 2017, the NYSDEC requested that Pfizer, the Company and the current owner of the Harriman Site, ELT

(dollars in thousands, except per share data)

Harriman LLC (“ELT”), conduct an investigation of additional constituents not addressed under the 1997 ROD based on the detection of those constituents at the Harriman Site and other properties in the area. The parties have requested more information from the State of New York to evaluate the request, while also responding to NYSDEC that no further investigation was warranted.

As it is too soon to determine whether the NYSDEC’s requests or the reports and remedial plans, when finalized, will result in any significant changes to the Company’s responsibilities, no change to the reserve has been made. ELT is conducting other investigation and remediation activities under a separate NYSDEC directive.

No final remedy for the site has been determined, which will follow further discussions with the NYSDEC. The Company estimates the range for its share of the liability at the site to be between \$2,000 and \$7,000. As of December 31, 2018, the Company’s reserve was \$3,365. At this time, the Company is unable to provide an estimate of the ultimate investigative and remedial costs to the Company for any final remedy selected by the NYSDEC.

The Company intends to enforce all of its contractual rights to recover costs and for indemnification under a 2007 settlement agreement, and has filed such claims in an arbitration proceeding against ELT and the immediately preceding owner, Vertellus Specialties Holdings (“Vertellus”). ELT has filed counterclaims, and has threatened to file additional counterclaims, for contractual indemnification and for breach of the settlement agreement against the Company. Currently, the arbitration proceeding is stayed indefinitely. In May 2016, some but not all of the Vertellus entities who are parties to the Company’s 2007 settlement agreement filed for restructuring under Chapter 11 of the U.S. Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware. The Company has filed several claims as creditors in the bankruptcy proceeding and will continue to monitor the bankruptcy proceeding.

Scientific Chemical Processing (“SCP”) Superfund Site

A subsidiary of Cambrex was named a PRP of the SCP Superfund site, located in Carlstadt, New Jersey, along with approximately 130 other PRPs. The site is a former waste processing facility that accepted various waste for recovery and disposal including processing wastewater from this subsidiary. The PRPs are in the process of implementing a final remedy at the site. The SCP Superfund site has also been identified as a PRP in the Berry’s Creek Superfund site (see previous discussion). While the Company continues to dispute the methodology used by the PRP group to arrive at its interim allocation for cash contributions, the Company has paid the funding requests. A final allocation of SCP Site costs (excluding Berry’s Creek costs) is expected to be finalized in 2019. As of December 31, 2018, the Company’s reserve was \$732, of which approximately \$468 is expected to be covered by insurance.

Newark Bay Complex

The USEPA and a private party group are evaluating remediation plans for the Passaic River, Newark Bay, Hackensack River, Arthur Kill, Kill Van Kull and adjacent waters (the “Newark Bay Complex”). Although the Company is not involved in the USEPA action, it continues to monitor developments related to the site due to its past involvement in a previously settled state action relating to the Newark Bay Complex. The USEPA has finalized its decision on a cleanup plan for 8.3 miles of the lower Passaic River, and has estimated the cost of this plan at \$1.38 billion. Due to the uncertainty of the future scope and timing of any possible claims against the Company, no liability has been recorded.

The Company is involved in other related and unrelated environmental matters where the range of liability is not reasonably estimable at this time and it is not foreseeable when information will become available to provide a basis for adjusting or recording a reserve, should a reserve ultimately be required.

Other

The Company has commitments incident to the ordinary course of business including corporate guarantees of certain subsidiary obligations to the Company's lenders related to financial assurance obligations under certain environmental laws for remediation; closure and third party liability requirements of certain of its subsidiaries and a former operating location; contract provisions for indemnification protecting its customers and suppliers against third party liability for the manufacture and sale of Company products that fail to meet product warranties and contract provisions for indemnification protecting licensees against intellectual property infringement related to licensed Company technology or processes.

(dollars in thousands, except per share data)

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Additionally, as permitted under Delaware law, the Company indemnifies its officers, directors and employees for certain events or occurrences while the officer, director or employee is, or was, serving at the Company's request in such capacity. The term of the indemnification period is for the officer's, director's or employee's lifetime. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited; however, the Company has a director and officer insurance policy that covers a portion of any potential exposure. The Company currently believes the estimated fair value of its indemnification agreements is not material based on currently available information, and as such, the Company had no liabilities recorded for these agreements as of December 31, 2018.

The Company's subsidiaries are party to a number of other proceedings that are not considered material at this time.

Impact of Recent Accounting Pronouncements

Please refer to Note 3 to the Company's consolidated financial statements for a discussion on recently issued accounting pronouncements.

Item 7A Quantitative and Qualitative Disclosures about Market Risk.

The information required in this section can be found in the "Market Risks" section of Item 7 on page 33 of this Form 10-K.

(dollars in thousands, except per share data)

Item 8 Financial Statements and Supplementary Data.

The following consolidated financial statements and selected quarterly financial data of the Company are filed under this item:

| | Page Number |
|---|------------------|
| | (in this Report) |
| <u>Reports of Independent Registered Public Accounting Firm</u> | 39 |
| <u>Consolidated Balance Sheets as of December 31, 2018 and 2017</u> | 41 |
| <u>Consolidated Income Statements for the Years Ended December 31, 2018, 2017 and 2016</u> | 42 |
| <u>Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2018, 2017 and 2016</u> | 43 |
| <u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2018, 2017 and 2016</u> | 44 |
| <u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2018, 2017 and 2016</u> | 45 |
| <u>Notes to Consolidated Financial Statements</u> | 46 |
| <u>Selected Quarterly Financial and Supplementary Data (unaudited)</u> | 81 |

The financial statement schedules are filed pursuant to Item 15 of this report.

(dollars in thousands, except per share data)

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors

Cambrex Corporation

East Rutherford, NJ

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cambrex Corporation (the “Company”) and subsidiaries as of December 31, 2018 and 2017, the related consolidated statements of income and comprehensive income, stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and schedules (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated February 13, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company’s auditor since 2007.

Woodbridge, NJ

February 13, 2019

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Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors

Cambrex Corporation

East Rutherford, NJ

Opinion on Internal Control over Financial Reporting

We have audited Cambrex Corporation's (the "Company's") internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company and subsidiaries as of December 31, 2018 and 2017, the related consolidated statements of income and comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and schedules and our report dated February 13, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Item 9A, Management's Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding

prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ BDO USA LLP

Woodbridge, NJ

February 13, 2019

CAMBREX CORPORATION AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(dollars in thousands, except per share data)

| | December 31, | |
|--|--------------------|------------------|
| | 2018 | 2017 |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$95,852 | \$183,284 |
| Trade receivables, less allowances of \$667 and \$1,061 at respective dates | 146,330 | 75,144 |
| Contract assets | 33,490 | - |
| Other receivables | 5,198 | 20,891 |
| Inventories, net | 111,062 | 138,542 |
| Prepaid expenses and other current assets | 18,160 | 4,217 |
| Total current assets | 410,092 | 422,078 |
| Property, plant and equipment, net | 360,528 | 254,299 |
| Goodwill | 261,095 | 43,626 |
| Intangible assets, net | 187,205 | 13,868 |
| Deferred income taxes | 1,409 | 3,198 |
| Other non-current assets | 3,099 | 3,496 |
| Total assets | \$1,223,428 | \$740,565 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$47,012 | \$35,017 |
| Contract liabilities, current | 11,713 | 4,707 |
| Taxes payable | 1,651 | 43 |
| Accrued expenses and other current liabilities | 44,036 | 42,774 |
| Total current liabilities | 104,412 | 82,541 |
| Long-term debt | 300,000 | - |
| Contract liabilities, non-current | 42,701 | 39,000 |
| Deferred income taxes | 57,276 | 7,806 |
| Accrued pension benefits | 42,218 | 41,141 |
| Other non-current liabilities | 23,094 | 25,213 |
| Total liabilities | 569,701 | 195,701 |
| Commitments and contingencies (see Notes 20 and 21) | | |
| Stockholders' equity: | | |
| Common Stock, \$.10 par value; authorized 100,000,000 issued | | |
| 34,870,124 and 34,270,975 shares at respective dates | 3,487 | 3,427 |
| Additional paid-in capital | 182,691 | 165,979 |
| Retained earnings | 538,463 | 429,826 |
| Treasury stock, at cost, 1,264,109 and 1,424,153 shares at | (10,777) | (12,140) |

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| | respective dates | |
|--|------------------|-----------|
| Accumulated other comprehensive loss | (60,137) | (42,228) |
| Total stockholders' equity | 653,727 | 544,864 |
| Total liabilities and stockholders' equity | \$1,223,428 | \$740,565 |

See accompanying notes to consolidated financial statements.

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CAMBREX CORPORATION AND SUBSIDIARIES

CONSOLIDATED INCOME STATEMENTS

(dollars in thousands, except per share data)

| | Years Ended December 31, | | |
|--|--------------------------|-----------|-----------|
| | 2018 | 2017 | 2016 |
| Gross Sales | \$514,997 | \$525,936 | \$491,538 |
| Commissions, allowances and rebates | 1,018 | 1,995 | 2,369 |
| Net sales | 513,979 | 523,941 | 489,169 |
| Other revenues, net | 18,114 | 10,515 | 1,475 |
| Net revenue | 532,093 | 534,456 | 490,644 |
| Cost of goods sold | 335,405 | 304,153 | 286,256 |
| Gross profit | 196,688 | 230,303 | 204,388 |
| Selling, general and administrative expenses | 68,506 | 68,984 | 58,042 |
| Research and development expenses | 15,547 | 16,901 | 14,292 |
| Acquisition and integration expenses | 11,139 | - | 840 |
| Restructuring expenses | - | - | 1,158 |
| Operating expenses | 95,192 | 85,885 | 74,332 |
| Operating profit | 101,496 | 144,418 | 130,056 |
| Other expenses/(income) | | | |
| Interest expense, net | 3,967 | 1,253 | 717 |
| Unrealized gain on investment in equity securities | (13,023) | - | - |
| Other expenses, net | 747 | 1,340 | 1,800 |
| Income before income taxes | 109,805 | 141,825 | 127,539 |
| Provision for income taxes | 16,596 | 38,061 | 40,214 |
| Income from continuing operations | 93,209 | 103,764 | 87,325 |
| Loss from discontinued operations, net of tax | (791) | (1,314) | (5,647) |
| Net income | \$92,418 | \$102,450 | \$81,678 |
| Basic earnings per share | | | |
| Income from continuing operations | \$2.80 | \$3.18 | \$2.72 |
| Loss from discontinued operations, net of tax | \$(0.02) | \$(0.04) | \$(0.17) |
| Net income | \$2.78 | \$3.14 | \$2.55 |
| Diluted earnings per share | | | |
| Income from continuing operations | \$2.77 | \$3.10 | \$2.65 |
| Loss from discontinued operations, net of tax | \$(0.02) | \$(0.04) | \$(0.17) |
| Net income | \$2.75 | \$3.06 | \$2.48 |
| Weighted average shares outstanding: | | | |
| Basic weighted average shares outstanding | 33,243 | 32,662 | 32,086 |
| Effect of dilutive stock based compensation | 422 | 824 | 883 |
| Diluted weighted average shares outstanding | 33,665 | 33,486 | 32,969 |

See accompanying notes to consolidated financial statements.

CAMBREX CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(dollars in thousands)

| | Years Ended December 31, | | |
|--|--------------------------|-----------|----------|
| | 2018 | 2017 | 2016 |
| Net income | \$92,418 | \$102,450 | \$81,678 |
| Foreign currency translation adjustments: | | | |
| Foreign currency translation adjustments during the period | (15,696) | 22,250 | (8,481) |
| Reclassification adjustments for losses included in net income | - | - | 71 |
| Pension plans: | | | |
| Actuarial (loss)/gain | | | |
| Actuarial (loss)/gain arising during the period | (4,039) | 461 | |