

ACETO CORP
Form 10-K
September 11, 2015

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 June 30, 2015

Commission file number 000-04217

ACETO CORPORATION

(Exact name of registrant as specified in its charter)

New York 11-1720520
(State or other
jurisdiction of (I.R.S.
incorporation Employer
or Identification
organization) Number)

4 Tri Harbor Court, Port Washington, NY 11050
(Address of principal executive offices)

(516) 627-6000
(Registrant's telephone number, including area code)

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

Common Stock, par value \$.01 per share (Title of Class)	The NASDAQ Global Select Market (Name of each exchange on which registered)
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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 and posted on its corporate website, if any, every interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

The aggregate market value of the voting stock of the Company held by non-affiliates of the Company based on the closing price of the common stock on December 31, 2014 as reported on the NASDAQ Global Select Market was approximately \$616,032,815.

The Registrant has 29,356,192 shares of common stock outstanding as of September 8, 2015.

Documents incorporated by reference: The information required in response to Part III of this Annual Report on Form 10-K is hereby incorporated by reference to the specified portions of the Registrant's definitive proxy statement for the annual meeting of shareholders.

ACETO CORPORATION AND SUBSIDIARIES

FORM 10-K

FOR THE FISCAL YEAR ENDED JUNE 30, 2015

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PART I

CAUTIONARY STATEMENT RELATING TO THE SAFE HARBOR PROVISIONS OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

This Annual Report on Form 10-K contains forward-looking statements as that term is defined in the federal securities laws. The events described in forward-looking statements contained in this Annual Report on Form 10-K may not occur. Generally, these statements relate to our business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, financing plans, projected or anticipated benefits from acquisitions that we may make, or projections involving anticipated revenues, earnings or other aspects of our operating results or financial position, and the outcome of any contingencies. Any such forward-looking statements are based on current expectations, estimates and projections of management. We intend for these forward-looking statements to be covered by the safe-harbor provisions for forward-looking statements. Words such as “may,” “will,” “expect,” “believe,” “anticipate,” “project,” “plan,” “intend,” “estimate,” and “continue,” and their opposites and similar expressions are intended to identify forward-looking statements. We caution you that these statements are not guarantees of future performance or events and are subject to a number of uncertainties, risks and other influences, many of which are beyond our control that may influence the accuracy of the statements and the projections upon which the statements are based. Factors that may affect our results include, but are not limited to, the risks and uncertainties discussed in Item 1A of this Annual Report on Form 10-K.

Any one or more of these uncertainties, risks and other influences could materially affect our results of operations and whether forward-looking statements made by us ultimately prove to be accurate. Our actual results, performance and achievements could differ materially from those expressed or implied in these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether from new information, future events or otherwise.

NOTE REGARDING DOLLAR AMOUNTS

In this Annual Report on Form 10-K, all dollar amounts are expressed in thousands, except share prices and per-share amounts.

Item 1. Business

General

Aceto Corporation, together with its consolidated subsidiaries, are referred to herein collectively as “Aceto”, “the Company”, “we”, “us”, and “our”, unless the context indicates otherwise. Aceto was incorporated in 1947 in the State of New York. We are a global leader in the marketing, sales and distribution of finished dosage form generic pharmaceuticals, nutraceutical products, pharmaceutical active ingredients and intermediates, specialty performance chemicals inclusive of agricultural intermediates and agricultural protection products. Our business is organized along product lines into three principal segments: Human Health, Pharmaceutical Ingredients and Performance Chemicals.

We believe our main business strengths are sourcing, regulatory support, quality assurance and marketing and distribution. We distribute more than 1,100 chemical compounds used principally as finished products or raw materials in the pharmaceutical, nutraceutical, agricultural, coatings and industrial chemical industries. With business operations in ten countries, Aceto’s global reach is distinctive in the industry, enabling us to source and supply quality products on a worldwide basis. Leveraging local professionals, we source more than two-thirds of our products from Asia, buying from approximately 500 companies in China and 200 in India. No single supplier accounted for as much as 10% of purchases in fiscal 2015 and 2014.

Strategic relationships with manufacturers of pharmaceutical, nutraceutical, agricultural and specialty chemical products in the United States and internationally serve as a valuable resource to Aceto customers, enabling them to procure vital chemical based products necessary for their diverse and complex applications. A strong global technical network differentiates Aceto from commodity distribution companies. With regional managers in the United States, Europe and Asia, we provide regulatory support and quality assurance for customers and suppliers worldwide. Our regulatory network ensures that all products we distribute are produced to applicable required standards and conform to customer specifications for their intended end use.

Our presence in China, Germany, France, the Netherlands, Singapore, India, Hong Kong, Philippines, the United Kingdom and the United States, along with strategically located warehouses worldwide, enable us to respond quickly to demands from customers worldwide, assuring that a consistent, high-quality supply of pharmaceutical, nutraceutical, specialty chemicals and agricultural protection products are readily accessible. We are able to offer our customers competitive pricing, continuity of supply, and quality control. Highly experienced staff, many of whom are technically trained, enable Aceto to meet individual customer needs. Our marketing, sales, regulatory and technical professionals possess an intimate knowledge of worldwide sources of supply and product applications, as well as statutory and technical requirements. Many of our professionals are respected leaders in their industry, bringing 25 or more years of experience to customer applications. This longevity has fostered confidence and loyalty among customers and suppliers.

Aceto partners with customers during the product development process, creating new applications for existing products, as well as new product sourcing opportunities. We offer solutions for product and production challenges, while assisting with quality assurance, government approvals and compliance. All of these value-added services allow Aceto's customers to be more responsive to their end use customers and more competitive in the global marketplace. We believe our more than 65 years of experience, our reputation for reliability and stability, and our long-term relationships with suppliers have fostered loyalty among our customers.

We remain confident about our business prospects. We anticipate organic growth through our plans to introduce new products for finished dosage form generic drugs, the further globalization of our nutraceutical business, the continued globalization of our Performance Chemicals business, the expansion of our agricultural protection products by investing in product lines and intellectual property, the continued enhancement of our sourcing operations in China and India, and the steady improvement of our quality assurance and regulatory capabilities.

We believe our track record of continuous product introductions demonstrates our commitment to be recognized by the worldwide generic pharmaceutical industry as an important, reliable supplier. Our plans involve seeking strategic acquisitions that enhance our earnings and forming alliances with partners that add to our capabilities, when possible.

Other than product rights and license agreements for certain of our finished dosage form generic products which are part of our Human Health business and U.S. Environmental Protection Agency (EPA) registrations for our Performance Chemicals, we hold no patents, franchises or concessions that we consider material to our operations.

Information concerning revenue and gross profit attributable to each of our reportable segments and geographic information is found in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations", and in Note 19 to the Consolidated Financial Statements, Part II, Item 8, "Financial Statements and Supplementary Data."

Human Health

Products that fall within the Human Health segment include finished dosage form generic drugs and nutraceutical products. On April 30, 2014, Rising Pharmaceuticals, Inc. ("Rising"), a wholly owned subsidiary of Aceto, acquired 100% of the issued and outstanding membership interests of PACK Pharmaceuticals, LLC ("PACK"). PACK, a national marketer and distributor of generic prescription and over-the-counter pharmaceutical products, had headquarters in Buffalo Grove, Illinois, a suburb of Chicago, Illinois. During fiscal 2015, PACK was fully integrated with Rising and is now part of Rising's operations in New Jersey. We believe that the acquisition of PACK by Rising has advanced Aceto's strategy to expand further into the finished dosage pharmaceutical business. PACK and Rising have very similar business models including operating their businesses in collaboration with selected pharmaceutical

development partners and with networks of finished dosage form manufacturing partners, focusing on niche products and selling generic prescription products and over-the-counter pharmaceutical products under their respective labels to leading wholesalers, chain drug stores, distributors and mass market merchandisers. The strategically important and complementary business combination of PACK with our Rising business further increased the mix of higher margin finished dosage generic pharmaceuticals in Aceto's revenue base and doubled the size of our development pipeline of new generic products.

According to an IMS Health press release on November 20, 2014, "more specialty drug innovation, greater patient access to medicines and reduced impact from patent expiries will be the primary drivers of an increase in global medicine spending of up to 30 percent by 2018. The increase in annual spending will spike this year when absolute growth will be about \$70 billion, up from \$44 billion in 2013 and \$26 billion in 2012." The IMS report, entitled, *The Global Outlook for Medicines Through 2018*, states "total global spend for pharmaceuticals will increase by \$305-335 billion on a constant-dollar basis, compared to \$219 billion during the past five years. Global spending is forecast to grow at a 4-7 percent compound annual rate over the next five years."

Aceto supplies the raw materials used in the production of nutritional and packaged dietary supplements, including vitamins, amino acids, iron compounds and biochemicals used in pharmaceutical and nutritional preparations. After we identified a positive change in the attitudes of Europeans towards nutritional products, we globalized this business, creating an operating company headquartered in Germany, Aceto Health Ingredients GmbH. This globally structured business then became the model for all of our business segments, providing international reach and perspective for our customers.

Pharmaceutical Ingredients

The Pharmaceutical Ingredients segment has two product groups: Active Pharmaceutical Ingredients (APIs) and Pharmaceutical Intermediates.

As the use of generic drugs has grown significantly over the years, we believe Aceto's presence in this market also increased, both domestically and internationally. We supply APIs to many of the major generic drug companies, who we believe view Aceto as a valued partner in their effort to develop and market generic drugs. The process of introducing a new API from pipeline to market spans a number of years and begins with Aceto partnering with a generic pharmaceutical manufacturer and jointly selecting an API, several years before the expiration of a composition of matter patent, for future generisizing. We then identify the appropriate supplier, and concurrently utilizing our global technical network, ensure they meet the highest standards of quality to comply with regulations. The generic pharmaceutical company will submit the Abbreviated New Drug Application (ANDA) for U.S. Food and Drug Administration (FDA) approval or European-equivalent approval. The introduction of the API to market occurs after all the development testing has been completed and the ANDA or European-equivalent is approved and the patent expires or is deemed invalid. Aceto has a robust pipeline of APIs poised to reach commercial levels, both in the United States and Europe. Additionally, as the pressure to lower the overall cost of healthcare increases, and the prices of generic drugs continue to be competitive, Aceto has focused on, and works very closely with our customers to develop new API opportunities to provide alternative, more economical, second-source options for existing generic drugs. By leveraging our worldwide sourcing, regulatory and quality assurance capabilities, we provide to generic drug manufacturers an alternative, economical source for existing API products.

Aceto has long been a supplier of pharmaceutical intermediates, the complex chemical compounds that are the building blocks used in producing APIs. These are the critical components of all drugs, whether they are already on the market or currently undergoing clinical trials. Faced with significant economic pressures as well as ever-increasing regulatory barriers, the innovative drug companies look to Aceto as a source for high quality intermediates. Aceto employs, on occasion, the same second source strategy for our pharmaceutical intermediates business that we use in our API business. Historically, pharmaceutical manufacturers have had one source for the intermediates needed to produce their products. As manufacturers find their margins under pressure due to increased competition and government controls they continue to look for ways to reduce costs. Utilizing our global sourcing, regulatory support and quality assurance network, Aceto works with the large, global pharmaceutical companies, sourcing lower cost, quality pharmaceutical intermediates that will meet the same high level standards adhered to by their current commercial products.

According to an IMS Health press release on April 14, 2015, a new report, entitled, *Medicine Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014*, "found that total dollars spent on medications in the U.S. rose 13.1 percent on a nominal basis last year, up from a 3.2 percent increase in 2013. Primary drivers include higher spending on innovative new treatment options, the lower impact of patent expiries and increases in list prices of branded medicines. The factors that came together to drive the extraordinary spending growth in 2014 are expected to have less impact in future years, resulting in more moderate levels of growth."

Performance Chemicals

The Performance Chemicals segment includes specialty chemicals and agricultural protection products.

Aceto is a major supplier to many different industrial segments that require outstanding performance from chemical raw materials and additives. We provide chemicals which make plastics, surface coatings, textiles, fuels and lubricants to perform to their designed capabilities. These additive specialty products include antioxidants, photo initiators, catalysts, curatives, brighteners and adhesion promoters.

Aceto is a supplier of chemicals to ecofriendly technologies. For example, we supply ultraviolet photo initiators which allow inks and coatings to be cured by ultraviolet light instead of solvents, as well as curing agents and optical brighteners for powder (non-solvent) coatings. These growing technologies are critical in protecting and enhancing the world's ecology.

We also provide specialty chemicals for the food, beverage and fragrance industries. Aceto's raw materials are also used in sophisticated technology products, such as high-end electronic parts (circuit boards and computer chips) and binders for specialized rocket fuels. Aceto is also a leader in the supply of diazos and couplers to the paper and film industries. Specific end uses for these products include microfilm, blueprints and photo tooling of printed circuit boards.

We also provide organic intermediates and colorants including automotive, industrial and residential coatings, dyes for colorful textiles for both natural and synthetic fibers, FDA-approved colorants for foods and pharmaceuticals and high quality agrochemicals. The color producing industry manufactures a wide assortment of products and Aceto is the supplier of choice to these producers of "color." From textiles and plastics to inks and paints, our specialty colorant intermediates allow manufacturers to develop an endless rainbow of colorful possibilities.

According to a July 15, 2015 Federal Reserve Statistical Release, in the second quarter of calendar year 2015, the index for consumer durables, which impacts the Specialty Chemicals business of the Performance Chemicals segment, is expected to increase at an annual rate of 10.4%.

Aceto's agricultural protection products include herbicides, fungicides and insecticides which control weed growth as well as the spread of insects and microorganisms that can severely damage plant growth. The agricultural world is dependent on a large variety of deterrent products and we believe Aceto has become a valued partner to the global generic agricultural industry by providing superior quality functional products. One of Aceto's most widely used agricultural protection products is a sprout inhibitor that extends the storage life of potatoes. Other products are used in sugar cane, rice, corn, fruit and nut growing applications. We work with the large agrochemical distributors to provide alternate sources for key products. Utilizing our global sourcing and regulatory capabilities, we identify and qualify manufacturers either producing the product or with knowledge of the chemistry necessary to produce the product and then file an application with the EPA for a product registration. Aceto has an ongoing working relationship with manufacturers in China and India to determine which of the non-patented, or generic, agricultural protection products they produce can be effectively marketed in the Western world. Over the past several years, we have successfully brought a number of products to market. In addition, we have a strong pipeline, which includes future additions to our product portfolio. The combination of our global sourcing and regulatory capabilities makes the generic agricultural market a niche for us and we will continue to offer new product additions in this market as we move forward. In the National Agricultural Statistics Services release dated June 30, 2015, the total crop acreage planted in the United States in 2015 remained relatively flat at 326 million acres compared to 327 million acres in 2014. The number of peanut acres planted in 2015 increased 18% from 2014 levels while sugarcane acreage harvested increased 3% from 2014. In addition, the potato acreage harvested in 2015 rose approximately 1% from the 2014 level.

Research and Development Expenses

Research and development expenses (R&D) represent investment in our generic finished dosage form product pipeline, which includes both Rising and PACK products. R&D expenses during fiscal years 2015, 2014 and 2013 were \$5,942, \$5,222 and \$2,834 respectively.

Long-lived Assets

Long-lived assets, excluding property held for sale, by geographic region as of June 30, 2015, 2014 and 2013 were as follows:

Long-lived assets

	2015	2014	2013
United States	\$152,886	\$160,544	\$80,870
Europe	2,544	3,458	2,684
Asia-Pacific	1,893	2,042	2,213
Total	\$157,323	\$166,044	\$85,767

Suppliers and Customers

We purchase products from specifically approved plants and supply products to customers from plants whose products they have approved. We regularly visit our suppliers to evaluate them not only on the basis of ability to deliver satisfactory products on a timely and cost efficient basis, but also on their commitment to operate in a safe and environmentally responsible manner. During the fiscal years ended June 30, 2015 and 2014 approximately 65% and 64%, respectively, of our purchases were from Asia and approximately 12% and 14%, respectively, were from Europe.

Our customers are primarily located throughout the United States, Europe and Asia. We will continue our program of regular visits to our suppliers' plants, and will continue to educate them on the quality of product and service required by our customers. We are uniquely able to do this, as almost all of our sales representatives are technically trained (e.g. chemists, chemical engineers, biologists, pharmacologists, etc.) most with in-plant or industrial laboratory experience. Our customers include a wide range of companies in the industrial chemical, agricultural, and human health and pharmaceutical industries, and range from small trading companies to Fortune 500 companies. During fiscal years 2015, 2014 and 2013, sales made to customers in the United States totaled \$369,663, \$325,190 and \$291,433, respectively. Sales made to customers outside the United States during fiscal years 2015, 2014 and 2013 totaled \$177,288, \$184,989 and \$208,257, respectively, of which, approximately 62%, 59% and 62%, respectively, were to customers located in Europe. One customer accounted for 13% of net sales in fiscal 2015. No single customer accounted for as much as 10% of net sales in fiscal 2014 or 2013. No single product accounted for as much as 10% of net sales in fiscal 2015, 2014 or 2013.

Competition

The Company operates in a highly competitive business environment. We compete by offering high-quality products produced around the world by both large and small manufacturers at attractive prices. Because of our long standing relationships with many suppliers as well as our sourcing operations in both China and India, we are able to ensure that any given product is manufactured at a facility that can meet the regulatory requirements for that product. For the most part, we store our inventory of chemical-based products in public warehouses strategically located throughout the United States, Europe, and Asia, and we can therefore fill our customer orders on a timely basis. We have developed ready access to key purchasing, research, and technical executives of our customers and suppliers. This allows us to ensure that when necessary, sourcing decisions can be made quickly. We will also continue to search for new products, as well as for new sources for products where we feel our existing sources have lapsed in either product or delivery quality, and/or have failed to meet the needs of our customers or markets.

Environmental and Regulatory

We are subject to extensive regulation by federal, state and local agencies in the countries in which we do business. Of particular importance is the FDA in the U.S. It has jurisdiction over testing, safety, effectiveness, manufacturing, labeling, marketing, advertising and post-marketing surveillance of our Human Health products.

Certain of our products 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, transportation and discharge of materials into the environment and the maintenance of safe working conditions. We have designed safety procedures to comply with the standards prescribed by federal, state and local regulations. We promote the use of environmentally friendly recyclable packaging by our suppliers. We endeavor to meet our customers' packaging requirements. We only use warehouses and carriers approved to handle chemicals and that have appropriate permits and licenses.

Our global quality assurance network, with regional managers in the U.S., Europe and Asia, ensures that the quality of a product meets both its specifications and intended use. Our technical network performs a service that allows Aceto to source and qualify APIs, pharmaceutical intermediates, finished dosage form generics, agricultural products, specialty chemicals, and nutraceutical products from around the world. It also provides substantial regulatory support and technical assistance to manufacturers worldwide, enabling them to meet the stringent regulatory guidelines that govern the pharmaceutical, nutraceutical, specialty chemicals and agricultural protection industries.

A subsidiary of the Company markets certain agricultural protection products which are subject to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). FIFRA requires that test data be provided to the EPA to register,

obtain and maintain approved labels for pesticide products. The EPA requires that follow-on registrants of these products compensate the initial registrant for the cost of producing the necessary test data on a basis prescribed in the FIFRA regulations. Follow-on registrants do not themselves generate or contract for the data. However, when FIFRA requirements mandate that new test data be generated to enable all registrants to continue marketing a pesticide product, often both the initial and follow-on registrants establish a task force to jointly undertake the testing effort. The Company is presently a member of several such task force groups, which requires payments for such memberships.

Employees

At June 30, 2015, we had 270 employees, none of whom were covered by a collective bargaining agreement.

Available information

We file annual, quarterly, and current reports, proxy statements, and other information with the U.S. Securities and Exchange Commission (“SEC”). You may read and copy any document we file at the SEC’s public reference room at 100 F Street, NE, Washington, D.C. 20549.

You may call the SEC at 1-800-SEC-0330 for information on the public reference room. The SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including Aceto) file electronically with the SEC. The SEC’s website is www.sec.gov.

Our website is www.aceto.com. We make available free of charge through our Internet site, via a link to the SEC’s website at www.sec.gov, our annual reports on Form 10-K; quarterly reports on Form 10-Q; current reports on Form 8-K; Forms 3, 4 and 5 filed on behalf of our directors and executive officers; and any amendments to those reports and forms. We make these filings available as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information on our website is not incorporated by reference into this Annual Report on Form 10-K.

Item 1A. Risk factors

You should carefully consider the following risk factors and other information included in this Annual Report on Form 10-K. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we currently deem immaterial could also impair our business operations. If any of the following risk factors occur, our reputation, business, financial condition, operating results and cash flows could be materially adversely affected.

If we are unable to compete effectively with our competitors, many of which have greater market presence and resources than us, our reputation, business, financial condition, operating results and cash flows could be materially adversely affected.

Our financial condition and operating results are directly related to our ability to compete in the intensely competitive global pharmaceutical and chemical markets. We face intense competition from global and regional distributors of pharmaceutical and chemical products, many of which are large pharmaceutical and chemical manufacturers as well as distributors. Many of these companies have substantially greater resources than us, including, among other things, greater financial, marketing and distribution resources. We cannot assure you that we will be able to compete successfully with any of these companies. In addition, increased competition could result in price reductions, reduced margins and loss of market share for our products, all of which could materially adversely affect our reputation, business, financial condition, operating results and cash flows.

Our distribution operations of finished dosage form generic drugs and APIs are subject to the risks of the generic pharmaceutical industry.

The ability of our business to provide consistent, sequential quarterly growth is affected, in large part, by our participation in the launch of new products by generic manufacturers and the subsequent advent and extent of competition encountered by these products. Revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. This competition can result in significant and rapid declines in pricing with a corresponding decrease in net sales. Net selling prices of generic drugs typically decline over time, sometimes dramatically, as additional generic pharmaceutical companies receive approvals and enter the market for a given generic product and competition intensifies. When additional versions of one of our generic products enter the market, we generally lose market share and our selling prices and margins on that product decline.

We may experience declines in sales volumes or prices of certain of our products as the result of the concentration of sales to wholesalers and the continuing trend towards consolidation of such wholesalers and other customer groups

which could have a material adverse impact on our business, financial condition, operating results and cash flows.

Wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing our finished dosage form generic business. The result of these developments could have a material adverse effect on our business, financial position, results of operations and cash flows.

Our pipeline of products in development may be subject to regulatory delays at the FDA. Delays in key products could have material adverse effects on our reputation, business, financial condition, operating results and cash flows.

Our future revenue growth and profitability are partially dependent upon our ability to introduce new products on a timely basis in relation to our competitors' product introductions. Our failure to do so successfully could materially adversely affect our reputation, business, financial condition, operating results and cash flows. Many products require FDA approval or the equivalent regulatory approvals in our overseas markets prior to being marketed. The process of obtaining FDA/regulatory approval to market new and generic pharmaceutical products is rigorous, time-consuming, costly and often unpredictable. We may be unable to obtain requisite FDA approvals on a timely basis for new generic products.

If brand pharmaceutical companies are successful in limiting the use of generics through their legislative and regulatory efforts, our sales of generic products may suffer.

Many brand pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

pursuing new patents for existing products which may be granted just before the expiration of one patent which could extend patent protection for additional years or otherwise delay the launch of generics;

- using the Citizen Petition process to request amendments to FDA standards;

seeking changes to U.S. Pharmacopoeia, an organization which publishes industry recognized compendia of drug standards;

- attaching patent extension amendments to non-related federal legislation; and

engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs, which could have an impact on products that we are developing.

If brand pharmaceutical companies are successful in limiting the use of generic products through these or other means, our sales may decline. A material decline in product sales could have material adverse effects on our reputation, business, financial condition, operating results and cash flows.

Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce our revenues in future fiscal periods.

Based on industry practice, generic drug manufacturers have liberal return policies and have been willing to give customers post-sale inventory allowances. Under these arrangements, from time to time we give our customers credits on our generic products that our customers already hold in inventory after we have decreased the market prices of the same generic products due to competitive pricing. Therefore, if new competitors enter the marketplace and significantly lower the prices of any of their competing products, we could reduce the price of our product. As a result, we would be obligated to provide credits to our customers who are then holding inventories of such products, which could reduce sales revenue and gross margin for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesalers that have contracts with us for their sales to hospitals, group purchasing organizations, pharmacies or other customers.

A chargeback is the difference between the price the wholesaler pays and the price that the wholesaler's end-customer pays for a product. Although we establish reserves based on our prior experience and our best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that our reserves are adequate or that actual product returns, allowances and chargebacks will not exceed our estimates.

The regulatory approval process outside the U.S. varies depending on foreign regulatory requirements, and failure to obtain regulatory approval in foreign jurisdictions would prevent the marketing of our products in those jurisdictions.

We have certain worldwide intellectual property rights to market some of our products and product candidates. We intend to seek approval to market certain of our products outside of the U.S. To market our products in the European Union and other foreign jurisdictions, we must obtain separate regulatory authorization and comply with numerous and varying regulatory requirements. Approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to marketing that product in those countries. The approval procedure varies among

countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth herein and approval by the FDA does not ensure approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country ensure approval by regulatory authorities in other foreign countries or the FDA. If we fail to comply with these regulatory requirements or obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue from abroad will be adversely affected.

Our growth and development will depend on developing, commercializing and marketing new products, including both our own products and those developed with our collaboration partners. If we do not do so successfully, our growth and development will be impaired.

Our future revenues and profitability will depend, to a significant extent, upon our ability to successfully commercialize new generic pharmaceutical products in a timely manner. As a result, we must continually develop and test new products, and these new products must meet regulatory standards and receive requisite regulatory approvals. Products we are currently developing may or may not achieve the technology success or receive the regulatory approvals or clearances necessary for us to market them. Furthermore, the development and commercialization process is time-consuming and costly, and we cannot assure you that any of our products, if and when developed and approved, can be successfully commercialized. Some of our collaboration partners may decide to make substantial changes to a product's formulation or design, may experience financial difficulties or have limited financial resources, any of which may delay the development, commercialization and/or marketing of new products. In addition, if a co-developer on a new product terminates our collaboration agreement or does not perform under the agreement, we may experience delays and, possibly, additional costs in developing and marketing that product.

If we experience product recalls, we may incur significant and unexpected costs, and our business reputation could be adversely affected.

We may be exposed to product recalls and adverse public relations if our products are alleged to cause injury or illness, or if we are alleged to have violated governmental regulations. A product recall could result in substantial and unexpected expenditures, which would reduce operating profit and cash flow. In addition, a product recall may require significant management attention. Product recalls may hurt the value of our brands and lead to decreased demand for our products. Product recalls also may lead to increased scrutiny by federal, state or international regulatory agencies of our operations and increased litigation and could have a material adverse effect on our reputation, business, financial condition, operating results and cash flows.

Dependence on a limited number of suppliers of Human Health and Pharmaceutical Ingredients products could lead to delays, lost revenue or increased costs.

Our future operating results may depend substantially on our suppliers' ability to timely provide Human Health and Pharmaceutical Ingredients products in connection with ANDAs and such suppliers' ability to supply us with these ingredients or materials in sufficient volumes to meet our production requirements. A number of the ingredients or materials that we use are available from only a single or limited number of qualified suppliers, and may be used across multiple product lines. If there is a significant increase in demand for an ingredient or other material resulting in an inability to meet demand, if an ingredient or material is otherwise in short supply or becomes wholly unavailable, or if a supplier has a quality issue, we may experience delays or increased costs in obtaining that ingredient or material. If we are unable to obtain sufficient quantities of ingredients or other necessary materials, we may experience production delays in our supply.

Each of the following could also interrupt the supply of, or increase the cost of, ingredients or other materials:

- an unwillingness of a supplier to supply ingredients or other materials to us;
- consolidation of key suppliers;
- failure of a key supplier's business process;
- a key supplier's inability to access credit necessary to operate its business; or
- failure of a key supplier to remain in business, to remain an independent supplier, or to adjust to market conditions.

Any interruption in the supply or increase in the cost of ingredients or other materials provided by single or limited source suppliers could have a material adverse effect on our reputation, business, financial condition, operating results and cash flows.

Our success in our Human Health segment is linked to the size and growth rate of the generic pharmaceutical, vitamin, mineral and supplement markets and an adverse change in the size or growth rate of these markets could have a material adverse effect on us.

An adverse change in size or growth rate of the generic pharmaceutical, vitamin, mineral and supplement markets could have a material adverse effect on us. Underlying market conditions are subject to change based on economic conditions, consumer preferences and other factors that are beyond our control, including media attention and scientific research, which may be positive or negative.

Healthcare reform and a reduction in the reimbursement levels by governmental authorities, HMOs, MCOs or other third-party payors could materially adversely affect our business, financial condition, operating results and cash flows.

Third party payors increasingly challenge pricing of pharmaceutical products. The trend toward managed healthcare, the growth of organizations such as HMOs and MCOs and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand. Such cost containment measures and healthcare reform could affect our ability to sell our products and could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Any failure to comply with the complex reporting and payment obligations under Medicare, Medicaid and other government programs may result in litigation or sanctions.

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims, marketing and pricing laws. We are also subject to Medicaid and other government reporting and payment obligations that are highly complex and somewhat ambiguous. Violations of these laws and reporting obligations are punishable by criminal and/or civil sanctions and exclusion from participation in federal and state healthcare programs such as Medicare and Medicaid. The recent healthcare reform legislation made several changes to the federal anti-kickback statute, false claims laws, and health care fraud statute such as increasing penalties and making it easier for the government to bring sanctions against pharmaceutical companies. If our past, present or future operations are found to be in violation of any of the laws described above or other similar governmental regulations, we may be subject to the applicable penalty associated with the violation which could adversely affect our ability to operate our business and negatively impact our financial results. Further, if there is a change in laws, regulations or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, results of

operations, financial condition and cash flows.

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Our future results could be materially affected by a number of public health issues whether occurring in the United States or abroad.

Public health issues, whether occurring in the United States or abroad, could disrupt our operations, disrupt the operations of suppliers or customers, or have a broader adverse impact on consumer spending and confidence levels that would negatively affect our suppliers and customers. We may be required to suspend operations in some or all of our locations, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Our revenue stream and related gross profit is difficult to predict.

Our revenue stream is difficult to predict because it is primarily generated as customers place orders and customers can change their requirements or cancel orders. Many of our sales orders are short-term and could be cancelled at any time. As a result, much of our revenue is not recurring from period to period, which contributes to the variability of our results from period to period. In addition, certain of our products carry a higher gross margin than other products, particularly in the Human Health and Pharmaceutical Ingredients segments. Reduced sales of these higher margin products could have a material adverse effect on our operating results. We believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance.

From time to time we may need to rely on licenses to proprietary technologies, which may be difficult or expensive to obtain.

We may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially market our products may be inhibited or prevented, which could have a material adverse effect on our business, financial condition, operating results and cash flows.

Changes to the industries and markets that Aceto serves could have a material adverse effect on our business, financial condition, operating results and cash flows.

The business environment in which we operate remains challenging. Portions of our operations are subject to the same business cycles as those experienced by automobile, housing, and durable goods manufacturers. Our demand is largely derived from the demand for our customers' products, which subjects us to uncertainties related to downturns in our customers' business and unanticipated customer production shutdowns or curtailments. A material downturn in

sales or gross profit due to weak end-user markets and loss of customers could have a material adverse effect on our business, financial condition, operating results and cash flows.

Our operating results could fluctuate in future quarters, which could adversely affect the trading price of our common stock.

Our operating results could fluctuate on a quarterly basis as a result of a number of factors, including, among other things, the timing of contracts, orders, the delay or cancellation of a contract, and changes in government regulations. Any one of these factors could have a significant impact on our quarterly results. In some quarters, our revenue and operating results could fall below the expectations of securities analysts and investors, which would likely cause the trading price of our common stock to decline.

We have significant inventories on hand.

The Company maintains significant inventories. Any significant unanticipated changes in future product demand or market conditions, including, among other things, the current uncertainty in the global market, could materially adversely affect the value of inventory and our business, financial condition, operating results and cash flows.

Failure to obtain products from outside manufacturers could adversely affect our ability to fulfill sales orders to our customers.

We rely on outside manufacturers to supply products for resale to our customers. Manufacturing problems, including, among other things, manufacturing delays caused by plant shutdowns, regulatory issues, damage or disruption to raw material supplies due to weather, including, among other things, any potential effects of climate change, natural disaster or fire, could occur. If such problems occur, we cannot assure that we will be able to deliver our products to our customers profitably or on time.

Increases in the cost of shipping with our third-party shippers could have a material adverse effect on our business, financial condition, operating results and cash flows.

Shipping is a significant expense in the operation of our business. Accordingly, any significant increase in shipping rates could have an adverse effect on our operating results. Similarly, strikes or other service interruptions by those shippers could cause our operating expenses to rise and adversely affect our ability to deliver products on a timely basis.

We could incur significant uninsured environmental and other liabilities inherent in the chemical/pharmaceutical distribution industry that could materially adversely affect our business, financial condition, operating results and cash flows.

The business of distributing chemicals and pharmaceuticals is subject to regulation by numerous federal, state, local, and foreign governmental authorities. These regulations impose liability for loss of life, damage to property and equipment, pollution and other environmental damage that could occur in our business. Many of these regulations provide for substantial fines and remediation costs in the event of chemical spills, explosions and pollution. While we believe that we are in substantial compliance with all current laws and regulations, we can give no assurance that we will not incur material liabilities that are not covered by insurance or exceed our insurance coverage or that such insurance will remain available on terms and at rates acceptable to us. Additionally, if existing environmental and other regulations are changed, or additional laws or regulations are passed, the cost of complying with those laws could be substantial, thereby materially adversely affecting our business, financial condition, operating results and cash flows.

In fiscal years 2011, 2009, 2008 and 2007, the Company received letters from the Pulvair Site Group, a group of potentially responsible parties (PRP Group) who are working with the State of Tennessee (the State) to remediate a contaminated property in Tennessee called the Pulvair site. The PRP Group has alleged that Aceto shipped hazardous substances to the site which were released into the environment. The State had begun administrative proceedings

against the members of the PRP Group and Aceto with respect to the cleanup of the Pulvair site and the PRP Group has begun to undertake cleanup. The PRP Group is seeking a settlement of approximately \$1,700 from the Company for its share to remediate the site contamination. Although the Company acknowledges that it shipped materials to the site for formulation over twenty years ago, the Company believes that the evidence does not show that the hazardous materials sent by Aceto to the site have significantly contributed to the contamination of the environment and thus believes that, at most, it is a de minimis contributor to the site contamination. Accordingly, the Company believes that the settlement offer is unreasonable. Management believes that the ultimate outcome of this matter will not have a material adverse effect on the Company's financial condition or liquidity.

Our subsidiary, Arsynco, has environmental remediation obligations in connection with its former manufacturing facility in Carlstadt, New Jersey. Estimates of how much it would cost to remediate environmental contamination at this site have increased since the facility was closed in 1993. If the actual costs are significantly greater than estimated, it could have a material adverse effect on our financial condition, operating results and cash flows.

In March 2006, Arsynco received notice from the EPA of its status as a PRP under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) for a site described as the Berry's Creek Study Area ("BCSA"). Arsynco is one of over 150 PRPs which have potential liability for the required investigation and remediation of the site. The estimate of the potential liability is not quantifiable for a number of reasons, including the difficulty in determining the extent of contamination and the length of time remediation may require. In addition, any estimate of liability must also consider the number of other PRPs and their financial strength. In July 2014, Arsynco received notice from the U.S. Department of Interior ("USDOI") regarding the USDOI's intent to perform a Natural Resource Damage (NRD) Assessment at the BCSA. Arsynco has to date declined to participate in the development and performance of the NRD assessment process. Based on prior practice in similar situations, it is possible that the State may assert a claim for natural resource damages with respect to the Arsynco site itself, and either the federal government or the State (or both) may assert claims against Arsynco for natural resource damages in connection with Berry's Creek; any such claim with respect to Berry's Creek could also be asserted against the approximately 150 PRPs which the EPA has identified in connection with that site. Any claim for natural resource damages with respect to the Arsynco site itself may also be asserted against BASF, the former owners of the Arsynco property. In September 2012, Arsynco entered into an agreement with three of the other PRPs that had previously been impleaded into New Jersey Department of Environmental Protection, et al. v. Occidental Chemical Corporation, et al., Docket No. ESX-L-9868-05 (the "NJDEP Litigation") and were considering impleading Arsynco into the same proceeding. Arsynco entered into an agreement to avoid impleader. Pursuant to the agreement, Arsynco agreed to (1) a tolling period that would not be included when computing the running of any statute of limitations that might provide a defense to the NJDEP Litigation; (2) the waiver of certain issue preclusion defenses in the NJDEP Litigation; and (3) arbitration of certain potential future liability allocation claims if the other parties to the agreement are barred by a court of competent jurisdiction from proceeding against Arsynco. In July 2015, Arsynco was contacted by an allocation consultant retained by a group of the named PRPs, inviting Arsynco to participate in the allocation among the PRPs' investigation and remediation costs relating to the BCSA. Arsynco declined that invitation. Since an amount of the liability cannot be reasonably estimated at this time, no accrual is recorded for these potential future costs. The impact of the resolution of this matter on the Company's results of operations in a particular reporting period is not currently known.

The distribution and sale of some of our products are subject to prior governmental approvals and thereafter ongoing governmental regulation.

Our products are subject to laws administered by federal, state and foreign governments, including the Toxic Substances Control Act as well as regulations requiring registration and approval of many of our products. More stringent restrictions could make our products less desirable, which would adversely affect our revenues and profitability. Some of our products are subject to the EPA registration and re-registration requirements, and are registered in accordance with FIFRA. Such registration requirements are based, among other things, on data demonstrating that the product will not cause unreasonable adverse effects on human health or the environment when used according to approved label directions. Governmental regulatory authorities have required, and may require in the future, that certain scientific data requirements be performed on our products and this may require us, on our behalf or in joint efforts with other registrants, to perform additional testing. Responding to such requirements may cause delays in or the cessation of the sales of one or more of our products which would adversely affect our profitability. We can provide no assurance that any testing approvals or registrations will be granted on a timely basis, if at all, or that our resources will be adequate to meet the costs of regulatory compliance or that the economic benefit of complying with the requirement will exceed our cost.

Incidents related to hazardous materials could materially adversely affect our reputation, business, financial condition, operating results and cash flows.