INVACARE CORP
Form 10-K
March 09, 2018

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

FORM 10-K

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017
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 1-15103

INVACARE CORPORATION
(Exact name of Registrant as specified in its charter)

Ohio	95-2680965
(State or other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

One Invacare Way, Elyria, Ohio 44035
(Address of principal executive offices) (Zip Code)
Registrant's telephone number, including area code: (440) 329-6000

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

Title of each class	Name of exchange on which registered
Common Shares, without par value	New York Stock Exchange

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

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. Yes ¨ No ý
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 ý
Indicate by check mark whether the Registrant (1) has filed all reports 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 the filing requirements for the past 90 days. Yes ý No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such short period that the registrant was required to submit and post such files). Yes ý No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section229.405) 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 definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.
Large Accelerated filer ¨ Accelerated filer ý

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 by Rule 12b-2 of the Act). Yes ¨ No ý

As of June 30, 2017, the aggregate market value of the 31,816,530 Common Shares of the Registrant held by non-affiliates was $419,978,196 and the aggregate market value of the 18,357 Class B Common Shares of the Registrant held by non-affiliates was $242,312. While the Class B Common Shares are not listed for public trading on any exchange or market system, shares of that class are convertible into Common Shares at any time on a share-for-share basis. The market values indicated were calculated based upon the last sale price of the Common Shares as reported by The New York Stock Exchange on June 30, 2017, which was $13.20. For purposes of this information, the 1,031,950 Common Shares and 0 Class B Common Shares which were held by Executive Officers and Directors of the Registrant were deemed to be the Common Shares and Class B Common Shares held by affiliates.

As of March 6, 2018, there were 32,874,804 Common Shares and 6,357 Class B Common Shares outstanding.

Documents Incorporated By Reference

Portions of the Registrant’s definitive Proxy Statement to be filed in connection with its 2018 Annual Meeting of Shareholders are incorporated by reference into Part III (Items 10, 11, 12, 13 and 14) of this report.

Except as otherwise stated, the information contained in this Annual Report on Form 10-K is as of December 31, 2017.

INVACARE CORPORATION
2017 ANNUAL REPORT ON FORM 10-K CONTENTS

Part I Item 1. Business

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Item 1. Business.

GENERAL

Invacare Corporation (“Invacare,” “company,” including its subsidiaries, unless otherwise noted) is a leading manufacturer and distributor in its markets for medical products used in non-acute care settings. At its core, the company designs, manufactures and distributes medical products that help people to move, breathe, rest and perform essential hygiene. The company provides medical product solutions for congenital (e.g., cerebral palsy, muscular dystrophy, spina bifida), acquired (e.g., stroke, spinal cord injury, traumatic brain injury, post-acute recovery, pressure ulcers) and degenerative (e.g., ALS, multiple sclerosis, chronic obstructive pulmonary disease (COPD), elderly, bariatric) ailments. The company's products are important parts of care for people with a wide range of challenges, from those who are active and heading to work or school each day and may need additional mobility or respiratory support, to those who are cared for in residential care settings, at home and in rehabilitation centers. The company sells its products principally to home medical equipment providers with retail and e-commerce channels, residential care operators, distributors and government health services in North America, Europe and Asia/Pacific. Invacare’s products are sold through its worldwide distribution network by its sales force, independent manufacturers’ representatives, and distributors.

Invacare is committed to providing medical products that deliver the best clinical value, which promote recovery, independence, active lifestyles and support long-term conditions and palliative care. Yes, You Can.® continues to be the company's global tagline as it is indicative of the "can do" attitude of many of the people who use the company's products and their care providers. In everything it does, the company strives to leave its stakeholders with its brand promise - Making Life's Experiences Possible®.

The company is a corporation organized under the laws of the State of Ohio in 1971. When the company was first established as a stand-alone enterprise in December 1979, it had $19.5 million in net sales and a limited product line of basic wheelchairs and patient aids. Over the course of time, the company made approximately fifty acquisitions and, after some recent divestitures to harmonize its portfolio, Invacare's net sales in 2017 were approximately $1.0 billion. Based upon the company’s distribution channels, breadth of product line and net sales, Invacare is a leading company in many of the following medical product categories: custom power wheelchairs; custom manual wheelchairs; electromotive technology to augment wheelchairs and recreational products; recreational adaptive sports products; non-acute bed systems; patient transfer and bathing equipment; and supplementary respiratory therapy devices.

THE NON-ACUTE DURABLE MEDICAL EQUIPMENT INDUSTRY

The non-acute durable medical equipment market includes a broad range of equipment and services that enable the care and lifestyle needs of individuals with a broad range of conditions. With expected long-term pressure on controlling healthcare spending per capita, the company believes the market for equipment and services that support higher acuity care in lower acuity settings will continue to grow. Healthcare payors and providers continue to optimize therapies for improved outcomes and reduced cost protocols which result in earlier discharge, including recovery and treatment at non-acute settings. Care in these settings may reduce exposure to concomitant issues and be preferred by patients.

With healthcare costs continuing to increase, the interests of patients and healthcare providers are converging to focus on the most cost-effective delivery of the best care. As payors become more judicious in their spending on healthcare,

companies that provide better care or demonstrate better clinical outcomes will have an advantage. With its diverse product portfolio, clinical solutions, global scale and focus on the non-acute care setting, the company believes it is well positioned to serve this growing market.

Macro trends are occurring to the global aging population. While institutional care will likely remain an important part of healthcare systems in the wealthiest economies, the company believes care settings other than traditional hospitals will increasingly provide higher acuity care. With a broad product offering, diversified channels of trade, and infrastructure serving many of the largest healthcare economies, the company believes it is well positioned to benefit from these demographic trends and changes to the provision of healthcare.

North America Market

The United States' population is growing and aging. As a result, there is a greater prevalence of disability among major populations and a greater need for assistance and care. The U.S. Census Bureau has projected the U.S. population will continue to grow towards to an estimated 400 million by 2050. Along the way, the bolus of Baby Boomers will continue to raise the average age of the population. By 2030, the government estimates the percent of the U.S. population over the age of 65 will rise to be more than 20% of all residents, a 50% increase compared to 13% of the population in 2010.

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In the United States, healthcare provision is supported by reimbursement from the federal Centers for Medicare and Medicaid Services (“CMS”), the Veterans Administration, state agencies, private payors and healthcare recipients themselves. In total, CMS estimates U.S. national healthcare expenditures to grow by more than 5% annually between 2017 and 2026. At this rate, healthcare spending would exceed GDP growth by 1%, which will sustain pressure to deploy care in ways that deliver the best outcomes for lower cost.

The Canadian health care system is a publicly funded model that provides coverage to all citizens. The provinces and territories administer and deliver most of Canada's health care services, and all health insurance plans are expected to meet the national principles of the Canada Health Act. The objective of this Act is to provide consumer-centered support and funding to residents who have long-term physical disabilities and to give access to personalized assistive devices appropriate for the individual’s basic needs. Each provincial and territorial health insurance plan differs in terms of the reimbursement policies and product specifications. This allows healthcare services to be adjusted to regional needs. Invacare sells across Canada taking into consideration the differences in each region.

Europe, Middle East and Africa Markets

While the healthcare equipment market in each country in Europe has distinct characteristics, many of the factors driving demand and affecting reimbursement are consistent with those in North America: population aging; more patients with chronic illnesses; preference to increasingly deliver healthcare outside hospitals; and the use of technology to increase productivity and reduce ancillary costs. Each country has variations in product specifications and service requirements, regulations, distribution needs and reimbursement policies. These differences, as well as differences in the competitive landscape, require the company to tailor its approach to each local market. The company's core strategy is to address these markets with global product platforms that are localized with country-specific adjustments as necessary. This is especially the case for power wheelchairs, manual wheelchairs, and respiratory products. Customers in all European markets typically make product selections based upon quality, features, alignment with local reimbursement requirements, ability to reduce total cost of care, and customer service.

The company serves various markets in the Middle East and Africa. It approaches these markets with the global portfolio of products developed and manufactured elsewhere. Sales in these territories are made somewhat opportunistically to balance the changes in level of demand and specific products required. Often, sales are to fulfill episodic tenders and do not often represent consistent sustained trade. Sales reported in the European segment result

from business conducted principally in Western European markets.

Asia/Pacific Market

The company's Asia/Pacific segment is comprised of revenues from products sold into Australia, New Zealand, China, Japan, Korea, India and Southeast Asia. Invacare's Asia/Pacific businesses sell through six distribution channels. Mobility and seating products are sold via a dealer network with almost all sales directly government-funded. Homecare products are sold via a dealer network that sells products to the consumer market. Long-term care products are sold via a dealer network and directly to care facilities. The company operates a rental business in New Zealand supporting the three largest providers in New Zealand’s North Island. Sales to other parts of Asia are sold via distributors and agents based in China, Japan, Korea, India and Southeast Asia.

Reimbursement

In most markets, the company does not make significant sales directly to end-users. In some cases, the company sells directly to a government payor, for example, in the United States, the United Kingdom and certain Scandinavian countries. In other cases, the company's customers purchase products to have available for sale to or use by end-users. These customers then work with end-users to determine what equipment may be needed to address the end-user's medical needs. Products are then provided to the end-user, and the company's customer may seek reimbursement on behalf of the consumer or sell the products, as appropriate. Product mix, pricing and payment terms vary by market. The company believes its market position and technical expertise will allow it to respond to ongoing changes in demand and reimbursement.

PRODUCT CATEGORIES

The company manufactures and distributes products in three key product categories:

Mobility and Seating

- Power Wheelchairs. Invacare designs, manufactures and distributes complex power wheelchairs for individuals who require powered mobility. The range includes products that can be highly customized to meet an individual end-user's needs, as well as products that are inherently versatile and meet a broad range of requirements. Center-wheel drive power wheelchair lines are marketed under the Invacare® TDX® (Total Driving eXperience) brand name as well as the ROVI® X3 power base offered through the Motion Concepts subsidiary. The TDX line of power wheelchairs offers a combination of power, stability and maneuverability,

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including the Invacare® SureStep® suspension with Stability Lock and available G-Trac™ Technology. Seating systems offer elevate, power tilt and recline features. The company also offers rear-wheel drive power wheelchair technology through the Invacare® Storm Series®. The company has several subsidiaries that specialize in complementary technology to enhance the utility of wheelchairs for unique and complex physiological needs. For example, the company's Adaptive Switch Labs (ASL) subsidiary has developed alternative electronic control systems and human/machine input devices that enable wheelchair and environmental control via alternative interfaces to joysticks, such as sip/puff, eye-gaze, or head position inputs. The Motion Concepts subsidiary designs and produces custom powered seating and power positioning systems. Alber sells innovative power add-on devices that enable manual wheelchair users to have optional electric power to augment manual propulsion and enable caretakers to more easily maneuver manual wheelchairs. In addition, Dynamic Controls (DCL) makes sophisticated electronic control systems for power wheelchairs that enable users to operate the device and permit wireless programming, remote diagnostics, and touchscreen controls. The company continues to be a leader in this market with unique intellectual property in wheelchair suspension, alternative controls, and electronics.

- Custom Manual Wheelchairs. Invacare designs, manufactures and markets a range of custom manual wheelchairs and recreational products for independent everyday use, outdoor recreation, casual and competitive sports, such as basketball, racing and tennis. These products are marketed under the Invacare® and Invacare® Top End® brand names. The company also has a premiere line of lightweight aesthetically stylish custom manual wheelchairs under the Küschall® brand. These custom manual wheelchairs provide a wide range of mobility solutions for everyday activities. The company’s competitive advantages include a wide range of features and functionality and the ability to build purposeful custom wheelchairs, as well as wheelchairs that collapse to fit into very small spaces for ease of transportability.
- Seating and Positioning Products. At the core of care for seated end-users is the need for proper seating and positioning. Invacare designs, manufactures and markets some of the industry’s best custom seating and positioning systems, custom molded and modular seat cushions, back supports and accessories to enable care givers to optimize the posture of their clients in mobility products. The Invacare® Seating and Positioning series provides seating solutions for less complex needs. The Invacare® Matrx® Series offers versatile modular seating components with unique proprietary designs and materials that optimize pressure management and

help ensure long-term proper posture. The company's PinDot® series provides custom molded seat modules that can accommodate the most unique anatomic needs and can be adapted to fit with a wide range of mobility products. This high-level of customization and ability to rapidly produce custom products is highly specialized in the market, and is valued by therapists who need timely solutions for their clients’ most complex clinical needs.

Lifestyle Products

- Pressure Relieving Sleep Surfaces. Invacare manufactures and distributes a complete line of therapeutic pressure relieving overlays and mattress systems. The Invacare® Softform and microAIR® brand names feature a broad range of pressure relieving foam mattresses or powered mattresses with alternating pressure, low-air-loss, or rotational mattresses, which redistribute weight and assist with moisture management. These mattresses are designed to provide comfort, support and relief to those patients who are immobile or have limited mobility; who may have fragile skin or be susceptible to skin breakdown; and who spend long periods in bed.
- Safe Resident Handling. Invacare manufactures and distributes products needed to assist in transferring individuals from surface to surface (e.g., bed to chair). Designed for use in the home or in institutional settings, these products include ceiling and floor lifts, sit-to-stand devices and a comprehensive line of slings.
- Beds. Invacare manufactures and distributes a wide variety of Invacare branded manual, semi-electric and fully-electric beds for both residential care and home use for a range of patient sizes. The company's offering includes bed accessories, such as bedside rails, overbed tables and trapeze bars. The company’s bed systems introduced the split-spring bed design, which is easier for home medical equipment providers to deliver, assemble and clean.

Invacare’s beds also feature patented universal bed-ends, where the headboard and footboard may be used interchangeably. This enables customers to more efficiently deploy their inventory.

- Manual Wheelchairs. Invacare designs, manufac-tures and distributes a complete line of manual wheelchairs. The company's manual wheelchairs are sold for use in the home and in institutional settings. Consumers include people who are chronically or temporarily disabled and require basic mobility with little or no frame modification and may propel themselves or be moved by a caregiver. The company’s manual wheelchairs are marketed under the Invacare® brand name. Examples include the 9000 and Tracer® wheelchair product lines.

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- Personal Care. Invacare distributes a full line of personal care products, including ambulatory aids such as rollators, walkers, and wheeled walkers. Also available are bathing safety aids, such as tub transfer benches and shower chairs, as well as patient care products, such as commodes and other toileting aids. In some markets where payors value durable long-lasting devices, especially outside of the U.S., personal care products continue to be an important part of the Lifestyles business. In certain markets, and in the U.S. in particular, this product area is being focused on residential care.

Respiratory Therapy Products

The company designs and manufactures products that concentrate oxygen for consumers who need supplemental oxygen for breathing. Invacare® oxygen products meet a wide variety of needs, including stationary systems for use while at home and portable systems for mobile use. Historically, oxygen therapy was provided through delivery of large tanks of liquid oxygen or the routine delivery of tanks of compressed oxygen to patients. Industry trends continue to displace modes of oxygen therapy that involve delivery, which is costlier to provide and less convenient for patients who need to coordinate the exchange of oxygen containers. Published industry data suggests a large portion of the costs associated with home oxygen therapy are directly associated with delivery-related activities required to meet the ambulatory oxygen therapy needs of patients. Invacare's newer modalities of oxygen supply replace these costlier and constraining delivery-based forms of care.

- Stationary Oxygen Concentrators. Invacare oxygen concentrators are manufactured under the Platinum® and Perfecto2™ brand names and are available in five-, nine-, and ten-liter models. All Invacare stationary concentrators are designed to provide patients with durable equipment that reliably concentrate oxygen at home or in a healthcare setting. Stationary oxygen concentrators are typically used by people needing nocturnal oxygen, or those who have advanced-stage lung diseases and whose lifestyles keep them largely at home.
- Portable Oxygen Concentrators. The fastest growing modality of providing supplementary oxygen is the battery-powered portable category. Invacare's recently launched Platinum® Mobile Oxygen Concentrator has among the most competitive features in the four- and five-liter equivalent category, including the addition in 2017 of the industry's first wireless informatics platform in the five-pound category to support the needs of providers and end-users.
- Oxygen Refilling Devices. The Invacare® HomeFill® Oxygen System is an alternative source of ambulatory oxygen that allows patients to fill their own convenient

small portable oxygen cylinders from a stationary oxygen concentrator at home. This enables users to have high flow stationary oxygen while at home and an easy form of mobile oxygen while away. As a result, medical equipment providers can significantly reduce time-consuming and costly service calls associated with cylinder and/or liquid oxygen deliveries while at the same time enhancing the lifestyle of the patient.

GEOGRAPHIC SEGMENTS

Europe

The company's Europe segment operates as an integrated unit across the European, Middle Eastern and African markets with sales and operations throughout Europe. The Europe segment is coordinated with other global business units for new product development, supply chain resources and additional corporate resources. This segment primarily includes: mobility and seating; lifestyle; and respiratory therapy product lines. The company manufactures power wheelchair products, wheelchair power add-ons and hygiene products in different facilities in Germany. During 2017, manual wheelchair products were manufactured in Switzerland, Sweden and France with recently announced plans to consolidate these operations in France. The company manufactures beds in Portugal and Sweden for various markets.

Invacare manufactures therapeutic support surfaces, and seating and positioning products in the U.K. Respiratory products, such as oxygen concentrators and Invacare® HomeFill® systems, are imported from company facilities in the U.S. In total, the Europe segment comprised 55.4%, 51.1% and 46.9% of the net sales from continuing operations in 2017, 2016 and 2015, respectively.

North America

North America includes the following segments combined for the United States and Canada:

- North America/Home Medical Equipment (NA/HME) - This segment primarily includes: mobility and seating, lifestyle and respiratory therapy product lines. Products are sold through rehabilitation providers, home healthcare providers, and government provider agencies, such as the Veterans Administration. This segment previously included Garden City Medical Inc. ("GCM"), which was sold on September 30, 2016. The NA/HME segment represented 33.2%, 38.5% and 41.6% of the net sales from continuing operations in 2017, 2016 and 2015, respectively.
- Institutional Products Group (IPG) - This segment sells healthcare furnishings including long-term care beds, case goods, safe patient handling equipment, and other equipment and accessories for long-term care customers. This segment also provides interior design

services for nursing homes and assisted living facilities undertaking renovation projects and new construction. The IPG segment comprised 6.2%, 6.1% and 7.6% of net sales from continuing operations in 2017, 2016 and 2015, respectively.

Asia/Pacific

The company’s Asia/Pacific segment combines two businesses - a sales and services business supporting customers principally in Australia and New Zealand and, to a lesser extent, other pan-Asian markets. The Asia/Pacific segment also includes Dynamic Controls Limited (DCL), the company's business that designs and manufactures control systems for Invacare respiratory and powered mobility products and supplies components for other third-party devices. The Asia/Pacific segment represented 5.2%, 4.3% and 3.9% of the net sales from consolidated continuing operations in 2017, 2016 and 2015, respectively.

Divested Operations

On September 30, 2016, the company divested GCM which sourced and distributed primarily lifestyle products under the brand ProBasics™ by PMI. GCM was part of the NA/HME segment of the company.

Invacare divested the rentals businesses on July 2, 2015, which were included in the IPG segment. Prior to the disposition of these rentals businesses, IPG had rented long-term care medical equipment and accessory products through these rentals businesses.

The company determined that the sale of GCM and the rentals businesses did not meet the criteria for classification as discontinued operations and therefore results from these businesses remain in their respective segments unless otherwise noted.

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

For financial information regarding reportable segments, including revenues from external customers, products, segment profitability, assets and other information by segments, see Business Segments in the Notes to the Consolidated Financial Statements of this Annual Report on Form 10-K.

WARRANTY

Generally, the company’s products are covered by warranties against defects in material and workmanship from the date of sale to the customer for various periods depending on the product. Certain components, principally wheelchair and bed frames, carry a lifetime warranty.

COMPETITION

The durable medical equipment markets are highly competitive, and Invacare products face significant competition from other well-established manufacturers and distributors. Each country has a set of unique conditions including healthcare coverage, forms and levels of reimbursement, presence of payor and provider structures and various competitors. Many factors may play a role in the selection of products and success of the company including specific features, aesthetics, quality, availability, service levels and price. Various competitors, from time to time, have instituted price-cutting programs in an effort to gain market share and may do so again in the future. In addition, as

reimbursement pressures may persist in major markets, like the U.S. These pressures have and may again significantly alter market dynamics. Increasingly, customers have access to manufacturers in low cost locations and are able to source certain products directly in lieu of purchasing from Invacare or its traditional competitors, principally for less complex products where price is the prime selection criterion.

The company believes that successfully increasing market share is dependent on providing value to the customer based on clinical benefits, quality, performance, durability of the company’s products and services. Customers also value the technical and clinical expertise of the company’s sales force, the effectiveness of the company's distribution system, the strength of its dealer and distributor network, the availability of prompt and reliable service for its products, and the ease of doing business with the company. The company's focus on quality is paramount. By embracing quality in all aspects of the company’s activities, the company believes that its products will be better aligned to customer needs, more quickly brought to market and ultimately will result in a better customer experience and economic return. The company expects its focus on quality excellence to be a competitive advantage.

SALES, MARKETING AND DISTRIBUTION

North America

In the United States, Invacare products are marketed primarily to clinical specialists in rehabilitation centers, long-term care facilities, government agencies and residential care settings. The company markets to these medical professionals, who refer their patients to HME providers to obtain specific types of the company’s medical equipment. The company sells its products to these providers.

In 2017, the NA/HME salesforce was primarily organized into two groups of specialized sales professionals focused on complex rehabilitation and post-acute care. Each team is focused on clinically complex products and solutions to support customer needs.

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The IPG post-acute sales organization consists of company sales representatives and independent representative agencies supported by a marketing group that generates awareness and demand at skilled nursing facilities for Invacare products and services. IPG also provides interior design services and products for nursing homes and assisted living facilities undertaking renovation projects and new construction.

The company contributes extensively to editorial coverage in trade publications concerning the products the company manufactures. Company representatives attend numerous trade shows and conferences on a national and regional basis in which Invacare products are displayed to providers, health care professionals, managed care professionals and consumers. The company also drives awareness of its brand through its website, as well as with online communities of people who may use its products.

The company raises consumer awareness of its products through its sponsorship of a variety of wheelchair sporting events and support of various philanthropic causes benefiting the consumers of the company’s products. In 2017, the company sponsored Miss Wheelchair USA, a program promoting self-confidence, community service and celebrating the achievements of women with disabilities. Sponsorship of several individual wheelchair athletes and teams continued in 2017, including top-ranked male and female racers and handcyclists and wheelchair basketball teams. In addition, the company continued to support disabled veterans with its 37th year of continuous sponsorship of the National Veterans Wheelchair Games, the largest annual wheelchair sporting event in the world. The company also sponsored Invictus Games, a global sporting event, to inspire recovery in veterans from all over the world. These sporting events bring a competitive and recreational sports experience to military veterans who use various assistive technology devices for their mobility needs due to spinal cord injury, neurological conditions or amputation.
The company's products are distributed through a network of facilities and directly from some manufacturing sites to optimize cost, inventory and delivery performance.
Europe
The company’s European operations primarily conduct manufacturing, marketing and distribution functions in Western Europe and coordinate export sales activities through local distributors for markets in the Middle East and Africa. The company uses an employee sales force and independent distributors. In markets where the company has its own sales force, product sales are made to medical equipment dealers and directly to government agencies. Marketing functions are staffed by central and regional teams to optimize coverage and content. The company operates distribution centers in various locations to optimize cost and delivery performance.

Asia/Pacific

The company's Asia/Pacific segment comprises revenue from two businesses. Invacare Asia/Pacific sells and rents durable medical equipment, principally in Australia and New Zealand. It uses an employee sales force and service representative to support this revenue. The other business, DCL, uses a global employee sales force to sell electronic controls systems and components to related parties in Invacare and to independent customers. Products are distributed throughout Asia from global sources via a network of distribution nodes designed to optimize cost, inventory and delivery performance.

Marketing in direct markets in Asia/Pacific are managed regionally. Sponsorship efforts are focused around programs designed to introduce people with disabilities to sports as a pathway to inclusion. In 2017, Invacare Australia sponsored the Summer Down Under Series, which culminated in the Oz Day 10K classic wheelchair race on Australia Day. In 2017, Invacare New Zealand sponsored the Halberg Junior Disability Games and worked with local organizations to improve access for people with disabilities. Invacare supports a number of sporting organizations in the region, including Invictus New Zealand.

PRODUCT LIABILITY COSTS

The company is self-insured in North America for product liability exposures through its captive insurance company, Invatection Insurance Company, which currently has a policy year that runs from September 1 to August 31 and insures annual policy losses up to $10,000,000 per occurrence and $13,000,000 in the aggregate. The company also has additional layers of external insurance coverage, related to all lines of insurance coverage, insuring up to $75,000,000 in aggregate losses per policy year arising from individual claims anywhere in the world that exceed the captive insurance company policy limits or the limits of the company's per-country foreign liability limits, as applicable. There can be no assurance that Invacare's current insurance levels will continue to be adequate or available at affordable rates.

Product liability reserves are recorded for individual claims based upon historical experience, industry expertise and other indicators. Additional reserves, in excess of the specific individual case reserves, are provided for incurred unreported claims based upon actuarial valuations at the time such valuations are conducted. Historical claims experience and other assumptions are taken into consideration by the company in estimating the ultimate reserves. For example, the actuarial analysis assumes that historical loss experience is an indicator of future experience, that the distribution of exposures by geographic area and nature of operations for ongoing operations is expected to be very similar to historical operations with no dramatic changes and that the government

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indices used to trend losses and exposures are appropriate. Estimates made are adjusted on a regular basis and can be impacted by actual loss awards and claim settlements. While actuarial analysis is used to help determine adequate reserves, the company is responsible for determining and recording adequate reserves in accordance with accepted loss reserving standards and practices.

PRODUCT DEVELOPMENT AND ENGINEERING

The company's strategy includes developing a cadence of meaningful new products in key markets and product areas. As the results of work among the company's development groups in N. America, Europe and Asia, Invacare launched a series of new innovations in 2017, including the following:

- The Invacare® TDX® SP2 Power Wheelchair with LiNX® Technology and Ultra Low Maxx Seating. The TDX SP2 power wheelchair builds on several of Invacare's core patented technologies, including SureStep® suspension, Stability Lock and G-Trac™ tracking technology, which ensure smooth driving and maneuverability. LiNX is revolutionary technology that allows high-end complex rehabilitation needs to be met with exceptional functionality and ease of use. The LiNX electronics system includes a touch screen display, wireless programming and remote monitoring for better clinical evaluations, easy, intuitive programming and great connected functionality for providers.

- The company expanded its healthcare informatics offering via the launch of the enhanced Invacare® Platinum® Mobile Oxygen Concentrator with Connectivity. This product brings new technology to respiratory end-users and home medical equipment providers that helps build patient confidence, offers a lightweight portable oxygen solution, and allows the end-user and provider to share product data easily for improved usability.

- Invacare Europe launched the new Orion and Comet Scooters. Built from high-quality robust materials, the new scooters offer maximum durability, strength and reliability. Featuring ten new interchangeable shroud colors and an extensive range of accessories, these scooters are adaptable to individual needs.

- The küschall K-Series attract, küschall Champion, and küschall Advance active manual wheelchairs were launched in the United States in February 2017. Featuring a minimalist aesthetic philosophy, küschall products are designed to be lighter and sleeker with fewer parts so that people see the individual in the chair, not the chair itself.

MANUFACTURING AND SUPPLIERS

The company's objective is to efficiently deploy resources in its supply network to achieve the best quality, service performance and lowest total cost. The company targets to achieve this result with a combination of inputs from Invacare facilities, contract manufacturers and key suppliers.

The company continues to emphasize quality excellence and efficiency across its manufacturing and distribution operations. The company is expanding its culture of deploying current Good Manufacturing Practices ("cGMP") and Lean Manufacturing principles to eliminate waste throughout the network and will continue to pursue improvements. At its core, the company's operations produce and distribute both custom-configured products for specialized clinical situations and standard products.

The company procures raw materials, components and finished goods from a global network of internal and external sources. The company utilizes regional sourcing offices to identify, develop and manage its external supply base.

Where appropriate, Invacare utilizes suppliers across multiple regions to ensure flexibility, continuity and responsiveness. The company's network of engineering design centers, product management groups and sources of supply are used to optimize cost and satisfy customer demand.

North America

The company operates several vertically integrated factories in North America, each with specific capabilities: custom powered wheelchairs and seating products (Elyria, OH); manual and passive manual wheelchairs and patient aids (Reynosa, MX); beds, institutional case goods and respiratory therapy products (Sanford, FL); manual recreational and wheelchair products (Pinellas Park, FL), passive manual and pediatric wheelchairs (Simi Valley, CA); and seating and positioning systems (Toronto, ONT). Products made in North American operations are sold in North America and are shipped as finished goods and as subcomponents to internal and external customers globally. The company is rationalizing its North American distribution network to optimize delivery performance, inventory and cost.

Europe

The company has eight manufacturing and assembly facilities in Europe with capabilities to manufacture patient aids, wheelchairs, powered mobility accessories, bath safety products, beds, therapeutic support surfaces, and patient transport products. The Europe segment uses these internal sources and some external sources of finished goods and components to create the portfolio of products it distributes. Products distributed in Europe are used by internal and external customers worldwide.

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Asia/Pacific

Invacare Asia/Pacific manufactures control systems and components used primarily in mobility and respiratory devices that serve global markets through the company's wholly-owned factory in Suzhou, Jiangsu Province, China. The company operates distribution nodes in several countries to supply customer needs while optimizing cost, inventory and service levels.

GOVERNMENT REGULATION

The company is governed by regulations that affect the manufacture, distribution, marketing and sale of its products and regulate healthcare reimbursement that may affect its customers and the company directly. These policies differ among and within every country in which the company operates. Changes in regulations, guidelines, procedural precedents, enforcement and healthcare policy take place frequently and can impact the size, growth potential and profitability of products sold in each market.

In many markets, healthcare costs have been consistently increasing in excess of the rate of inflation and as a percentage of GDP. Efforts to control payor's budgets have impacted reimbursement levels for healthcare programs. Private insurance companies often mimic changes in government programs. Reimbursement guidelines in the home healthcare industry have a substantial impact on the nature and type of equipment consumers can obtain and thus, affect the product mix, pricing and payment patterns of the company's customers who are typically the medical equipment providers to end-users.

The company has continued its efforts to influence public policies that impact home-based and long-term non-acute healthcare. The company has been actively educating federal and state legislators about the needs of the patient communities it serves and has worked with policy authors to ensure the industry's healthcare consumer needs are represented. The company believes its efforts have given the company a competitive advantage. Customers and end-users recognize the company's advocacy efforts, and the company has the benefit of remaining apprised of emerging policy direction.

FDA

The United States Food and Drug Administration ("FDA") regulates the manufacture, distribution and marketing of medical devices. Under such regulation, medical devices are classified as Class I, Class II or Class III devices, depending on the level of risk posed to patients, with Class III designating the highest-risk devices. The company's principal products are designated as Class I or Class II. In general, Class I devices must comply with general controls, including, but not limited to, requirements related to

establishment registration and device listing, labeling, medical device reporting, and the Quality System Regulation (QSR). In addition to general controls, certain Class II devices must comply with design controls, premarket notification, and applicable special controls. Domestic and foreign manufacturers of medical devices sold in the U.S. are subject to being inspected by FDA. In addition, some foreign governments have adopted regulations relating to the design, manufacture and marketing of health care products.

Other Medical Device Regulators

Outside the U.S., it is customary for foreign governments to have a ministry of health or similar body that regulates and enforces regulations relating to the design, manufacture, distribution and marketing of medical devices. In some cases, there are common standards for design and testing. In some cases, there are country-specific requirements. These regulations are not always harmonized with those from other jurisdictions and in some cases, the consequence in costs, time to enter a market or support a product may be significant.

2012 Consent Decree, Taylor Street and Corporate Facilities

In December 2012, the company became subject to a consent decree of injunction filed by FDA with respect to the company's Corporate facility and its Taylor Street manufacturing facility in Elyria, Ohio, which was an exhibit to the company's Form 8-K filed on December 20, 2012. The consent decree initially limited the company's (i) manufacture and distribution of power and manual wheelchairs, wheelchair components and wheelchair sub-assemblies at or from its Taylor Street manufacturing facility, except in verified cases of medical necessity, (ii) design activities related to wheelchairs and power beds that take place at the impacted Elyria facilities and (iii) replacement, service and repair of products already in use from the Taylor Street manufacturing facility. Under the terms of the consent decree, in order to resume full operations, the company had to successfully complete independent, third-party expert certification audits at the impacted Elyria facilities, comprised of three distinct certification reports separately submitted to, and accepted by, FDA; submit its own report to the FDA; and successfully complete a reinspection by FDA of the company’s Corporate and Taylor Street facilities.

On July 24, 2017, following its reinspection of the Corporate and Taylor Street facilities, FDA notified the company that it was in substantial compliance with the QSR and, at that time, the company was permitted to resume full operations at those facilities including the resumption of unrestricted sales of products made in those facilities.

The consent decree will continue in effect for a minimum of five years from July 24, 2017, during which time the company’s Corporate and Taylor Street facilities must

complete to two semi-annual and then four annual audits performed by a company-retained expert firm. The expert audit firm will determine whether the facilities remain in continuous compliance with the Federal Food, Drug and Cosmetic Act (FDA Act), regulations and the terms of the consent decree. The FDA has the authority to inspect these facilities and any other FDA registered facility, at any time. As of the date of the filing of this Form 10-K, the first expert audit of the Corporate and Taylor Street facilities has been completed and the result submitted to FDA.

Under the consent decree, FDA has the authority to order the company to take a wide variety of actions if FDA finds that the company is not in compliance with the consent decree, FDA Act or FDA regulations, including requiring the company to cease all operations relating to Taylor Street products. FDA also can order the company to undertake a partial cessation of operations or a recall, issue a safety alert, public health advisory, or press release, or to take any other corrective action FDA deems necessary with respect to Taylor Street products.

FDA also has authority under the consent decree to assess liquidated damages of $15,000 per violation per day for any violations of the consent decree, FDA regulations or the FDA Act. FDA also may assess liquidated damages for shipments of adulterated or misbranded devices in the amount of twice the sale price of any such adulterated or misbranded device. The liquidated damages are capped at $7,000,000 for each calendar year. The liquidated damages are in addition to any other remedies otherwise available to FDA, including civil money penalties.

For additional information regarding the consent decree, please see the following sections of this Annual Report on Form 10-K: Item 1. Business - Government Regulation; Item 1A. Risk Factors; and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Outlook and - Liquidity and Capital Resources.

Other FDA Matters

As required, the company’s facilities which produce products for sale in the U.S. are registered with FDA. Those facilities are subject to inspections by FDA at any time. Recent inspections of company facilities by or on behalf of FDA are summarized in the following paragraphs.

In June 2017, FDA inspected the company's Corporate and Taylor Street facilities in connection with the consent decree, as described above, and issued an inspectional observation on Form 483. The company submitted its response to the agency in a timely manner. On July 24, 2017, the FDA notified the company that it was in substantial compliance with the QSR and that it was permitted to resume full operations at those facilities.

In September 2017, Alber GmbH, a wholly owned subsidiary of the company, received a warning letter from the FDA. The warning letter required completion of corrective actions to address FDA Form 483 observations issued following an inspection of Alber’s facility in Albstadt, Germany in May 2017. As a consequence of the warning letter, all Alber devices could not be imported into the United States until all findings were corrected to FDA’s satisfaction. On January 3, 2018, FDA notified the company that Alber’s responses to the warning letter were adequate, and that FDA had, as of that date, removed the import suspension. FDA is expected to conduct a follow-up inspection of Alber’s facility in Q2 2018 and the warning letter cannot be fully resolved until successful completion of the inspection. The company cannot predict the outcome of this inspection.

In October 2017, FDA inspected the Corporate and Taylor Street facilities to investigate an anonymous complaint concerning one of the company’s Verification of Medical Necessity documents under the consent decree. There were no Form 483 observations issued by FDA at the conclusion of the inspection.

In November 2017, FDA inspected the company’s facility in Pinellas Park, Florida and issued its observations on Form 483, one of which was annotated as corrected and verified at the conclusion of the inspection. The company has submitted its response to the agency in a timely manner.

In November 2017, the FDA inspected the company's facility in Sanford, Florida and issued its observations on Form 483, and the company submitted its response to the agency in a timely manner. The Sanford facility is the subject of a warning letter from the FDA issued in December 2010 related to quality systems processes and procedures and the company continues to work on addressing the FDA's citations.

In November 2017, the FDA inspected the company's facility in Porta Westfalica, Germany, and there were no inspectional observations issued at the end of the inspection.

In December 2017, the California Department of Public Health, on behalf of FDA, inspected the company's facility in Simi Valley, California and there were no inspectional observations issued at the end of the inspection.

The company will continue working to resolve outstanding matters with FDA including issues raised in inspectional observations. It is expected that all facilities will continue to be inspected by FDA or other agencies. The frequency, duration, scope, findings and consequences of these inspections cannot be predicted.

From time to time, the company may undertake voluntary recalls or field corrective actions of the company's products to correct product issues that may arise. These

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actions are necessary to ensure the company's products adhere to high standards of quality, safety and effectiveness. The company continues to operate these programs to ensure compliance with applicable regulations and keeps abreast of proposed regulations and various technical standards, particularly those which could have a material adverse effect on the company.

National Competitive Bidding

In the United States, CMS is a significant payor and governs healthcare reimbursement for Medicare and Medicaid services. On January 1, 2011, CMS began its National Competitive Bidding ("NCB") program in nine metropolitan statistical areas across the country ("Round 1") to reduce healthcare spending. On July 1, 2013, CMS expanded the program to an additional 91 metropolitan statistical areas ("Round 2"). These bid programs have resulted in new, lower Medicare payment rates in these 100 areas. In January 2016, CMS began the deployment of NCB rates to the remainder of the Medicare population that had not yet been impacted by the program. These were primarily less densely populated, rural areas. In 2016, CMS divided the United States into eight regions and applied the average reimbursement reduction per NCB product category in each region from Round 1 and Round 2 to the rural providers in those eight regions. The company’s exposure to effects of NCB rate reductions and any similar reductions from private payors or state agencies can increase the company's credit risk associated with customers whose revenue, based on reimbursement, may be significantly reduced. As reimbursement rates are reduced, the company’s customers may experience pressure on profitability and liquidity. The company therefore remains judicious in its extension of credit to its customers and is vigilant about collections efforts.

In addition, the consequence of reduced reimbursement has and may continue to compel customers to consider alternative sources of supply, which may be available at lower purchase prices, thereby reducing sales of the company or the price at which customers will transact for certain products.

Although reductions in CMS payments are disruptive to the homecare industry, the company believes it can grow and thrive in this environment. The company intends to continue productivity initiatives to lower the costs to serve customers, thereby enabling the company to profitably meet lower customer price targets. The company also produces certain solutions, which can provide lower total cost of business for its customers. As an example, the company’s respiratory therapy products can help offset reimbursement reductions by eliminating the need for routine home exchange services of pre-filled oxygen cylinders with end-users. Delivery costs can be a substantial element of cost for its customers. The company's HomeFill oxygen system, Platinum Mobile oxygen concentrator, as well as the company’s oxygen concentrators, can provide effective

convenient therapy for consumers and cost-effective equipment solutions for providers by eliminating customer's costs associated with home cylinder exchange. Similarly, the informatics capabilities the company launched for power wheelchairs and respiratory devices in 2017 enable customers to more cost effectively provide service and support their end-user customers. The company intends to continue developing solutions that help providers improve profitability and reduce the overall cost of care for payors.

BACKLOG

The company generally manufactures its products to meet near-term demands by shipping from stock or by building to order based on the specialized nature of certain products. Therefore, the company does not have substantial backlog of orders of any particular product nor does it believe that backlog is a significant factor for its business.

EMPLOYEES

As of December 31, 2017, the company had approximately 4,200 employees.

FOREIGN OPERATIONS AND EXPORT SALES

The company also markets its products for export to other foreign countries. In 2017, the company's products were sold in over 100 countries. For information relating to net sales, operating income and identifiable assets of the company’s foreign operations, see Business Segments in the Notes to the Consolidated Financial Statements.

AVAILABLE INFORMATION

The company files Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments thereto, as well as proxy statements and other documents with the Securities and Exchange Commission (SEC). The public may read and copy any material that the company files with the SEC at the SEC’s Public Reference Room located at 100 F Street, NE, Washington D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website, www.sec.gov, which contains all reports, proxy statements and other information filed by the company with the SEC.

Additionally, Invacare’s filings with the SEC are available on or through the company’s website, www.invacare.com, as soon as reasonably practicable after they are filed electronically with, or furnished to, the SEC. Copies of the company’s filings also can be requested, free of charge, by writing to: Shareholder Relations Department, Invacare Corporation, One Invacare Way, Elyria, OH 44035. The contents of the company's website are not part of this Annual Report on Form 10-K.

Part I Item 1. Business

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FORWARD-LOOKING INFORMATION

This Form 10-K contains forward-looking statements within the meaning of the “Safe Harbor” provisions of the Private Securities Litigation Reform Act of 1995. Terms such as “will,” “should,” “could,” “plan,” “intend,” “expect,” “continue,” “be and “anticipate,” as well as similar comments, denote forward-looking statements that are subject to inherent uncertainties that are difficult to predict. Actual results and events may differ significantly from those expressed or anticipated as a result of risks and uncertainties, which include, but are not limited to, the following: adverse effects of the company’s consent decree of injunction with the U.S. Food and Drug Administration (FDA), including but not limited to, compliance costs, inability to bid on or win certain contracts, inability to rebuild negatively impacted customer relationships, unabsorbed capacity utilization, including fixed costs and overhead; any circumstances or developments that might adversely impact the third-party expert auditor’s required audits of the company’s quality systems at the facilities impacted by the consent decree, including any possible failure to comply with the consent decree or FDA regulations; regulatory proceedings or the company's failure to comply with regulatory requirements or receive regulatory clearance or approval for the company's products or operations in the United States or abroad; adverse effects of regulatory or governmental inspections of company facilities at any time and governmental warning letters or enforcement actions; circumstances or developments that may make the company unable to implement or realize the anticipated benefits, or that may increase the costs, of its current business initiatives; possible adverse effects on the company's liquidity that may result from delays in the implementation or realization of benefits of its current business initiatives, or from any requirement to settle conversions of its outstanding convertible notes in cash; product liability or warranty claims; product recalls, including more extensive warranty or recall experience than expected; possible adverse effects of being leveraged, including interest rate or event of default risks; exchange rate fluctuations, particularly in light of the relative importance of the company's foreign operations to its overall financial performance and including the existing and potential impacts from the Brexit referendum; potential impacts of the United States administration’s policies, and any legislation or regulations that may result from those policies, and of new United States tax laws, rules, regulations or policies; legal actions, including adverse judgments or settlements of litigation or claims in excess of available insurance limits; adverse changes in government and other third-party payor reimbursement levels and practices both in the U.S. and in other countries (such as, for example, more extensive pre-payment reviews and post-payment audits by payors, or the continuing impact of the Medicare National Competitive U.S. Bidding program); ineffective cost reduction and restructuring efforts or inability to realize anticipated cost savings or achieve desired efficiencies from such efforts; delays, disruptions or excessive costs incurred

in facility closures or consolidations; tax rate fluctuations; additional tax expense or additional tax exposures, which could affect the company's future profitability and cash flow; inability to design, manufacture, distribute and achieve market acceptance of new products with greater functionality or new product platforms that deliver the anticipated benefits; consolidation of health care providers; lower cost imports; uncollectible accounts receivable; difficulties in implementing/upgrading Enterprise Resource Planning systems; risk of cybersecurity attack, data breach or data loss and/or delays in or inability to recover or restore data and IT systems; risks inherent in managing and operating businesses in many different foreign jurisdictions; decreased availability or increased costs of materials which could increase the company's costs of producing or acquiring the company's products, including possible increases in commodity costs or freight costs; heightened vulnerability to a hostile takeover attempt or other shareholder activism; provisions of Ohio law or in the company's debt agreements, charter documents or other agreements that may prevent or delay a change in control, as well as the risks described from time to time in the company's reports as filed with the Securities and Exchange Commission. Except to the extent required by law, the company does not undertake and specifically declines any obligation to review or update any forward-looking statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments or otherwise.

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Item 1A. Risk Factors.

The company’s business, operations and financial condition are subject to various risks and uncertainties. One should carefully consider the risks and uncertainties described below, together with all the other information in this Annual Report on Form 10-K and in the company’s other filings with the SEC, before making any investment decision with respect to the company’s securities. The risks and uncertainties described below may not be the only ones the company faces. Additional risks and uncertainties not presently known by the company or that the company currently deems immaterial may also affect the company’s business. If any of these known or unknown risks or uncertainties occur, develop or worsen, the company’s business, financial condition, results of operations and future growth prospects could change substantially.

The company is subject to a consent decree of injunction ("consent decree") with the U.S. Food and Drug Administration (“FDA”), the effects of which have been, and continue to be, costly to the company and could result in continued adverse consequences to the company's business.

In December 2012, the company became subject to a consent decree of injunction filed by FDA with respect to the company's Corporate facility and its Taylor Street manufacturing facility in Elyria, Ohio. The consent decree initially limited the company's (i) manufacture and distribution of power and manual wheelchairs, wheelchair components and wheelchair sub-assemblies at or from its Taylor Street manufacturing facility, except in verified cases of medical necessity, (ii) design activities related to wheelchairs and power beds that take place at the impacted Elyria facilities and (iii) replacement, service and repair of products already in use from the Taylor Street manufacturing facility. Under the terms of the consent decree, in order to resume full operations, the company had to successfully complete independent, third-party expert certification audits at the impacted Elyria facilities, comprised of three distinct certification reports separately submitted to, and accepted by, FDA; submit its own report to the FDA; and successfully complete a reinspection by FDA of the company’s Corporate and Taylor Street facilities.

On July 24, 2017, following its reinspection, FDA notified the company that it was in substantial compliance with the QSR and, at that time, the company was permitted to resume full operations at those facilities including the resumption of unrestricted sales of products made in those facilities.

The consent decree will continue in effect for a minimum of five years from July 24, 2017, during which time the company's Corporate and Taylor Street facilities must complete two semi-annual and then four annual audits

performed by a company retained expert firm. The expert audit firm will determine whether the facilities remain in continuous compliance with the FDA Act, regulations and the terms of the consent decree. The FDA has the authority to inspect these facilities and any other FDA registered facility, at any time. The FDA also has the authority to order the company to take a wide variety of remedial actions if the FDA finds that the company is not in compliance with the consent decree or FDA regulations. The FDA also has authority under the consent decree to assess liquidated damages for any violations of the consent decree, FDA regulations or the FDA Act. Any such failure by the company to comply with the consent decree or FDA regulations, or any need to complete significant remediation as a result of any such audits or inspections, or actions taken by the FDA as a result of any such failure to comply, could have a material adverse effect on the company’s business, financial condition, liquidity or results of operations.

The limitations previously imposed by the FDA consent decree negatively affected net sales in the NA/HME segment and, to a certain extent, the Asia/Pacific segment beginning in 2012. The limitations led to delays in new product introductions. Further, uncertainty regarding how long the limitations would be in effect limited the company’s ability to renegotiate and bid on certain customer contracts and otherwise led to a decline in customer orders.

Although the company has been permitted to resume full operations at the Corporate and Taylor Street facilities, the negative effect of the consent decree on customer orders and net sales in the NA/HME and Asia/Pacific segments has been considerable, and it is uncertain as to whether, or how quickly, the company will be able to rebuild net sales to more typical historical levels, irrespective of market conditions. Accordingly, when compared to the company's 2010 results, the previous limitations in the consent decree had, and likely may continue to have, a material adverse effect on the company's business, financial condition and results of operations. See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The company’s failure to comply with medical device regulatory requirements or receive regulatory clearance or approval for the company’s products or operations in the United States or abroad could adversely affect the company’s business.

The company’s medical devices are subject to extensive regulation in the United States by FDA, and by similar governmental authorities in the foreign countries where the company does business. FDA regulates virtually all aspects of a medical device’s development, testing, manufacturing, labeling, promotion, distribution and marketing. In addition, the company is required to file reports with FDA if the company’s products may have caused, or contributed to, a death or serious injury, or if they malfunction and would be

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likely to cause, or contribute to, a death or serious injury if the malfunction were to recur. In general, unless an exemption applies, the company's mobility and respiratory therapy products must receive a pre-market clearance from FDA before they can be marketed in the United States. FDA also regulates the export of medical devices to foreign countries. The company cannot be assured that any of the company's devices, to the extent required, will be cleared by FDA through the pre-market clearance process or that FDA will provide export certificates that are necessary to export certain of the company's products. Export certificates are required for the company to have its products registered for sale in certain foreign countries. In connection with the FDA warning letter received by the company's Sanford, Florida facility in December 2010, as described below, FDA has refused to provide new export certificates for company products until the matters covered in the warning letter are resolved. Currently, the company cannot obtain new certificates of export for Sanford, Florida facility products until the warning letter has been closed. The inability to obtain export certificates for products produced at its Sanford facility has limited the company's ability to support new foreign markets with such products.

Additionally, the company is required to obtain pre-market clearances to market modifications to the company's existing products or market its existing products for new indications. FDA requires device manufacturers themselves to make and document a determination as to whether or not a modification requires a new clearance; however, FDA can review and disagree with a manufacturer's decision. The company has applied for, and received, a number of pre-market clearances for modifications to marketed devices. The company may not be successful in receiving clearances in the future or FDA may not agree with the company's decisions not to seek clearances for any particular device modification. FDA may require a clearance for any past or future modification or a new indication for the company's existing products. Such submissions may require the submission of additional data and may be time consuming and costly, and ultimately, may not be cleared by FDA.

If FDA requires the company to obtain pre-market clearances for any modification to a previously cleared device, the company may be required to cease manufacturing and marketing the modified device or to recall the modified device until the company obtains FDA clearance, and the company may be subject to significant regulatory fines or penalties. In addition, FDA may not clear these submissions in a timely manner, if at all. FDA also may change its policies, adopt additional regulations or revise existing regulations, each of which could prevent or delay pre-market clearance of the company's devices, or could impact the company's ability to market a device that was previously cleared. Any of the foregoing could adversely affect the company's business.

The company's failure to comply with the regulatory requirements of FDA and other applicable U.S. regulatory requirements may subject the company to administrative or judicially imposed sanctions. These sanctions include warning letters, civil penalties, criminal penalties, injunctions, consent decrees, product seizure or detention, product recalls and total or partial suspension of production.

As part of its regulatory function, FDA routinely inspects the facilities of medical device companies and has continued to actively inspect the company's facilities, other than through the processes established under the consent decree. Recent inspections for which follow-up remains ongoing are summarized in Item 1. Business-Government Regulation-FDA-Other FDA Matters. The FDA has informed the company of further upcoming inspections to its facilities, and the company believes that additional inspections beyond those for which it has been notified will likely occur in the near future. Accordingly, the company expects that the FDA will from time to time, inspect substantially all the company's domestic and foreign FDA-registered operational facilities and may do so repeatedly. The results of regulatory claims, proceedings or investigations are difficult to predict. An unfavorable resolution or outcome of any matter that may arise out of any FDA inspection of the company's facilities, could materially and adversely affect the company's business, financial condition, liquidity and results of operations.

In many of the foreign countries in which the company manufactures or markets its products, the company is subject to extensive medical device regulations that are similar to those of FDA, including those in Europe. The regulation of the company's products in Europe falls primarily within the European Economic Area, which consists of the European Union member states, as well as Iceland, Liechtenstein and Norway. Only medical devices that comply with certain conformity requirements of the Medical Device Directive are allowed to be marketed within the European Economic Area. In addition, the national health or social security organizations of certain foreign countries, including those outside Europe, require the company's products to be qualified before they can be marketed in those countries. Failure to receive, or delays in the receipt of, relevant foreign qualifications in the European Economic Area or other foreign countries could have a material adverse effect on the company's business.

Being in the health care industry, the company is subject to extensive government regulation, and if the company fails to comply with applicable health care laws or regulations, the company could suffer severe civil or criminal sanctions or may be required to make significant changes to the company's operations that could have a material adverse effect on the company's results of operations.

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The company sells its products principally to medical equipment and home health care providers who resell or rent those products to consumers. Many of those providers (the company's customers) are reimbursed by third-party payors, including Medicare and Medicaid, for the company products sold to their customers and patients. The U.S. federal government and the governments in the states and other countries in which the company operates regulate many aspects of the company's business and the business of the company's customers. As a part of the health care industry, the company and its customers are subject to extensive government regulation, including numerous laws directed at preventing fraud and abuse and laws regulating reimbursement under various government programs. The marketing, invoicing, documenting and other practices of health care suppliers and manufacturers are all subject to government scrutiny. Government agencies periodically open investigations and obtain information from health care suppliers and manufacturers pursuant to the legal process. Violations of law or regulations can result in severe administrative, civil and criminal penalties and sanctions, including disqualification from Medicare and other reimbursement programs, which could have a material adverse effect on the company's business. While the company has established numerous policies and procedures to address compliance with these laws and regulations, there can be no assurance that the company's efforts will be effective to prevent a material adverse effect on the company's business from noncompliance issues. For example, as discussed in the preceding Risk Factors, the company is subject to a FDA consent decree affecting its Corporate facility and Taylor Street manufacturing facility in Elyria, Ohio and subject to FDA warning letters related to its Sanford, Florida and Albstadt, Germany facilities.

Health care is an area of rapid regulatory change. Changes in the law and new interpretations of existing laws may affect permissible activities, the costs associated with doing business, and reimbursement amounts paid by federal, state and other third-party payors, all of which may affect the company and its customers. The company cannot predict the future of federal, state and local regulation or legislation, including Medicare and Medicaid statutes and regulations, or possible changes in health care policies in any country in which the company conducts business. Future legislation and regulatory changes could have a material adverse effect on the company's business.

The company's products are subject to recalls, which could be costly and harm the company's reputation and business.

The company is subject to ongoing medical device reporting regulations that require the company to report to FDA or similar governmental authorities in other countries if the company's products cause, or contribute to, death or serious injury, or if they malfunction and would be likely to

cause, or contribute to, death or serious injury if the malfunction were to recur. In light of a deficiency, defect in design or manufacturing or defect in labeling, the company may voluntarily elect to recall or correct the company's products. In addition, FDA and similar governmental authorities in other countries could force the company to do a field correction or recall the company's products in the event of material deficiencies or defects in design or manufacturing. A government mandated or voluntary recall or field correction by the company could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. Any recall or field correction could divert managerial and financial resources and could harm the company's reputation with its customers, product users and the health care professionals that use, prescribe and recommend the company's products. The company could have product recalls or field actions that result in significant costs to the company in the future, and these actions could have a material adverse effect on the company's business. The company will continue to review the adequacy of its recall accruals as the recalls progress, as its warranty reserves are subject to adjustment in future periods as new developments can impact the company's estimate of the cost of these matters.

Changes in government and other third-party payor reimbursement levels and practices have negatively impacted and could continue to negatively impact the company's revenues and profitability.

The company's products are sold primarily through a network of medical equipment and home health care providers, extended care facilities and other providers such as various government-provider agencies throughout the world. Many of these providers (the company's customers) are reimbursed for the products and services provided to their customers and patients by third-party payors, such as government programs, including Medicare and Medicaid, private insurance plans and managed care programs. Most of these programs set maximum reimbursement levels for some of the products sold by the company in the United States and abroad. If third-party payors deny coverage, make the reimbursement process or documentation requirements more uncertain or further reduce their current levels of reimbursement (i.e., beyond the reductions described below), or if the company's costs of production do not decrease to keep pace with decreases in reimbursement levels, the company may be unable to sell the affected product(s) through its distribution channels on a profitable basis.

Reduced government reimbursement levels and changes in reimbursement policies have in the past added, and could continue to add, significant pressure to the company's revenues and profitability. For example, in 100 metropolitan areas, the CMS introduced its NCB program which set new, lower payment rates for medical equipment and supplies. Round 1 of NCB for nine metropolitan areas in

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the U.S. went into effect in January 2011. The reimbursement rates for nine product categories were reduced by an average of 32 percent in these nine metropolitan areas. Effective July 2013, CMS commenced round 2 of the NCB program, which was expanded to include an additional 91 metropolitan areas. In January 2016, CMS began the deployment of NCB rates to the remainder of the Medicare population that had not yet been impacted by the program, primarily to rural areas. CMS has divided the United States into eight regions and applied the average reimbursement reduction per NCB product category in each region from Round 1 and Round 2 to the rural providers in those eight regions. Fifty percent of the reimbursement reduction became effective in January 2016. The remaining half of the reduction was applied in July 2016, although in December 2016 Congress retroactively delayed that payment cut until January 1, 2017.

CMS announced that the NCB program has resulted in $202.1 million in savings in its first year of implementation in the nine metropolitan areas with significant savings primarily in oxygen and oxygen supplies, mail-order diabetic supplies and standard power wheelchairs. The CMS Office of the Actuary estimated that the NCB program would save Medicare an estimated $25.8 billion, and beneficiaries an estimated $17.2 billion, over ten years.

Similar trends and concerns are occurring in state Medicaid programs. These recent changes to reimbursement policies, and any additional unfavorable reimbursement policies or budgetary cuts that may be adopted in the future, could adversely affect the demand for the company’s products by customers who depend on reimbursement from the government-funded programs. The percentage of the company’s overall sales that are dependent on Medicare or other insurance programs may increase as the portion of the U.S. population over age 65 continues to grow, making the company more vulnerable to reimbursement level reductions by these organizations. Reduced government reimbursement levels also could result in reduced private payor reimbursement levels because some third-party payors index their reimbursement schedules to Medicare fee schedules. Reductions in reimbursement levels also may affect the profitability of the company’s customers and ultimately force some customers without strong financial resources to become unable to pay their bills as they come due or go out of business. The reimbursement reductions may prove to be so dramatic that some of the company’s customers may not be able to adapt quickly enough to survive. The company is one of the industry’s largest creditors and an increase in bankruptcies or financial weakness in the company’s customer base could have an adverse effect on the company’s financial results.

Outside the U.S., reimbursement systems vary significantly by country. Many foreign markets have government-managed health care systems that govern reimbursement for home health care products. The ability of hospitals and other providers supported by such systems to

purchase the company’s products is dependent, in part, upon public budgetary constraints. Various countries have tightened reimbursement rates and other countries may follow. If adequate levels of reimbursement from third-party payors outside of the U.S. are not obtained, international sales of the company’s products may decline, which could adversely affect the company’s net sales.

The impact of all the above is uncertain and could have a material adverse effect on the company’s business, financial condition, liquidity and results of operations.

The adoption of healthcare reform and other legislative developments in the U.S. may adversely affect the company’s business, results of operations and/or financial condition.

The U.S. Affordable Care Act enacted in 2010 includes provisions intended to expand access to health insurance coverage, improve the quality and reduce the costs of healthcare over time. Specifically, as one means to pay for the costs of the Affordable Care Act, the law imposes a 2.3% sales-based excise tax on U.S. sales by manufacturers or

importers of most medical devices. The excise tax is deductible by the manufacturer or importer on its federal income tax return. The company has determined that most of its products are exempt from the tax based on the retail exemption provided in the Affordable Care Act as defined by the regulations. However, certain products that it sells for institutional use are subject to the excise tax. Based on the company's interpretation of the regulations, the impact from the tax has been immaterial for the company. However, the excise tax may increase the company’s cost of doing business, particularly if the exemptions do not ultimately apply as the company expects based on its interpretations of the regulations. In January 2018, Congress passed a moratorium to suspend the excise tax until January 2020.

The Affordable Care Act and the programs implemented by the law may reduce reimbursements for the company's products, may impact the demand for the company’s products and may impact the prices at which the company sells its products. In addition, various healthcare programs and regulations may be ultimately implemented at the federal or state level. Such changes could have a material adverse effect on the company’s business, results of operations and/or financial condition.

If the company’s business transformation efforts are ineffective, the company’s strategic goals, business plans, financial performance or liquidity could be negatively impacted.

The company is in the midst of a multi-year turnaround strategy intended to substantially transform its business and re-orient its resources to a more clinically complex mix of products and solutions. To date, this strategy has included

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actions to re-orient the company's North American commercial team, restart the company's innovation pipeline, shift its product mix, develop and expand its talent, and strengthen its balance sheet. As part of these actions, the company has increased the size of its salesforce and support in North America, invested in product development, discontinued a significant amount of non-core product, and issued convertible debt. The strategy also will include steps to realign infrastructure and processes, such as restructuring actions, intended to drive efficiency and reduce costs.

The company may not be successful in achieving the full long-term growth and profitability, operating efficiencies and cost reductions, or other benefits expected from these efforts. The company also may experience business disruptions associated with these activities. Further, the benefits of the strategy, if realized, may be realized later than expected, the costs of implementing the strategy may be greater than anticipated, and the company may lack adequate cash or capital or may not be able to attract and retain the necessary talent, to complete the transformation. If these measures are not successful, the company may undertake additional transformation efforts, which could result in future expenses. If the company's business transformation efforts prove ineffective, the company's ability to achieve its strategic goals and business plans, and the company's financial performance, may be materially adversely affected.

If the company's business transformation efforts prove ineffective and it continues to experience negative cash flows and losses, the company may require additional financing. Under these circumstances, such financing may be difficult or expensive to obtain, and the company can make no assurances that it would be available on terms acceptable to the company, if at all.

The company's revenues and profits are subject to exchange rate and interest rate fluctuations that could adversely affect its results of operations or financial position.

Currency exchange rates are subject to fluctuation due to, among other things, changes in local, regional or global economic conditions, the imposition of currency exchange restrictions and unexpected changes in regulatory or taxation environments. The predominant currency used by the company's subsidiaries outside the U.S. to transact business is the functional currency used for each subsidiary. Through the company's international operations, the company is exposed to foreign currency fluctuations, and changes in exchange rates can have a significant impact on net sales and elements of cost. The company conducts a significant number of transactions in currencies other than the U.S. dollar. In addition, because certain of the company's costs and revenues are denominated in other currencies, in particular costs and revenues from its European operations, the company's results of operations are exposed to foreign exchange rate

fluctuations as the financial results of those operations are translated from local currency into U.S. dollars upon consolidation. For example, during 2017, the devaluation of the Euro had a negative impact on the translation of company's European segment net income into U.S. dollars, and the foreign currency impact of the Brexit referendum in the U.K. had a negative impact on acquisition of dollar and Euro denominated goods in the U.K. If other countries also exit the European Union, similar negative impacts may result.

The company uses foreign exchange forward contracts primarily to help reduce its exposure to transactional exchange rate risk. Despite the company's efforts to mitigate these risks, however, the company's revenues and profitability may be materially adversely affected by exchange rate fluctuations. The company does not have any similar arrangements that mitigate the company's exposure to foreign exchange translation risk, and does not believe that any meaningful arrangement to do so is available to the company.

The company also is exposed to market risk through various financial instruments, including fixed rate and floating rate debt instruments. The company does at times use interest rate swap contracts to mitigate its exposure to interest

rate fluctuations, but those efforts may not adequately protect the company from significant interest rate risks. Interest on some of the company’s debt is based on the London Interbank Offered Rate (LIBOR), which is currently historically low. Increases in LIBOR could have a significant impact on the company’s reported interest expense, to the extent that the company has outstanding borrowings subject to LIBOR-based interest rates.

If the company's information technology systems fail, or if the company experiences an interruption in the operation of its information technology systems, then the company's business, financial condition and results of operations could be materially adversely affected.

The company relies upon the capacity, reliability and security of its information technology, or IT, systems across all of its major business functions, including research and development, manufacturing, sales, financial and administrative functions. Since the company is geographically diverse, has various business segments and has grown over the years through various acquisitions, it also has many disparate versions of IT systems across its organization. As a result of these disparate IT systems, some of which may no longer be supported by the hardware or software vendors, the company faces the challenge of supporting these older systems, implementing upgrades or migrating to new platforms when necessary and aggregating data that is timely and accurate. The failure of the company's information technology systems, whether resulting from the disparate or older versions of IT systems across its various segments, business functions or otherwise, its inability to

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successfully maintain, enhance and/or replace its information technology systems, or any compromise of the integrity or security of the data that is generated from information technology systems, or any shortcomings in the company's disaster recovery platforms, could adversely affect the company's results of operations, disrupt business and make the company unable, or severely limit the company's ability to respond to customer demands. In addition, the company's information technology systems are vulnerable to damage or interruption from: earthquake, fire, flood and other natural disasters; employee or other theft; cybersecurity attacks by computer viruses, malware or hackers; power outages; and computer systems, internet, telecommunications or data network failure.

Any interruption of the company's information technology systems could result in decreased revenue, increased expenses, increased capital expenditures, customer dissatisfaction and potential lawsuits, any of which could have a material adverse effect on the company's results of operations, liquidity or financial condition.

Increased IT security threats and more sophisticated and targeted computer crime could pose a risk to the company’s systems, networks, products and services.

Increased global IT security threats and more sophisticated and targeted computer crime pose a risk to the security of the company’s systems and networks as well as the confidentiality, availability and integrity of the company’s data, including potential general data protection regulation and Health Insurance Portability and Accountability Act risks. While the company attempts to mitigate these risks by employing a number of measures, including employee training, monitoring of its networks and systems, and maintenance of backup and protective systems, the company’s systems, networks, products and services remain potentially vulnerable to advanced persistent threats. Through its sales channels, the company may collect and store confidential information that customers provide to, among other things, purchase products or services, enroll in promotional programs and register on the company’s website. The company may also acquire and retain information about suppliers and employees in the normal course of business. The company also creates and maintains proprietary information that is critical to its business, such as its product designs and manufacturing processes.

Despite the company’s efforts to secure its systems and networks, the company could experience a significant data security breach. Computer hackers may attempt to penetrate the company’s or its vendors’ information systems and, if successful, misappropriate confidential customer, supplier, employee or other business information, such as company intellectual property. Third parties could also gain control of company systems and use them for criminal purposes. Depending on their nature and scope, such threats could result

in the loss of existing customers, difficulty in attracting new customers, exposure to claims from customers, financial institutions, payment card associations, employees and other persons, imposition of regulatory sanctions or penalties, in additional expenses or lost revenues, or in other adverse consequences, any of which could have a material adverse effect on the company’s business and results of operations.

The company is dependent upon its processes and procedures to ensure essential operational functions can continue during events that disrupt normal operations.

A major natural or manmade disaster such as terrorist attack, fire, hurricane, tornado, earthquake, or flood could cause damage to the company or key supplier facilities, limiting the company’s ability to sustain operations. The damage could result in an inability to meet customer demands resulting in the loss of associated sales and profits, and in property losses in excess of insurance coverage. While the company has put in place procedures to ensure essential functions continue in the event of a crisis, there is no guarantee that its procedures will be adequate or sufficient to handle a given unforeseen event.

The industry in which the company operates is highly competitive and some of the company’s competitors may have greater financial resources, a more effective market strategy or better strategic execution.

The home medical equipment market is highly competitive and the company’s products face significant competition from other well-established manufacturers or potential new market entrants. Reduced government reimbursement levels and changes in reimbursement policies, such as the National Competitive Bidding program implemented by CMS, may drive competitors, particularly those that have greater financial resources than the company's to offer drastically reduced pricing terms in an effort to take market share from the company or secure government acceptance of their products and pricing. new or disruptive products which compete with the company's products may be introduced in the market or may find higher level or customer acceptance than the company's products. Any increase in competition may cause the company to lose market share or compel the company to reduce prices to remain competitive, which could have a material adverse effect on the company’s results of operations. The company's failure to recognize changing market demands or a failure to develop or execute a strategy to meet such changes could also result in a material adverse effect on the company’s results of operations.

The consolidation of health care customers and the company’s competitors could result in a loss of customers or in additional competitive pricing pressures.

Numerous initiatives and reforms instituted by legislators, regulators and third-party payors to reduce home

Part I Item 1A. Risk Factors