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CONMED CORP
Form 10-K
February 23, 2016

United States
Securities and Exchange Commission
Washington, D.C.
20549

Form 10-K
Annual Report Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2015

Commission file number 0-16093

CONMED CORPORATION
(Exact name of registrant as specified in its charter)

New York
(State or other jurisdiction of incorporation or
organization)

16-0977505
(I.R.S. Employer Identification No.)

525 French Road, Utica, New York
(Address of principal executive offices)

13502
(Zip Code)

(315) 797-8375
(Registrant's telephone number, including area code)

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

Common Stock, \$.01 par value per share
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer (as defined in Rule 405 of the Securities Act).
Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the
Exchange Act.
Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the
Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was
required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if
any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T
(§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required
to submit and post such files). Yes No

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§232.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

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

As of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the shares of voting common stock held by non-affiliates of the registrant was approximately \$1,613,906,000 based upon the closing price of the Company's common stock on the NASDAQ Stock Market.

The number of shares of the registrant's \$0.01 par value common stock outstanding as of February 15, 2016 was 27,712,715.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Definitive Proxy Statement and any other informational filings for the 2016 Annual Meeting of Shareholders are incorporated by reference into Part III of this report.

CONMED CORPORATION
 ANNUAL REPORT ON FORM 10-K
 FOR YEAR ENDED DECEMBER 31, 2015
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CONMED CORPORATION

Item 1. Business

Forward Looking Statements

This Annual Report on Form 10-K for the Fiscal Year Ended December 31, 2015 (“Form 10-K”) contains certain forward-looking statements (as such term is defined in the Private Securities Litigation Reform Act of 1995) and information relating to CONMED Corporation (“CONMED”, the “Company”, “we” or “us” — references to “CONMED”, the “Company”, “we” or “us” shall be deemed to include our direct and indirect subsidiaries unless the context otherwise requires) which are based on the beliefs of our management, as well as assumptions made by and information currently available to our management.

When used in this Form 10-K, the words “estimate”, “project”, “believe”, “anticipate”, “intend”, “expect” and similar expressions are intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, including those identified under the caption “Item 1A-Risk Factors” and elsewhere in this Form 10-K which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following:

- general economic and business conditions;
- changes in foreign exchange and interest rates;
- cyclical customer purchasing patterns due to budgetary and other constraints;
- changes in customer preferences;
- competition;
- changes in technology;
- the introduction and acceptance of new products;
- the ability to evaluate, finance and integrate acquired businesses, products and companies;
- changes in business strategy;
- the availability and cost of materials;
- the possibility that United States or foreign regulatory and/or administrative agencies may initiate enforcement actions against us or our distributors;
- future levels of indebtedness and capital spending;
- quality of our management and business abilities and the judgment of our personnel;
- the availability, terms and deployment of capital;
- the risk of litigation, especially patent litigation as well as the cost associated with patent and other litigation;
- the risk of a lack of allograft tissues due to reduced donations of such tissues or due to tissues not meeting the appropriate high standards for screening and/or processing of such tissues;
- compliance with and changes in regulatory requirements; and
- various other factors referenced in this Form 10-K.

See “Item 7-Management’s Discussion and Analysis of Financial Condition and Results of Operations”, “Item 1-Business” and “Item 1A-Risk Factors” for a further discussion of these factors. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. We do not undertake any obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Form 10-K or to reflect the occurrence of unanticipated events.

General

CONMED Corporation was incorporated under the laws of the State of New York in 1970. CONMED is a medical technology company that provides surgical devices and equipment for minimally invasive procedures. The Company's products are used by surgeons and physicians in a variety of specialties including orthopedics, general surgery, gynecology, neurosurgery and gastroenterology. Headquartered in Utica, New York, the Company's 3,400 employees distribute its products worldwide from several manufacturing locations.

We have historically used strategic business acquisitions and exclusive distribution relationships to diversify our product offerings, increase our market share in certain product lines, realize economies of scale and take advantage of growth opportunities in the healthcare field.

We are committed to offering products with the highest standards of quality, technological excellence and customer service. Substantially all of our facilities have attained certification under the ISO international quality standards and other domestic and international quality accreditations.

Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports are accessible free of charge through the Investor Relations section of our website (<http://www.conmed.com>) as soon as practicable after such materials have been electronically filed with, or furnished to, the United States Securities and Exchange Commission (the "SEC"). Our SEC filings are also available for reading and copying at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site (<http://www.sec.gov>) containing reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Business Strategy

Our principal objectives are to improve the quality of surgical outcomes and patient care through the development of innovative medical devices, the refinement of existing products and the development of new technologies which reduce risk, trauma, cost and procedure time. We believe that by meeting these objectives we will enhance our ability to anticipate and adapt to customer needs and market opportunities, and provide shareholders with superior investment returns. We intend to achieve future growth and earnings through the following initiatives:

Introduction of New Products and Product Enhancements. We continually pursue organic growth through the development of new products and enhancements to existing products. We seek to develop new technologies which improve the durability, performance and usability of existing products. In addition to our internal research and development efforts, we receive new ideas for products and technologies, particularly in procedure-specific areas, from surgeons, inventors and other healthcare professionals.

Pursue Strategic Acquisitions. We pursue strategic acquisitions, distribution and similar arrangements in existing and new growth markets to achieve increased operating efficiencies, geographic diversification and market penetration. Targeted companies have historically included those with proven technologies and established brand names which provide potential sales, marketing and manufacturing synergies. This includes the January 4, 2016 acquisition of SurgiQuest, Inc. ("SurgiQuest") as further described in Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 15 to the Consolidated Financial Statements.

Realize Manufacturing and Operating Efficiencies. We continually review our production systems for opportunities to reduce operating costs, consolidate product lines or identical process flows, reduce inventory requirements and optimize existing processes. Our vertically integrated manufacturing facilities allow for further opportunities to reduce overhead, increase operating efficiencies and capacity utilization.

Geographic Diversification. We believe that significant growth opportunities exist for our surgical products outside the United States. Principal foreign markets for our products include Europe, Latin America and Asia/Pacific Rim. Critical elements of our future sales growth in these markets include leveraging our existing relationships with foreign surgeons, hospitals, third-party payers and foreign distributors (including sub-distributors and sales agents), maintaining an appropriate presence in emerging market countries and continually evaluating our routes-to-market.

Active Participation in the Medical Community. We believe that excellent working relationships with physicians and others in the medical industry enable us to gain an understanding of new therapeutic and diagnostic alternatives, trends and emerging opportunities. Active participation allows us to quickly respond to the changing needs of physicians and patients. In addition, we are an active sponsor of medical education both in the United States and

internationally, offering training on new and innovative surgical techniques as well as other medical education materials for use with our products.

Products

The following table sets forth the percentage of net sales for each of our product lines during each of the three years ended December 31:

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	Year Ended December 31,			
	2015	2014	2013	
Orthopedic surgery	54	% 54	% 54	%
General surgery	38	38	37	
Surgical visualization	8	8	9	
Consolidated net sales	100	% 100	% 100	%
Net sales (in thousands)	\$719,168	\$740,055	\$762,704	

Orthopedic Surgery

A significant portion of our business is derived from sales in our orthopedic surgery product lines, including sports medicine, powered surgical instruments, and sports biologics and tissue. These lines are marketed under a number of brands, including Hall[®], CONMED Linvatec[®], Concept[®] and Shutt[®].

We offer a comprehensive range of devices and products to repair injuries which have occurred in the articulating joint areas of the body. Many of these injuries are the result of sports related events or similar traumas. Our sports medicine products include powered resection instruments, arthroscopes, reconstructive systems, tissue repair sets, metal and bioabsorbable implants as well as related disposable products and fluid management systems. It is our standard practice to place some of these products, such as shaver consoles and pumps, with certain customers at no charge in exchange for commitments to purchase disposable products over certain time periods. This capital equipment is loaned and subject to return if certain minimum single-use purchases are not met. Single-use products include products such as shaver blades, burs and pump tubing. We have benefited from the introduction of new arthroscopic products and technologies, such as bioabsorbable screws, “push-in” and “screw-in” suture anchors and resection shavers.

In sports medicine, we compete with Smith & Nephew, plc; Arthrex, Inc.; Stryker Corporation; Johnson & Johnson: DePuy Mitek, Inc. and Zimmer Biomet, Inc.

Our powered instruments offering is sold principally under the Hall[®] Surgical brand name, for use in large and small bone orthopedic, arthroscopic, oral/maxillofacial, podiatric, plastic, ENT, neurological, spinal and cardiothoracic surgeries. Our newest product is the Hall 50[™] Powered Instrument System, specifically designed to meet the requirements of most orthopedic applications. The modularity and versatility of the Hall 50[™] Powered Instrument System allows a facility to purchase a single power system to perform total joint arthroplasty, trauma, arthroscopy and some small bone procedures.

In powered instruments, our competition includes Stryker Corporation; Medtronic plc, (Midas Rex and Xomed divisions); Johnson & Johnson: DePuy Synthes, Inc.; MicroAire Surgical Instruments, LLC, and Zimmer Holdings, Inc.

As more fully described in Note 4 to the Consolidated Financial Statements, on January 3, 2012, the Company entered into the Sports Medicine Joint Development and Distribution Agreement (the "JDDA") with Musculoskeletal Transplant Foundation (“MTF”) to obtain MTF's worldwide promotion rights with respect to allograft tissues within the field of sports medicine and related products. Under the terms of this agreement, we are now the exclusive worldwide promoter of these allograft tissues, which includes the reconstruction and/or replacement of tendon, ligament, cartilage or menisci, along with the correction of deformities within the extremities.

General Surgery

Our general surgery product line offers a large range of products in the areas of advanced surgical, endoscopic technologies, and critical care.

Our advanced surgical product offering includes an extensive line of state-of-the-art electro-surgical generators, handpieces, smoke management systems and accessories. Our endomechanical instrumentation products offer a full line of instruments including trocars, suction irrigation devices, graspers, scissors and dissectors used in minimally invasive surgery. We offer a unique and premium uterine manipulator called VCARE® for use in increasing the efficiency of laparoscopic hysterectomies and other gynecologic laparoscopic procedures. Our competition includes Medtronic plc; Covidien; Ethicon Endo-Surgery, Inc.; ERBE Elektromedizin GmbH; Megadyne; Johnson & Johnson; and Applied Medical Resources Corporation.

On January 4, 2016, we acquired SurgiQuest for \$265 million in cash (on a cash-free, debt-free basis). SurgiQuest develops, manufactures and markets the AirSeal® System, the first integrated access management technology for use in laparoscopic

and robotic procedures. This proprietary and differentiated access system is complementary to our current advanced surgical offering.

Our endoscopic technologies offering includes a comprehensive line of minimally invasive diagnostic and therapeutic products used in conjunction with procedures which require flexible endoscopy. This offering includes mucosal management devices, forceps, scope management accessories, bronchoscopy devices, dilatation, stricture management devices, hemostasis, biliary devices and polypectomy. Our competition includes Boston Scientific Corporation - Endoscopy; Cook Medical, Inc.; Merit Medical Endotek; Olympus, Inc.; STERIS Corporation - U.S. Endoscopy; and EndoChoice, Inc.

Our critical care offering includes a line of vital signs and cardiac monitoring products including pulse oximetry sensors, ECG electrodes & accessories, and cardiac defibrillation & pacing pads. We also offer a complete line of suction instruments and tubing that are used throughout all areas of the hospital as well as in Ambulatory Surgery Centers and the emergency medical market. In addition, we offer a line of IV products for use in the critical care areas of the hospital and the emergency medical market. This offering's competition includes Medtronic plc: (Covidien Ltd) and 3M Company.

Surgical Visualization

Our surgical visualization product line offers imaging systems for use in minimally invasive orthopedic and general surgery procedures including 2DHD and 3DHD vision technologies. Competition includes Smith & Nephew, plc; Arthrex, Inc.; Stryker Corporation; Olympus, Inc.; Richard Wolf and Karl Storz GmbH.

International

Maintaining and expanding our international presence is an important component of our long-term growth plan. Our products are sold in over 100 foreign countries. International sales efforts are coordinated through local country dealers (including sub-distributors or sales agents) or through direct in-country sales. We distribute our products through sales subsidiaries and branches with offices located in Australia, Austria, Belgium, Canada, China, Denmark, Finland, France, Germany, Italy, Korea, the Netherlands, Poland, Spain, Sweden and the United Kingdom. In these countries, our sales are denominated in the local currency and amounted to approximately 34% of our total net sales in 2015. In the remaining countries where our products are sold through independent distributors, sales are denominated in United States dollars.

Competition

We compete in orthopedic, surgical visualization and general surgery medical device markets across the world. Our competitors range from large manufacturers with multiple business units to smaller manufacturers with limited product offerings. We believe we have appropriate product offerings and adequate market share to compete effectively in these markets. The global markets are constantly changing due to technological advances. We seek to closely align our research and development with our key business objectives, namely developing and improving products and processes, applying innovative technology to the manufacture of products for new global markets and reducing the cost of producing core products.

The breadth of our product lines in our key product areas enables us to meet a wide range of customer requirements and preferences. This has enhanced our ability to market our products to surgeons, hospitals, surgery centers, group purchasing organizations ("GPOs"), integrated delivery networks ("IDNs") and other customers, particularly as institutions seek to reduce costs and minimize the number of suppliers.

Marketing

A significant portion of our products are distributed domestically directly to more than 6,000 hospitals and other healthcare institutions as well as through medical specialty distributors. We are not dependent on any single customer and no single customer accounted for more than 10% of our net sales in 2015, 2014 and 2013.

A significant portion of our U.S. sales are to customers affiliated with GPOs, IDNs and other large national or regional accounts, as well as to the Veterans Administration and other hospitals operated by the Federal government. For hospital inventory management purposes, some of our customers prefer to purchase our products through independent third-party medical product distributors.

Our employee sales representatives are specially trained in our various product offerings. Each employee sales representative is assigned a defined geographic area and compensated on a commission basis or through a combination of salary and commission. The sales force is supervised and supported by either area directors or district managers. In certain geographies,

sales agent groups are used in the United States to sell our orthopedic products. These sales agent groups are paid a commission for sales made to customers while home office sales and marketing management provide the overall direction for marketing and positioning of our products. Our sales professionals provide surgeons and medical personnel with information relating to the technical features and benefits of our products.

Our health systems organization is responsible for interacting with large regional and national accounts (e.g. GPOs, IDNs, etc.). We have contracts with many such organizations and believe that the loss of any individual group purchasing contract will not materially impact our business. In addition, all of our sales professionals are required to work closely with distributors where applicable and maintain close relationships with end-users.

We sell to a diversified base of customers around the world and, therefore, believe there is no material concentration of credit risk.

Manufacturing

Raw material costs constitute a substantial portion of our cost of production. Substantially all of our raw materials and select components used in the manufacturing process are procured from external suppliers. We work closely with multiple suppliers to ensure continuity of supply while maintaining high quality and reliability. As a consequence of best supply chain practices, new product development and acquisitions, we often form strategic partnerships with key suppliers. As a consequence of these supplier partnerships, components and raw materials may be sole sourced. Due to the strength of these suppliers and the variety of products we provide, we do not believe the risk of supplier interruption poses an overall material adverse effect on our financial and operational performance. We schedule production and maintain adequate levels of safety stock based on a number of factors, including experience, knowledge of customer ordering patterns, demand, manufacturing lead times and optimal quantities required to maintain the highest possible service levels. Customer orders are generally processed for immediate shipment and backlog of firm orders is therefore not considered material to an understanding of our business.

Research and Development

New and improved products play a critical role in our continued sales growth. Internal research and development efforts focus on the development of new products and product technological and design improvements aimed at complementing and expanding existing product lines. We continually seek to leverage new technologies which improve the durability, performance and usability of existing products. In addition, we maintain close working relationships with surgeons, inventors and operating room personnel who often make new product and technology disclosures, principally in procedure-specific areas. For clinical and commercially promising disclosures, we seek to obtain rights to these ideas through negotiated agreements. Such agreements typically compensate the originator through payments based upon a percentage of licensed product net sales. Annual royalty expense approximated \$2.3 million, \$2.6 million and \$2.7 million in 2015, 2014 and 2013, respectively.

Amounts expended for Company research and development were approximately \$27.4 million, \$27.8 million and \$25.8 million during 2015, 2014 and 2013, respectively.

Intellectual Property

Patents and other proprietary rights, in general, are important to our business. We have rights to intellectual property, including United States patents and foreign equivalent patents which cover a wide range of our products. We own a majority of these patents and have exclusive and non-exclusive licensing rights to the remainder. In addition, certain of these patents have currently been licensed to third parties on a non-exclusive basis. We believe that the development of new products and technological and design improvements to existing products will continue to be of

primary importance in maintaining our competitive position.

Government Regulation and Quality Systems

The development, manufacture, sale and distribution of our products are subject to regulation by numerous agencies and legislative bodies, including the U.S. Food and Drug Administration ("FDA") and comparable foreign counterparts. In the United States, these regulations were enacted under the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments, and the regulations issued or proposed thereunder.

The FDA's Quality System Regulations set forth requirements for our product design and manufacturing processes, require the maintenance of certain records, provide for on-site inspection of our facilities and continuing review by the FDA. Many of our products are also subject to industry-defined standards. Authorization to commercially market our products in the U.S. is granted by the FDA under a procedure referred to as a 510(k) pre-market notification. This process requires us to notify the FDA

of the new product and obtain FDA clearance before marketing the device. We believe that our products and processes presently meet applicable standards in all material respects.

Medical device regulations continue to evolve world-wide. Products marketed in the European Union and other countries require preparation of technical files and design dossiers which demonstrate compliance with applicable international regulations. As government regulations continue to change, there is a risk that the distribution of some of our products may be interrupted or discontinued if they do not meet the country specific requirements.

We market our products in numerous foreign countries and therefore are subject to regulations affecting, among other things, product standards, sterilization, packaging requirements, labeling requirements, import laws and onsite inspection by independent bodies with the authority to issue or not issue certifications we may require to be able to sell products in certain countries. Many of the regulations applicable to our devices and products in these countries are similar to those of the FDA. The member countries of the European Union have adopted the European Medical Device Directives, which create a single set of medical device regulations for all member countries. These regulations require companies that wish to manufacture and distribute medical devices in the European Union to maintain quality system certifications through European Union recognized Notified Bodies. These Notified Bodies authorize the use of the CE Mark allowing free movement of our products throughout the member countries. Requirements pertaining to our products vary widely from country to country, ranging from simple product registrations to detailed submissions such as those required by the FDA. We believe that our products and quality procedures currently meet applicable standards for the countries in which they are marketed.

As noted above, our facilities are subject to periodic inspection by the United States Food and Drug Administration (“FDA”) and foreign regulatory agencies or notified bodies for, among other things, conformance to Quality System Regulation and Current Good Manufacturing Practice (“CGMP”) requirements and foreign or international standards. During the third quarter of 2013, the FDA inspected our Centennial, Colorado manufacturing facility and issued a Form 483 with observations on September 20, 2013. We subsequently submitted responses to the Observations, and the FDA issued a Warning Letter on January 30, 2014 relating to the inspection and the responses to the Form 483 Observations. Accordingly, we undertook corrective actions. During the fourth quarter of 2014, the FDA again inspected our Centennial, Colorado manufacturing facility and, on November 18, 2014, issued a Form 483 with eight observations, three of which the FDA characterized as repeat observations. On December 10, 2014, we responded to the Form 483 Observations. We have received some additional questions from the FDA and responded to these questions on April 25, 2015. The remediation costs to date have not been material, although there can be no assurance that responding to the Form 483 observations or a future inspection by the FDA will not result in an additional Form 483 or warning letter, or other regulatory actions, which may include consent decrees or fines.

Employees

As of December 31, 2015, we had approximately 3,400 full-time employees, including approximately 2,300 in operations, 140 in research and development and the remaining in sales, marketing and related administrative support. We believe that we have good relations with our employees and have never experienced a strike or similar work stoppage. None of our domestic employees are represented by a labor union.

Item 1A. Risk Factors

An investment in our securities, including our common stock, involves a high degree of risk. Investors should carefully consider the specific factors set forth below as well as the other information included or incorporated by reference in this Form 10-K. See “Forward Looking Statements”.

Our financial performance is dependent on conditions in the healthcare industry and the broader economy.

The results of our business are directly tied to the economic conditions in the healthcare industry and the broader economy as a whole. We will continue to monitor and manage the impact of the overall economic environment on the Company. Approximately 21% of our revenues are derived from the sale of capital products. The sales of such products are negatively impacted if hospitals and other healthcare providers are unable to secure the financing necessary to purchase these products or otherwise defer purchases.

Our significant international operations subject us to foreign currency fluctuations and other risks associated with operating in foreign countries.

A significant portion of our revenues are derived from foreign sales. Approximately 50% of our total 2015 consolidated net sales were to customers outside the United States. We have sales subsidiaries in a significant number of countries in Europe as well as Australia, Canada, China and Korea. In those countries in which we have a direct presence, our sales are denominated in the local

currency and those sales denominated in local currency amounted to approximately 34% of our total net sales in 2015. The remaining 16% of sales to customers outside the United States was on an export basis and transacted in United States dollars.

Because a significant portion of our operations consist of sales activities in foreign jurisdictions, our financial results may be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the markets in which we distribute products. While we have implemented a hedging strategy involving foreign currency forward contracts for 2015, our revenues and earnings are only partially protected from foreign currency translation if the United States dollar strengthens as compared with currencies such as the Euro. Further, as of the date of this Form 10-K, we have not entered into any foreign currency forward contracts beyond 2017. Our international presence exposes us to certain other inherent risks, including:

- imposition of limitations on conversions of foreign currencies into dollars or remittance of dividends and other payments by international subsidiaries;
- imposition or increase of withholding and other taxes on remittances and other payments by international subsidiaries;