UTAH MEDICAL PRODUCTS INC
Form 10-K
March 14, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
Commission File Number: 001-12575
UTAH MEDICAL PRODUCTS, INC.
(Exact name of registrant as specified in its charter)

Utah	87-0342734
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
7043 S 300 W, Midvale Utah	84047
(Address of principal executive offices)	(Zip Code)
Registrant's telephone number, including area code:	Telephone (801) 566-1200 Facsimile (801) 566-7305

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

Title of each class	Name of each exchange on which registered
Common Stock, $.01 Par Value	The NASDAQ Global Market
Preferred Stock Purchase Rights	

Securities registered pursuant to Section 12(g) of the Act:
(Title of Class)
None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 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, a smaller reporting company or an. "emerging growth company" See definitions of "large accelerated filer,"

"accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	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 to Section 7(a)(2)(B) of the Securities Act.

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. As of June 30, 2018, the aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was $376,542,268.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. As of March 1, 2019, common shares outstanding were 3,722,610.

DOCUMENTS INCORPORATED BY REFERENCE. The Company's definitive proxy statement for the Annual Meeting of Stockholders is incorporated by reference into Part III, Item 10, 11, 12, 13 and 14 of this Form 10-K.

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PART I

ITEM 1 – BUSINESS

Currency amounts throughout this report are in thousands except per-share amounts and where noted.

Utah Medical Products, Inc. (“UTMD” or “the Company”) is in the business of producing high quality cost effective medical devices that are predominantly proprietary, disposable and for hospital use. Success depends on 1) recognizing needs of clinicians and patients, 2) rapidly designing or acquiring economical solutions that gain premarketing regulatory concurrence, 3) reliably producing products that meet those clinical needs, and then 4) selling through

a) UTMD's own direct channels into markets where the Company enjoys an established reputation and has a critical mass of sales and support resources, or

b) relationships with other medical companies that have the resources to effectively distribute and support the Company's products.

UTMD's success in providing reliable solutions comes from its proven ability to integrate a number of engineering and technical disciplines in electronics, software, mechanical packaging, instrumentation, plastics processing and materials. The resulting differentiated devices represent significant incremental improvements in patient safety, clinical outcomes and/or total cost over preexisting clinical tools. UTMD's experience is that, in the case of labor saving devices, the improvement in cost effectiveness of clinical procedures also leads to an improvement in overall healthcare including lower risk of complications. UTMD markets a broad range of medical devices used in critical care areas, especially the neonatal intensive care unit (NICU), the labor and delivery (L&D) department and the women’s health center in hospitals, as well as products sold to outpatient clinics and physician's offices.

The opportunity to apply solutions to recognized needs results from an excellent core of practicing clinicians who introduce ideas to the Company, and key employees who are both clinical applications savvy and development engineering adept.

Domestically, except for the FILSHIE® Clip System, UTMD’s medical devices are sold directly to clinical end user facilities or their appointed stocking distributor. In addition, some of UTMD’s devices are sold through specialty distributors, national hospital distribution companies and other medical device manufacturers. Outside the U.S. (OUS), products are sold directly to end users in Canada, the United Kingdom (UK), France, Ireland and Australia, and through other medical device companies and through independent medical products distributors in many other countries. UTMD has representation globally in the major developed countries as well as many underdeveloped countries through more than 270 distributors, 129 of which purchased at least five thousand dollars in UTMD medical devices during 2018.

UTMD was formed as a Utah corporation in 1978. UTMD sold stock to the public one time in 1982 for $1,750 (before offering costs of $321). Since 1992, UTMD has returned $117,474 in the form of share repurchases, and an additional $54,688 in cash dividends, to its public stockholders.

Utah Medical Products Ltd., a wholly-owned subsidiary with manufacturing located in Ireland, was formed in 1995 to better serve UTMD’s OUS customers. In 1997, UTMD purchased Columbia Medical, Inc. (CMI), a company specializing in silicone injection molding, assembly and marketing vacuum-assisted obstetrical delivery systems. In 1998, UTMD acquired the neonatal product line of Gesco International, a subsidiary of Bard Access Systems and C.R. Bard, Inc. In 2004, UTMD acquired Abcorp, Inc., its supplier of fetal monitoring belts. In 2011, UTMD purchased all of the common shares of Femcare Holdings Ltd (Femcare) of the United Kingdom, and its subsidiaries. The

addition of Femcare provided product and distribution channel diversification and expansion. Sales of the products, or derivatives of the products, from the four acquisitions noted above, comprised 62% of UTMD's consolidated 2018 sales. In late 2016, UTMD formed Utah Medical Products Canada Ltd (dba Femcare Canada) as a sales and distribution operation to directly serve Canadian medical facilities. In early 2019, UTMD acquired the remaining 4.75 year life of Femcare's exclusive U.S. distribution agreement for the FILSHIE Clip System from CooperSurgical Inc.

UTMD's corporate headquarters are located at 7043 South 300 West, Midvale, Utah 84047 USA. The corporate office telephone number is 01 (801) 566 1200. Ireland operations are located at Athlone Business and Technology Park, Athlone, County Westmeath, Ireland. The Ireland telephone number is 353 (90) 647-3932. United Kingdom operations are located at 32 Premier Way, Romsey, Hampshire SO51 9DQ, United Kingdom. The UK phone number is 44 (179) 452-5100. Australia operations are located at Unit 12, 5 Gladstone Road, Castle Hill, NSW 2154, Australia. The Australia phone number is 612 9045 4110. Canada operations are located at 6355 Kennedy Road #15, Mississauga, ON L5T 2L5, Canada. The Canada phone number is 01 (905) 795-1102.

PRODUCTS

More complete descriptions including part numbers and pictures of UTMD's devices can be conveniently obtained at www.utahmed.com and www.femcare-nikomed.co.uk.

Labor and Delivery/ Obstetrics:

Fetal Monitoring Accessories.

Electronic Fetal Monitoring (EFM) is the standard of care in labor and delivery throughout the modern world. While not all pregnancies are high risk, fetal emergencies can occur suddenly in seemingly normal labors. The use of EFM allows conservation of nursing personnel and has virtually eliminated intrapartum fetal death. Accurate determination of contraction strength increases the safety of labor augmentation and reduces the need for Cesarean section for desultory labor. Infusion of fluid through an intrauterine catheter may cushion the umbilical cord and improve oxygenation of the fetus.

To assist the physician in controlling the effectiveness of administration of oxytocin and monitoring effects of amnioinfusion, contraction intensities, uterine resting tones and peak contraction pressures are closely monitored through the use of an invasive intrauterine pressure catheter system. In addition, to help identify the possible onset of fetal hypoxia, correlation of the changes in fetal heart rate (FHR) relative to the frequency and duration of contractions are often electronically monitored. UTMD's intrauterine pressure (IUP) catheters provide for clinician choices from a traditional fluid-filled system to INTRAN® PLUS, for over twenty-five years the most widely accepted transducer-tipped system. In addition, adjunct toco belts and chart paper are provided by UTMD to provide a package of fetal monitoring supplies. UTMD's IUP catheters include:

IUP 075 and UTMD's other custom fluid-filled clear catheter kits utilize a saline filled catheter that is placed within the uterine cavity, connected to a separate external reusable or disposable transducer. This product package, utilizing double lumen catheters, was the traditional mode of intrauterine monitoring prior to the introduction of INTRAN. An intrauterine pressure change is transmitted through the fluid column to the external pressure transducer.

Introduced in 1987, INTRAN was the first disposable intrauterine pressure catheter that placed the pressure transducer at the pressure source within the uterine cavity. This design eliminated the complicated setup of fluid filled systems and provided more accurate pressure waveforms. INTRAN I was discontinued in 1995 in favor of the more widely preferred INTRAN PLUS.

INTRAN PLUS was introduced in 1991. The INTRAN PLUS catheter combines the transducer tip concept of INTRAN I with a refined tip design, a zeroing switch or button that allows the clinician to reset the reference of the monitor, and a dedicated amniolumen which provides access to the amniotic fluid environment which may be helpful in the diagnosis and intervention of certain fetal conditions. In 1996, a viewport enhancement which allows physicians to observe amniotic fluid in a closed system was added to INTRAN PLUS. In 1997, UTMD introduced several variations to allow user preferences in tip size, zero switch/button location and amniotic fluid visualization.

UTMD markets tocodynamometer belts, catheters and accessories as outlined above, but does not market electronic monitors, the capital equipment that processes the electrical signals. In addition to products currently offered, UTMD has continued to investigate the feasibility of tools that enhance fetal monitoring techniques.

Vacuum-Assisted Delivery Systems (VAD).

UTMD's VAD Systems include CMI® soft silicone bell-shaped birthing cups and reusable hand-held vacuum pumps which are the safest products available for use in vacuum-assisted operative deliveries. UTMD's soft silicone cup is a bell-shaped cup design that should be preferred for fetal well-being in low or outlet fetal stations with occiput anterior presentations, which represent more than 90% of the cases where VAD is indicated. Operative vaginal deliveries using forceps or vacuum-assisted delivery systems provide knowledgeable physicians with a trial vaginal operative delivery prior to a more invasive C-section intervention. Although there are risks associated with vaginal operative

deliveries which may currently represent 3-4% of all U.S. hospital births, the procedures are generally regarded as safer long term for the mother, and at least as safe for the fetus, as abdominal (Cesarean) delivery in comparable clinical situations. UTMD's bell-shaped soft silicone TENDER TOUCH® cups enjoy a low reported complication rate compared to other vacuum cup designs, as evidenced by the FDA Medical Device Reporting System (MAUDE) which publicly lists serious injuries reported by hospitals using specific brand names of products.

Other Labor & Delivery Tools.

AROM-COT™ is a finger cover with a patented prong design to rupture maternal membranes with less patient pain and anxiety. MUC-X is an aspiration device used immediately after birth to clear neonatal respiratory passages and reduce exposure to potential infections. CORDGUARD® is a product which unifies the multiple steps of clamping the neonate's cord close to the umbilicus, severing the cord without splattering blood, drawing a clean cord blood sample and assisting in the removal of the placenta. CORDGUARD's sharpless, closed system reduces the risk of exposure to potentially infected blood, and consequently reduces the high cost of exposure treatment under OSHA and CDC guidelines. In addition, CORDGUARD facilitates obtaining neonatal blood that is otherwise hard to obtain safely and cleanly. BT-CATH® is a patented uterine balloon tamponade catheter for controlling severe postpartum hemorrhage. Its benefits include the ease of rapid deployment and ability to monitor further bleeding after the tamponade has been placed. Abcorp toco belts and straps for fetal monitoring by an external tocodynamometer are provided in latex-free form in several configurations. In 2014, UTMD extended the product line to include Bari-Belts™ and Bari-Bands™, a series of abdominal belts designed specifically for bariatric patients and bands to accommodate patients of all shapes and sizes. In 2015, UTMD obtained FDA clearance to market a new mechanical cervical ripening device, the CVX-RIPE™ catheter, designed to mechanically improve the favorability of the cervix of pregnant patients at term gestation, for whom induction of labor is medically indicated. The CVX-Ripe utilizes two adjacent conical silicone balloons, similar to the shape of an hourglass. This design is intended to allow the clinician to gently apply internal pressure to the cervical canal, as well as both the internal and external os, to reduce the time needed to allow induction as well as the total time to achieve a successful vaginal delivery.

Neonatal Intensive Care:

DISPOSA-HOOD™

The DISPOSA-HOOD is an infant respiratory hood that is used in the NICU to administer oxygen to neonates and flush CO2 (carbon dioxide) while maintaining a neutral thermal environment (NTE) critical to proper physiologic responses. The DISPOSA-HOOD, placed over the infant's head, incorporates a round diffusor connection specifically designed to disperse the incoming gases along the inner surfaces of the hood, rather than allowing them to blow directly on the infant's head. The design allows more precise FIO2 (fractional inspired oxygen) control, minimizes convective heat loss from the head, provides optimum flows for elimination of CO2 by ventilation and allows for humidification. DISPOSA-HOOD, in contrast to an incubator, allows for excellent access to and visualization of the underdeveloped infant. Because it is a disposable product, it also prevents potential cross contamination that might occur with an incubator. Less invasive than nasal cannulae, DISPOSA-HOOD avoids potential damage to fragile premature neonatal nasal/ orotracheal tissues, as well as facial tissues as cannulae are often secured with tape. A nasal cannula by itself cannot provide a NTE.

DELTRAN® PLUS

UTMD's DELTRAN blood pressure monitoring system has been adapted specifically for use in the NICU. The streamlined version eliminates needles used for blood sampling, avoids the loss of scarce neonatal blood volume and provides a closed system that reduces the risk of infection. The system features excellent visualization of clearing volume, and one-handed use. UTMD continues its customization of Deltran kits for specific hospital applications.

GESCO®

In the third quarter of 1998, UTMD acquired the neonatal product line of Gesco International. GESCO, best known for optimally biocompatible silicone catheters, gained an early distinctive reputation for its focus on the special developmental needs of tiny, critically-ill babies.

A class of catheters called umbilical vessel catheters (UVCs) are specially designed for administering vital medications and fluids immediately following birth through the infant's umbilical vessel into the inferior vena cava. Because of the neonate's small size and lack of vascular development, there is no better access to vital organs. The catheters are also called umbilical artery catheters (UACs) when placed in one of the umbilical arteries to measure blood pressure or monitor metabolic processes through blood analysis. In developing its UMBILI-CATH™ product line, Gesco pioneered the use of soft, biocompatible silicone catheters, helping to reduce the number of insertions

required as well as other complications associated with invasive applications. UTMD has expanded the UVC product line to include catheters made from a proprietary thermosensitive polyurethane (Tecoflex®) that offers many of the flexibility and biocompatibility advantages of silicone after insertion, with the greater rigidity of polyurethane preferred by many clinicians for insertion. In addition, GESCO provides a convenient catheterization procedure tray of instruments and supplies necessary to place UVC catheters, as well as perform other similar procedures.

The primary distinction of GESCO products is that they were developed with the special needs of the neonate in mind, not just cut-down or smaller versions of adult devices. For example, in the case of invasive catheters, the introducer, the soft rounded distal tip, mode of securing to the patient after insertion to avoid migration, luer-locking hub with minimal dead space, number of lumens, catheter radiopaque striping for visualization, variations in catheter lengths and diameters and special packaging are all features specially designed for neonates. UTMD continues to modify product features to incorporate current neonatal practitioner preferences.

The soft, biocompatible silicone catheter concept had important advantages in other applications including peripherally inserted central venous catheters (PICC lines), enteral feeding tubes, urinary drainage catheters and chest drainage tubes. GESCO developed and marketed initial versions of all of these neonatal products. In order to keep pace with the trend of caring for smaller babies, UTMD has added smaller diameter versions of its URI-CATH® and NUTRI-CATH® products. At the request of customers who prefer a stiffer catheter for insertion, UTMD added a Tecoflex polyurethane oral-connection only Nutri-Cath series in 2009.

In 2000, UTMD gained FDA premarketing clearance of a PICC family of products specifically designed to minimize trauma to the critically ill neonate, named PICC-NATE®. The PICC-NATE product line was designed with the input of experienced neonatal medical practitioners for use as a long-term indwelling catheter system for single-use, therapeutic central venous infusion of drug solutions, blood products or other fluids and for blood sampling. The soft, strong silicone PICC-Nate comes in two diameter sizes and two hub configurations. In early 2003, UTMD added a Tecoflex polyurethane version that offers many of the flexibility and biocompatibility advantages of silicone after insertion, with the greater rigidity of polyurethane preferred by many clinicians for insertion.

In 2006, UTMD developed a unique enteral feeding-only extension set named NUTRI-LOK® that addresses important safety risks in the NICU – inadvertent connections with IV lines and inadvertent disconnections of components of the system spanning the dispensing container through the infusion catheter. In October 2007, UTMD added dispensing syringes with interlocking connectors to its NUTRI-CATH/NUTRI-LOK family of enteral feeding devices. In 2008, UTMD expanded the NUTRI-LOK system with specialty extension sets for GI tubes and for continuous connection to a fluid pump. In 2009, UTMD added a Kangaroo bag for larger feeds along with other NUTRI-LOK accessories. In 2011, UTMD added variations in adapters and extension sets used with NUTRI-CATH. Recognizing the important need to prevent misadministration of enteral feeding or medication by the wrong route, the FDA in February 2015 released its final guidance, “Safety Considerations to Mitigate the Risks of Misconnections with Small Bore Connectors Intended for Enteral Applications.” The guidance includes compliance with ISO 80369-3 standard connectors. This new standard was released to create a universal connection that is not compatible with a luer connection or any other type of small bore medical connector. In 2016, UTMD introduced an alternative enteral feeding family of devices incorporating ENFit™ ISO 80369-3 compliant connectors. These purple connectors replace the current Nutri-Lok connectors on catheters and extension sets. UTMD also distributes ENFit oral syringes.

In 2006, UTMD completed the replacement of all DEHP plasticizer PVC materials in its Gesco product line that may come in contact with neonatal patients, addressing another safety concern related specifically to the possible maldevelopment of male neonates.

Other GESCO specialty products include a disposable peritoneal dialysis (PD) set that is a pre-assembled, sterile, closed system, called DIALY-NATE®. PD is an ideal method to aid compromised renal function in a neonate because critically-ill pediatric patients may not have sufficient blood volume to support hemodialysis. DIALY-NATE is provided in a form that allows timely PD implementation. In 2008, UTMD added a DIALY-NATE version that can be used with a variety of fluid warming systems. In 2010, UTMD introduced a bifurcated system that allows for higher volume manual PD applications. Since 2013, additional custom configurations have been added to satisfy specific clinical preferences.

Other specialty NICU devices include a silicone oral protection device used to prevent palatal soft tissue injury by orotracheal tubes, called PALA-NATE®; a pre-assembled, closed urinary drainage system, called URI-CATH®, which reduces risk of infection and valuable nursing time, and a lumbar sampling kit with a tiny, specially-beveled needle for obtaining cerebral spinal fluid samples, called MYELO-NATE®.

GESCO's first patented product, HEMO-NATE®, is a disposable filter designed to remove microaggregates from stored blood prior to transfusion into a neonate where any deficiency can have an overwhelmingly negative impact on a neonate's chances for survival, given an under-developed vasculature and small total blood volume. In 2001, UTMD introduced a new filter and an improved blood bag spike for HEMO-NATE, and a needleless version.

UTMD expects to continue to improve and expand its neonatal product line, seeking to reinforce a reputation as having the most reliable and developmentally-friendly specialty products available for the NICU.

Gynecology /Urology /Electrosurgery:
LETZ® System
The LETZ System (loop excision of the transformation zone) is used to excise cervical intraepithelial neoplasia (CIN) and other lower genital tract lesions related to human papilloma virus (HPV) infections. The electrosurgery procedure with hemostasis has become the standard of care for HPV cervical infection treatment, replacing cold knife scalpel, laser and cryotherapy procedural approaches because it is economical, safe, effective, quick and easy to perform, has fewer potential side effects and requires little physician training. A major incentive for performing the LETZ procedure is that it may be performed using local anesthetic in a physician's office, eliminating the time and expense of hospital or surgical center admittance. Most importantly clinically, in contrast to laser (tissue ablation) and cryotherapy (freezing of tissue), LETZ provides a fine tissue specimen for pathological assessment.

UTMD's LETZ System includes disposable electrodes, the FINESSE® electrosurgical generator and other miscellaneous components. A disposable loop electrode used to excise the tissue specimen is a pencil like tube with a thin tungsten wire loop attached. The loop is available in varying sizes and includes a Safe T Gauge® that can be positioned so the physician can accurately monitor and control the amount of tissue being excised. Excising too much tissue can compromise fertility and result in premature birth. UTMD continues to augment its specialty electrodes. For example, the Company introduced a patented conization electrode for deep endocervical disease called C-LETZ®, designed to limit the removal of healthy tissue margins that might compromise adequate cervical function. UTMD also will continue to provide other components to augment the use of its market-leading specialty electrodes with other manufacturers' electrosurgical generators.

After more than 20 years on the market, in 2012 UTMD completed a significant redesign, and achieved certification to the latest EN 60601 international safety standards, for a FINESSE+ electrosurgical generator. The FINESSE+ design includes dispersive pad contact monitoring for improved patient safety, improved circuitry for computer controlled-output that provides a precise tissue specimen for histopathology, a more efficient output stage resulting in less heat generation and longer electronic component life, an update to electronic components which reduces the number of required components and increases service life, and an easy change internal filter for integral smoke evacuation, a unique feature of FINESSE. UTMD obtained FDA premarketing clearance for FINESSE+ in January 2013.

FINESSE+ Generator; Specialty Loop, Ball, and Needle Electrodes; FILTRESSE® Evacuator; Other Specialty Electrodes; Other UTMD Supplies and Gynecologic Tools; Femcare Trocars and Cannulae; and Femcare Laparoscopic Instruments and accessories.

UTMD has FDA clearance to market its electrosurgical system and tools for use in general surgery applications, including dermatology, plastic surgery and otolaryngology. In 2002, UTMD introduced a product line of ultra-fine tipped microdissection needles, called OptiMicro™ Needles. These electrosurgical needles are particularly useful in

small-scale plastic and reconstructive surgery applications. In 2009, UTMD added extended length OptiMicro needle versions useful in certain head and neck procedures. FILTRESSE is a stand-alone surgical smoke filtration system that combines high filtration efficiency, low cost and convenient use in a surgical office setting. Other electrosurgery tools and accessories include disposable electrosurgical pens, dispersive pads, footswitches, filter packs, speculums, retractors, forceps, tenacula and hooks. UTMD acquired the distribution rights to a unique reusable four-way expander system which facilitates access to, and visualization of, the cervix, eliminating the need for less effective specula and lateral retractors. In 2007, UTMD developed OptiSpec®, a patented ultra-bright light for cervical visualization without physician distraction during exams, pap smears and other vaginal procedures requiring direct cervical visualization without the use of a colposcope. In 2011, UTMD acquired Femcare's single patient use trocars and cannulae available in shielded, bladeless, optical bladeless, blunt and thoracic designs. In addition, UTMD acquired Femcare's laparoscopic instrument range and accessories which includes instruments suitable for all routine laparoscopic procedures requiring dissection, cutting, grasping and coagulation, e.g., monopolar scissors, various grasping forceps, dissecting forceps, L and J hooks, spatulae, Veress needles, suction and irrigation tubing, insufflation tubing and connectors, pressure infusor bags and control valves.

EPITOME®

EPITOME is an electrosurgical scalpel which delivers precise performance in surgical incision and excision with hemostasis while minimizing thermal side effects. Where rapid yet precise dissection of dense tissue is necessary, such as in mammaplasty or abdominoplasty, UTMD believes that EPITOME has no close substitute. Furthermore, an independent study concludes that the EPITOME scalpel provides a significant improvement over other devices in wound healing. EPITOME allows a rapid incision without countertraction, yielding limited morbidity, less post-surgical pain and cosmetically superior results. EPITOME is useful where minimization of thermal tissue injury is important but control of bleeding needed. A bendable version of EPITOME with a smaller active electrode was introduced in 1998. Designed to significantly reduce the chance of tissue burns due to inadvertent electrode contact and where a smaller, bent scalpel tip is needed, the bendable EPITOME is of particular value, e.g., to thoracic surgeons in harvesting the internal mammary artery during coronary artery bypass surgery, as well as to otolaryngologists for tonsillectomies or uvulopalatoplasties.

FILSHIE® Clip System

UTMD acquired the FILSHIE Clip System as part of its acquisition of Femcare in March 2011. In 2018, sales of FILSHIE Clips, applicators and accessories represented 35% of UTMD's total U.S. Dollar denominated sales. The FILSHIE Clip is a female surgical contraception device used for tubal ligation, i.e., placed on the fallopian tubes, generally laparoscopically, but also postpartum during a C-Section procedure. The FILSHIE Clip, implanted in over six million women worldwide during the last 37 years, has empirically been proven to be the safest and most effective tubal occlusive device, is as easy or easier to achieve occlusion as any of the alternative surgical techniques, and has a substantially higher probability of reversibility when compared to all of the other approaches for women who later decide that they might like to get pregnant. Femcare has obtained numerous regulatory approvals for the FILSHIE Clip System, which in 2018 was sold directly by UTMD to medical facilities in Canada, Ireland, France, the UK and Australia, and through specialty distributors in many other countries including by CooperSurgical Inc. (CSI) in the U.S. In February 2019, UTMD acquired the exclusive distribution rights from CSI, and will begin to sell the FILSHIE Clip System directly to medical facilities in the U.S.

There are several tubal ligation methods with varying degrees of effectiveness, safety and opportunity to be reversed. The traditional tubal ligation approach, informally known as "getting one's tubes tied", is a form of female sterilization in which the fallopian tubes are severed and sealed, permanently occluded or pinched shut. If the sterilization procedure is carried out postpartum, the Pomeroy technique is often adopted. During this procedure a small loop of the fallopian tube is tied with a suture and the top section removed by cutting. A traditional method for interval sterilization is with the use of Bipolar Cautery (electrocautery). With this method, a current flows between the tips of forceps when applied to the fallopian tube. This current then "burns" a portion of the fallopian tube shut. Bipolar diathermy has a higher rate of ectopic pregnancy, a life-threatening complication, compared to other tubal occlusion methods. Although these common methods are relatively easy to perform, the failure rate of these methods, defined as the percentage of patients having undergone the procedure who subsequently get pregnant, has been reported to be about 3%. The FILSHIE Clip, which can be used at either interval (between menstrual periods) or post-partum (following childbirth), is at least as easy to use and has a reported failure rate an order of magnitude less than Bipolar Cautery and the Pomeroy technique.

Apart from Bipolar Cautery and the Pomeroy technique, other mechanical devices have been the Falope Ring (or Yoon Ring) and the Hulka Clip. Both these older methods have a higher failure rate than the FILSHIE Clip, are associated with more post-operative pain and have generally been abandoned in favor of other sterilization techniques. Sterilization carried out with the Falope Ring also reduces the chances of a successful reversal being carried out.

In more recent years, hysteroscopic sterilization devices were introduced as an alternative to laparoscopic tubal ligation. The devices were the Adiana by Hologic Inc and the ESSURE by Conceptus, Inc. (acquired by Bayer AG in 2013). Both of these transcervically implanted devices are no longer being marketed; Adiana was stopped in 2012 and ESSURE was stopped in 2017. Prior to Bayer ceasing the distribution of ESSURE, the device had received a

substantial amount of negative publicity regarding unwanted side effects, particularly from patients through social media. Unfortunately, because both the FILSHIE clip and ESSURE are surgically implanted devices designed to achieve sterilization by tubal occlusion, some readers of the media have incorrectly concluded that the negative side effects of ESSURE also apply to FILSHIE clips. UTMD would like to provide an explanation to stockholders why this association is incorrect.

In particular, within a few hundred thousand implanted ESSURE devices, thousands of women complained about possible autoimmune responses, allergic response to nickel and/or significant chronic pain. These symptoms simply do not apply to FILSHIE clips as the ESSURE device and FILSHIE clips are substantially different in design and use. ESSURE had a metal coil with a tip capable of perforation, with nickel components, hysteroscopically implanted (with some difficulty and risk of unwanted bodily injury) inside the Fallopian tubes, which then caused scar tissue to grow around it over time and occlude the tubes. FILSHIE clips are clamped over the tubes, laparoscopically or following a C-section, with immediately effective occlusion and almost no chance of patient injury beyond the normal risks of laparoscopic surgery. There are no nickel components in the FILSHIE clip. However, a minute amount of nickel does exist in medical grade silicone and titanium, generally accepted worldwide as the most biocompatible materials for human implants. A toxicology study by a reputable microbiology firm confirmed that the amount of nickel found in FILSHIE clips is significantly less than that found in normal drinking water and foods. Orthopedic implants, for example, are routinely made of titanium in massively greater amounts. There have been a few patient complaints of suspected allergic response to FILSHIE clips within millions of uses (including from patients allergic to copper, which there is none in FILSHIE clips), but no such reports from clinicians or in the clinical literature.

Pain associated normally with any laparoscopic procedure generally resolves within 48 hours, and is not severe nor does it become chronic unless the result of an infection. Sterile FILSHIE clips are provided to the surgeon in validated sterile packaging. Nevertheless, pain is the most prevalent (but rare) FILSHIE complaint. In women with implanted clips who have reported chronic pain, several other gynecological symptoms are present which are not related to FILSHIE clips. The obvious recourse for a person experiencing pain that she associates with an implanted device is to remove it. ESSURE, difficult if not impossible to remove, required very specialized surgical technique. In contrast, given currently widely available imaging and normal laparoscopic skills, FILSHIE clips can be removed safely, although removal is rarely requested.

A well-known and clinically reported potential side effect of FILSHIE Clip tubal ligation is clip migration. A clip occluded Fallopian tube eventually separates into two permanently closed stubs after tissue necrosis under a closed clip. Peritoneal tissue usually encapsulates an implanted clip while still in contact with the Fallopian tube. In some cases where tissue encapsulation is slow, migration of a clip occurs after sterilization has been achieved. Although the silicone lining of the clip helps prevent clip migration and reduces the risk of tubal regeneration, one clinical journal publication indicated migration occurs 6% of the time. Dr. FILSHIE, the inventor of the clip, expressed his opinion in 2002 that over 25% of patients will experience a migration of one or more clips, typically within the abdominal cavity. Once detached, the clip becomes encompassed in dense adhesive tissue normally without any symptoms, only rarely causing any complication. However, a low grade inflammatory response can occur. Because clips are biologically inert and relatively small, physicians generally have concluded that removing a migrated clip represents more risk to long term well-being than leaving it in the body. UTMD recently retained a clinical expert who in 2010 had published the results of a twenty-year retrospective review of all reported FILSHIE clip migration events in the English literature, in order to independently review all reported complaints contained in the US FDA MAUDE website and the Australia TGA DAEN website over the most recent ten years. His February 2019 written report generally observed that “There were no serious clinical or life-threatening complications that related directly or indirectly to the FILSHIE clips or their migration.”

In summary, UTMD stockholders should be confident that FILSHIE clips are a very safe and effective method of tubal occlusion.

The U.S. FDA released the FILSHIE Clip for marketing in the U.S. in 1996 after a Femcare PMA submission which included a prospective clinical trial involving 5,454 women implanted with FILSHIE clips. In late 2016, the FDA approved the use of Femcare’s Sterishot single use applicator for applying FILSHIE clips. An applicator is a precision instrument which closes the implanted FILSHIE clip on the Fallopian tube to achieve proper permanent tubal ligation. Reused applicators require extra handling, cleaning, resterilization and storage which have the potential to damage or misalign the delicate mechanism. Timely periodic servicing and recalibration is needed. In addition, the reuse of a

surgical instrument introduces the possibility of infection if not properly cleaned and resterilized between procedures. The precalibrated, single-use sterile Sterishot eliminates these safety, effectiveness and cost exposures. After more than eight years since being introduced outside the U.S. (OUS), the patented Sterishot is used in the majority of FILSHIE clip ligation procedures OUS, but was not effectively marketed by CSI. Beginning in February 2019, UTMD began directly marketing the FILSHIE Clip System in the U.S., preferably primarily in the form of Sterishot kits.

PATHFINDER PLUS™
PATHFINDER PLUS is a proprietary endoscopic irrigation device that allows a uro/gyn surgeon to precisely irrigate, clearing the visual field, with the same hand that controls the endoscope, eliminating the need for a separate assistant to irrigate without visualization. An example of a procedure where Pathfinder has found success is ureteroscopic stone ablation.

SUPRAPUBIC CATHETERIZATION
The Add-a-Cath introducer is a Femcare device designed for easy and safe suprapubic introduction of a catheter for bladder drainage. Suprapubic catheterization is generally well-recognized as a drainage method with fewer complications than with urethral catheterization. In 2013, UTMD introduced suprapubic catheterization procedure kits featuring the Add-a-Cath introducer, which UTMD now distributes directly to end users in the U.S. under the trade name “Supra-Foley”.

LIBERTY® System
LIBERTY is a device for the conservative treatment and effective control of urinary incontinence in women. UTMD believes that LIBERTY is the easiest-to-use, most cost effective incontinence treatment available that yields a therapeutic effect, not just a cover-up. LIBERTY consists of a battery operated electrical stimulation unit and an intravaginal electrode probe. This physiotherapy technique, which can be done in the privacy of the home, involves passive strengthening of the periurethral muscles. Pulsed, low voltage, high frequency current is applied primarily to the pudendal neuromuscular tissue causing the pelvic area muscles to contract, leading to better muscle tone. Because electrical stimulation has no known adverse side effects, LIBERTY provides women suffering from mild to moderate incontinence an effective, lower cost and lower risk alternative to more traumatic treatments such as surgery and drug therapy.

ENDOCURETTE™
In cooperation with Mayo Clinic, UTMD developed an advanced curette for uterine endometrial tissue sampling in the doctor’s office. The sampling procedure is intended primarily to rule out precancer or cancerous change of the uterus in premenopausal women with abnormal uterine bleeding, or women with postmenopausal bleeding. The device is part of a class of catheters designed to be used without dilatation of the cervix and without general anesthetic. The inherent weakness of this type of device, which is related to its small size, is that it may not remove enough tissue of the endometrium for an accurate histologic assessment, in contrast to a more invasive D&C hospital procedure. The tip of the EndoCurette was specially designed to obtain a more thorough tissue specimen compared to other catheters used without the need for dilatation, and without an increase in patient discomfort.

TVUS/HSG-Cath™
In order to further assess persistent abnormal or dysfunctional uterine bleeding and other suspected abnormalities of the uterus, or as a next step after endometrial tissue sampling with an EndoCurette, gynecologists may utilize transvaginal ultrasound imaging of the uterus. UTMD’s TVUS/HSG-Cath was designed and released for marketing in 2007 to provide effective cervical occlusion that allows distention of the uterus to differentiate anterior and posterior endometrium, among other irregularities, together with minimal visual obstruction of the uterus near the internal os. In addition, the TVUS/HSG-Cath may be used in hysterosalpingography radiographic procedures to assess the patency of fallopian tubes. A related device acquired in 2011 is Femcare’s Spackman Style uterine cannula designed for the manipulation of the uterus and injection of fluid to test the patency of the fallopian tubes.

LUMIN®
LUMIN® is a gynecological tool developed by UTMD for reliably and safely manipulating the uterus in laparoscopic procedures. LUMIN combines the strength, range of motion and versatility of the higher end reusable instruments with the lower cost and cleanliness of the inexpensive less functional disposable instruments presently on the market, while at the same time reducing the number of tools needed to move and secure the uterus.

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Blood Pressure Monitoring:

DELTRAN® Disposable Pressure Transducer (DPT)

In pressure monitoring, a transducer is used to convert physiological (mechanical) pressure into an electrical signal that is displayed on electronic monitoring equipment. UTMD developed and is now distributing its disposable transducer as a stand alone product, and as a component in sterile blood pressure monitoring kits through direct representatives and other medical companies in the U.S., as well as independent distributors and other medical device companies OUS.

The Company believes that the DELTRAN DPT which it designed over thirty years ago and currently manufactures, remains the standard in terms of accuracy, reliability and ease of use. Introduced in 1998, the DELTRAN PLUS provides a closed system for blood sampling, without the use of needles, reducing the risk of an unwanted infection for both the patient and the practitioner. In 2009, in conjunction with its other NICU devices, UTMD continued to configure neonatal Deltran custom kits which satisfy the special needs of conserving limited blood volume and protecting the neonate from infection.

Pressure Monitoring Accessories, Components and Other Molded Parts.

Components included in blood pressure monitoring kit configurations include flush devices, stopcocks, fluid administration sets, caps, pressure tubing, interface cables and organizers. The Company sells similar components designed for other medical device company applications which incorporate UTMD's technologies and designs. DELTA-CAL™ is a calibration device used to check proper functioning of an arterial pressure system. In addition, UTMD sells plastic molded parts on a subcontract basis to a number of medical and non-medical device companies. In addition, partly as a result of its excellent quality system and ISO13485 certification, UTMD performs subcontract assembly, testing and packaging of components that are proprietary to other medical device firms. UTMD believes that this practice helps better utilize its investment in fixed plant and equipment, and spreads overhead costs resulting in better gross profit margins on finished device sales.

MARKETING and COMPETITION

UTMD divides its sales into "domestic" U.S. sales and "outside the U.S." sales, which are finished device and component sales to entities outside the U.S.

1) Domestic sales.

For domestic sales to end-users of finished devices, marketing efforts are complex and fragmented. UTMD's marketing focus is with clinicians who take responsibility for obtaining optimal patient care outcomes, primarily through clinical meetings, trade shows and the Internet. In competitive bidding processes, UTMD works primarily with administrators who are responsible for hospital purchasing decisions.

UTMD competes primarily on the basis of improved patient safety and reliable device performance in the hands of a trained clinician. A number of UTMD's devices are strong brands because they are well-recognized by clinicians as clinically different and have been in use for decades. UTMD's broad offering of finished devices is comprised of dozens of specialty device types. Although there may be only a few competitors for each type, in the aggregate UTMD has dozens of U.S. medical device competitors. There are at least two competitors with significant market share for each of UTMD's device types.

As a general rule, because of UTMD's differences in design and reliability, competitors' devices represent substitutes rather than equivalent devices. The Company's primary marketing challenge is to keep its customers focused on those differences and their important clinical benefits. In recent years, UTMD's access to U.S. hospital clinicians has become increasingly restricted and the involvement of clinicians in medical device purchasing decisions, which is critical to the Company's success, has declined. To the degree that U.S. hospitals become less focused on patient safety and clinical outcomes and more on out-of-pocket unit price, UTMD's competitive position weakens.

In 2018, UTMD sold components and finished devices to 152 other companies in the U.S. (OEM sales). For over 40 years, the Company has utilized its manufacturing capabilities and engineering know-how to produce high quality components and finished devices for other companies. For U.S. companies which wish to distribute their products outside the U.S., UTMD's maintenance of certification to current ISO 13485 medical device quality standards is an important benefit. UTMD's website, which lists its capabilities, is often the basis for contacts for new OEM work.

Although there are other manufacturers in the U.S. with similar manufacturing capabilities, UTMD's primary competition comes from East Europe, India and China device component manufacturers which have much lower wage rate structures. To the extent that the U.S. Dollar (USD) gains strength in any period of time against foreign currencies, UTMD's ability to be cost-competitive with foreign manufacturers is diminished.

2) Outside the U.S. (OUS) sales.
OUS sales in 2018, as a percentage of consolidated total USD sales, represented 50% compared to 51% in 2017. Because UTMD's subsidiaries distribute devices directly to medical facilities OUS, two thirds of OUS sales are invoiced in foreign currencies. In addition, foreign subsidiary expenses are in the native currency of the respective country. Therefore, changes in foreign currency exchange (FX) rates can have a significant impact on UTMD's USD-reported financial results.

Prior to 2011, with only a few exceptions, UTMD's OUS sales were to other medical device companies and distributors, not to clinical end user facilities. After the acquisition of Femcare in 2011, UTMD began a transition to marketing directly to end users in countries where the FILSHIE Clip System had achieved significant acceptance. This also allowed increased distribution opportunities for other UTMD devices which previously did not have significant third party distributor interest. In 2018, UTMD distributed directly to medical facilities in Canada, the UK, France, Ireland and Australia. In addition, the Company's devices are sold in other countries OUS through over 270 independent regional distributors. UTMD's website provides information that frequently results in unsolicited contacts from OUS entities.

DISTRIBUTION

An important success factor in the medical device industry is access to medical practitioners. In the U.S., the hospital supplier environment has consolidated as a result of group purchasing organizations (GPOs), or their equivalents. It is UTMD's assessment that U.S. hospitals are not currently saving costs under GPO contracts when it comes to specialty medical devices that can reduce complications, utilization rates, clinician time and unwanted side effects, because administrators are focused purely on out-of-pocket costs and miss the broader total cost of care issues.

The longer term overall cost of care in the U.S. will continue to increase, with quality of care lower, as innovative suppliers are excluded from participating in the marketplace as a result of unnecessary regulatory and other purely administrative burdens. The length of time and number of administrative steps required in evaluating new products for use in hospitals has grown substantially. As a potential negative factor to future performance, as UTMD introduces new products it believes are safer and more effective, it may find itself excluded from certain customers because of the existence of long term supply agreements for existing products. UTMD may also be unable to establish viable relationships with other medical device companies that do have access to users but lack an interest in the Company's approach or demand too great a financial or administrative burden.

When U.S. hospital customers request it, UTMD provides its devices through national distribution companies, also known as Med/Surg distributors. Sales to Med/Surg distributors in 2018 comprised 14% of total domestic direct sales (excluding FILSHIE Clip System sales to CSI).

In the U.S., Canada, Ireland, France, the UK and Australia, UTMD sells its products with the support of its own directly employed customer service and sales force, independent consultants and selective independent manufacturer representatives. Direct sales representatives focus on applications for UTMD devices where customer training and support may be important. The direct sales force is comprised both of "outside" representatives operating remotely in specific geographic areas, and "inside" representatives who operate primarily by telephone from corporate offices. Direct representatives are trained to understand the medical procedures being performed within UTMD's clinical focus. Through the use of its one-on-one contacts with physicians and other clinical practitioners directly involved in patient care, the direct sales force positions UTMD to gain market leadership with specific solutions to clinical issues. In addition to its direct representatives, UTMD utilizes third party consulting clinical specialists to augment its customer training programs.

Additionally, UTMD sells component parts as well as finished devices to other companies for use with their product lines. This OEM distribution channel is simply maximizing utilization of manufacturing capabilities that are otherwise needed for UTMD's primary business, and does not compete with or dilute UTMD's direct distribution and marketing programs.

OUS, the Company distributes directly to end user facilities in Canada, the UK, France, Ireland and Australia, and sells to over 270 regional distributors and OEMs (other medical device manufacturers and/or distributors) in over a hundred countries. Ten percent of UTMD's independent OUS distributors represented 79% of UTMD's indirect OUS sales in the years of 2016 - 2018.

NEW PRODUCT DEVELOPMENT

New product development has been a key ingredient to UTMD's market identity. Product development takes several interrelated forms: 1) improvements, enhancements and extensions of current product lines in response to clinical needs or clinician requests, 2) introduction of new or augmented devices that represent a significant improvement in safety, effectiveness and/or total cost of care, and 3) acquisitions of products or technology from others. Manufacturing process development is an equally important aspect that cannot be separated from the successful design and development of devices.

Because of UTMD's reputation as a focused product developer, its financial strength and its established clinician user base, it enjoys a substantial inflow of new product development ideas. Internal development, joint development, product acquisitions and licensing arrangements are all included as viable options in the investigation of opportunities. Only a small percentage of ideas survive feasibility screening. For internal development purposes, projects are assigned to a project manager who assembles an interdisciplinary, cross-functional development team. The team's objective is to have a clinically acceptable, manufacturable and regulatory-released product ready for marketing by a specific date. Several projects, depending on the level of resources required, are underway at UTMD at any given time. Only a few assigned projects succeed in attaining a product that meets all of the Company's criteria. In particular, this includes a product that is highly reliable, easy to use, cost-effective, safe, useful and differentiated from the competition. Once a product is developed, tooled, fully tested and cleared for marketing by the applicable regulatory entity(ies) in the U.S. and/or other countries, there remains a reasonable probability it cannot be successfully marketed for any number of reasons, not the least of which is being beaten to the market by a competitor with a better solution, or not having access to users because of limitations in marketing and distribution resources or exclusionary contracts of GPOs.

UTMD's current product and process development projects are in the following areas: 1) augmentation and internal manufacturing of existing UTMD devices, 2) neonatal intensive care, 3) specialized procedures for the assessment and treatment of cervical/uterine disease, 4) labor and delivery procedures, and 5) product and process development for OEM customers. Internal product development expenses are expected to remain in the range of 1-2% of sales.

EMPLOYEES AND OTHERS

At December 31, 2018, the Company had 173 employees, eight regular consultants, 21 independent manufacturer's sales representatives and an additional eleven subcontract production employees in Utah. The subcontract employees represent UTMD's desire to provide handicapped persons additional work opportunities, hired through the Utah state-supported Work Activity Center. The Company utilizes independent consultants, several of which were prior employees. Almost all of UTMD's internally-manufactured devices are made either in Utah or in Ireland. The average tenure with the Company of the 154 employees in the U.S. and Ireland is fifteen years. This experience conveys an important benefit due to the level of training required to produce consistently high quality medical devices and appreciation of how UTMD's devices provide unique benefits for clinicians and patients. The Company's continued success will depend to a large extent upon its ability to retain skilled and experienced employees and consultants. No

assurances can be given that the Company will be able to retain or attract such people in the future, although management is committed to providing an environment in which reliable, creative and high achieving people wish to work.

None of the Company's officers or directors is bound by restrictive covenants from prior employers that limit their ability to contribute to UTMD’s programs. All professional employees agree to a code of conduct and sign a strict confidentiality agreement as a condition of employment, and as consideration for receipt of stock option awards and participation in the annual sales and management bonus program. All employees participate in contemporaneous performance based bonus programs. None of the Company's employees is represented by labor unions or other collective bargaining groups.

PATENTS, TRADEMARKS AND TECHNOLOGY LICENSES

The Company currently owns eleven unexpired and one pending U.S. patents, numerous associated patents in sovereignties OUS and is the licensee of certain other technology. There can be no assurance, however, that patents will be issued with respect to any pending applications, that marketable products will result from the patents or that issued patents can be successfully defended in a patent infringement situation. The Company also owns thirty-two U.S. registered trademarks which have achieved significant brand recognition. The Company believes that its trademarks and tradenames, many of which have become well known in the global medical community through decades of successful use of the associated medical devices, likely have and will continue to have substantially more intangible value than its patents.

The ability of the Company to achieve commercial success depends in part on the protection afforded by its patents and trademarks. However, UTMD believes that the protections afforded by patents and trademarks are less important to UTMD's business, taken as a whole, than a medical device's established incremental clinical utility, which may be dominated by a number of other factors including relative cost, ease of use, ease of training/adoption, perceived clinical value of different design features, risk of use in applicable procedures, the reliability of achieving a desired outcome in the hands of different users and market access to potential users. In cases where competitors introduce products that may infringe on UTMD's technology or trademarks, the Company has an obligation to its stockholders to defend its intangible property to the extent that it can afford to do so, and that it is material to the Company's success. The Company must also defend itself when competitors allege that UTMD may be infringing their technologies.

As a matter of policy, UTMD has acquired and will continue to acquire the use of technology from third parties that can be synergistically combined with UTMD proprietary product ideas. During 2018, royalties included in cost of goods sold were $209. Other royalties have been previously paid as a lump sum, or were incorporated into the price of acquisitions or into the cost of purchased components which practice certain patents of third parties. Also as a matter of policy, UTMD licenses its proprietary technology to others in circumstances where licensing does not directly compete with UTMD's own marketing initiatives. UTMD's future financial performance may also depend on the marketing ability of other companies that license UTMD's technology. During 2018 the Company received $76 in royalty income, compared to $86 in 2017 and $91 in 2016.

GOVERNMENT REGULATION

UTMD's products and manufacturing processes are subject to regulation by the U.S. Food & Drug Administration ("FDA"), as well as other regulatory entities globally. The FDA has authority to regulate the marketing, manufacturing, labeling, packaging and distribution of medical devices in the U.S. In addition, requirements exist under other federal laws and under state, local and foreign statutes that may apply to the manufacturing and marketing of the Company's medical devices.

All manufacturers of medical devices must register with the FDA and list all medical devices produced by them. In addition, prior to commercial distribution of some devices for human use, a manufacturer must file a notice with the FDA, setting forth certain information regarding the safety and effectiveness of the device that is acceptable in content to the FDA.

Devices which are classified in Class I are subject only to the general controls concerning adulteration, misbranding, good manufacturing practices, record keeping and reporting requirements. Devices classified in Class II must, in addition, comply with special controls or performance standards promulgated by the FDA.

Except for the FILSHIE Clip System, all of UTMD's present devices are unclassified, Class I or Class II devices. The FILSHIE Clip System is a Class III device which has more stringent regulatory controls. The Company is in compliance with all applicable U.S. regulatory standards including CFR Part 820, the FDA Quality System Regulation

(QSR) effective in 1997, also known as cGMPs (current good manufacturing practices). The Company's most recent FDA inspection was in July 2014, which did not result in the issuance of any FDA-483 observations.

In 1994, UTMD received certification of its quality system under the ISO9001/EN46001 standards ("ISO" stands for "International Organization of Standardization") which it maintained until December 2003. In October 2003, UTMD's Utah facility was certified under the more stringent ISO13485 standard for medical devices. UTMD's Ireland facility was certified under the concomitant ISO13488 standard. In July 2006, both facility ISO certifications were upgraded to the even more stringent ISO13485:2003 standard. Currently, UTMD's facilities in the UK, Ireland and Utah are all certified under the most recent ISO13485:2012 standard. UTMD remains on a continuous periodic audit schedule by its independent notified body in order to stay current with international regulatory standards, and retain its certifications. UTMD has received CE Mark certifications (demonstrates proof of compliance with the European Community's ISO standards) for essentially all of its products. The U.S. FDA QSR was developed in harmony with the ISO standards.

SOURCES AND AVAILABILITY OF RAW MATERIALS

Most of the components which the Company purchases from various vendors are readily available from a number of sources. That notwithstanding, the Company maintains safety stocks that anticipate the time required to source and qualify new vendors. Alternative sourcing of various components is continually underway. Vendors are qualified by Corporate Quality Assurance. In the few cases where the Company has a sole source, it either maintains or has agreement with the supplier to maintain excess safety stocks that would cover the time required to develop and qualify a new source. The Company has a vendor quality monitoring program that includes routinely checking incoming material for conformance to specifications, as required per written procedures.

U.S. EXPORTS

UTMD regards the OUS marketplace as an important element of its growth strategy. UTMD is keenly aware that not only are OUS markets different from the U.S. market, but also that each country has its own set of driving influences that affects the dynamics of the nature of care given and medical devices used. The Company operates four OUS facilities; in Romsey, Hampshire, England; in Castle Hill, NSW, Australia; in Mississauga, Ontario, Canada and in Athlone, County Westmeath, Ireland. These facilities offer a number of advantages: 1) from a marketing point of view, better response to Europe, Asia, Africa and Australia customers, including a better understanding of customer needs, less costly distribution and, in the EU, duty-free access to 500 million patients; 2) from a regulatory point of view, faster new product introductions; and 3) from a manufacturing point of view, reduced dependence on one manufacturing site and increased capacity for meeting customer needs.

Total 2018 trade revenues in USD terms from customers OUS were $20,806 (50% of total sales), compared to $21,129 (51% of total sales) in 2017 and $19,809 (50% of total sales) in 2016. OUS trade sales (U.S. exports) from the U.S. to OUS customers were $5,427 in 2018, $5,357 in 2017 and $5,587 in 2016. U.S. exports represented 26%, 25% and 28% of total OUS trade sales in 2018, 2017 and 2016, respectively. The U.S. export numbers exclude Utah intercompany sales of components and finished devices to UTMD foreign subsidiaries, which then distribute U.S.-made components and finished devices as part of their sales to OUS customers.

For sales by OUS geographic area, please see note 11 to the Consolidated Financial Statements.

BACKLOG

Backlog is defined as orders received and accepted by UTMD which have not shipped yet. As a supplier of primarily disposable hospital products, the nature of UTMD's non-distributor or non-OEM business requires fast response to customer orders. Virtually all direct shipments to end user facilities are accomplished within a few days of acceptance of purchase orders. Consequently, UTMD's backlog at any point in time is comprised mainly of orders from OEM and independent distributors, which purchase in larger quantities at less frequent intervals. Backlog shippable in less than 90 days was $3,164 as of January 1, 2019, $3,140 as of January 1, 2018 and $1,774 as of January 1, 2017.

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SEASONAL ASPECTS

The Company's business is generally not affected by seasonal factors, but it is affected by uneven purchasing patterns of OEM customers and independent distributors.

PRODUCT LIABILITY RISK MANAGEMENT

The risk of product liability lawsuits is a negative factor in the medical device industry because devices are frequently used in inherently risky situations to help clinicians achieve a more positive outcome than what might otherwise be the case. In any lawsuit against a company where an individual plaintiff suffers permanent physical injury, a possibility of a large award for damages exists whether or not a causal relationship exists. However, no such damages have been awarded against UTMD in its 39-year history of shipping many millions of devices.

UTMD is self-insured for product liability risk, and reserves funds against its current performance on an ongoing basis to provide for its costs of defense should any lawsuits be filed. The Company’s average cost of defense over the last twenty-six years was $17 per year, well below the deductible level of product liability insurance policies. This experience validates that the most important aspect of product liability risk management is the safe design and reliable integrity of manufactured products, not a third party insurance contract.

The best defense the Company believes that it has is the consistent conformance to specifications of its proven safe and effective products. Over the time span of the last twenty-five years, UTMD has been named as a defendant in a total of eight lawsuits. Four lawsuits involved a patient injury related to operative vaginal deliveries where a UTMD VAD birthing cup or hand pump was used. The VADS devices in all four cases did conform to specifications. UTMD was ultimately dismissed as a defendant in all four VADS lawsuits, and legal costs were not material to performance. In the first of the other two lawsuits not involving a Femcare device, regarding the use of EndoCurette, there was no evidence of patient injury. The lawsuit was settled in 2010 for an immaterial amount to avoid the diversion of management time and substantial costs of litigation, even though UTMD was confident that the case was without merit. In the second, UTMD was brought into a lawsuit by a defendant physician, speculating a design deficiency in a Finesse electrosurgical generator (ESU) which had been in use for eighteen years before the injury event, and used successfully by the same physician in multiple procedures after the event. The injured patient did not allege any fault by UTMD. The case was settled in 2012 without any UTMD involvement or liability. Excluding the FILSHIE Clip System acquired in 2011, there have been no product liability lawsuits during the last seven years.

Since acquiring Femcare in 2011, UTMD has had to defend two U.S. claims for failed sterilizations (not serious injuries), during which time approximately two million clips were used. In 2014, a patient claimed damages for becoming pregnant eight years after the placement of FILSHIE Clips. Her medical record indicated that she chose to employ FILSHIE Clips after being advised by her physician that he believed there would be a 1% chance of pregnancy. The case was dismissed after the patient who was also a malpractice attorney declined to respond in discovery. In 2017, UTMD was served with a complaint by a patient who had experienced an uncomplicated pregnancy and childbirth. A malpractice lawsuit had been filed against the attending physician in 2015, but the physician’s insurance company subsequently went bankrupt. Discovery in the case is presently ongoing, as the plaintiff has not designated an expert to support its position yet. There is no evidence of defective clips. A claim of defective design doesn’t have merit, either, supported by the successful past use of millions of clips. A claim of failure to properly warn of a remote chance of pregnancy doesn’t have merit as UTMD’s IFU is clear that there is such a risk, which the patient has acknowledged knowing and accepting prior to the implantation. The Company expects that the case will eventually be resolved, consistent with its past experience, at an immaterial cost.

In summary, since 1995 during which time over one hundred million finished devices and OEM components were distributed by UTMD, there have been no judgments resulting from a claim of defect in UTMD’s design or manufacture of its products, or a fault in its informational materials. In the current tort system in the U.S., meritless

product liability cases do get filed where aggressive attorneys calculate that a company will find it cheaper to settle for some nominal amount in lieu of potentially substantial defense costs of going to court.

FORWARD LOOKING INFORMATION

This report contains certain forward-looking statements and information relating to the Company that are based on the beliefs of management as well as assumptions made by management based on information currently available. When used in this document, the words "anticipate," "believe," "project," "estimate," "expect," "intend" and similar expressions, as t relate to the Company or its management, are intended to identify forward-looking statements. Such statements reflect the current view of the Company respecting future events and are subject to certain risks, uncertainties and assumptions, including the risks and uncertainties stated throughout the document. Although the Company has attempted to identify important factors that could cause the actual results to differ materially, there may be other factors that cause the forward statement not to come true as anticipated, believed, projected, expected, or intended. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may differ materially from those described herein as anticipated, believed, projected, estimated, expected or intended. Financial estimates are subject to change and are not intended to be relied upon as predictions of future operating results, and the Company assumes no obligation to update or disclose revisions to those estimates.

ITEM 1A – RISK FACTORS

Legislative healthcare reform in the United States, as embodied in The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (the Acts) added a substantial excise tax (MDET) in 2013-2015 that increased administrative costs and has led to decreased revenues in the U.S.:
The voluminous Acts, administrative rules to enforce the Acts and promised efforts to reform the Acts, make the U.S. medical device marketplace unpredictable, particularly for the thousands of small medical device manufacturers including UTMD that do not have the overhead structure that the larger medical device companies can afford. Fortunately, the U.S. Congress suspended the MDET for the years of 2016-2019. To the extent that the Acts will in the future continue to place additional burdens on small medical device companies in the form of the excise tax on medical device sales, additional oversight of marketing and sales activities and new reporting requirements, the result is likely to continue to be negative for UTMD's ability to effectively compete and support continued investments in new product development and marketing of specialty devices in the U.S.

Increasing regulatory burdens including premarketing approval delays may result in significant loss of revenue, unpredictable costs and loss of management focus on helping the Company proactively conform with requirements and thrive:
The Company's experience in 2001-2005, when the FDA improperly sought to shut it down, highlights the ongoing risk of being subject to a regulatory environment which can be arbitrary and capricious. The risks associated with such a circumstance relate not only to the substantial costs of litigation in millions of dollars, but also loss of business, the diversion of attention of key employees for an extended period of time, including new product development and routine quality control management activities, and a tremendous psychological and emotional toll on dedicated and diligent employees.

Since the FDA reserves to itself the interpretation of which vague industry standards comprise law at any point in time, it is impossible for any medical device manufacturer to ever be confident that it is operating within the Agency's version of the law. The unconstitutional result is that all companies, including UTMD, are considered guilty prior to proving their innocence.

Premarketing submission administrative burdens and substantial increases in "user fees" increase product development costs and result in delays to revenues from new or improved devices. It recently took two and a half years to gain FDA approval of the use of a clearly safer single use FILSHIE Clip applicator, which had been in use for over seven years OUS, in lieu of a reused applicator approved in the U.S. since 1996, made of substantially equivalent materials for the same intended use applying the same implanted clip.

The growth of Group Purchasing Organizations (GPOs) adds non-productive costs, typically weakens the Company's marketing and sales efforts and may result in lower revenues:

GPOs, theoretically acting as bargaining agents for member hospitals, but actually collecting revenues from the companies that they are negotiating with, have made a concerted effort to turn medical devices that convey special patient safety advantages and better health outcomes, like UTMD's, into undifferentiated commodities. GPOs have been granted an antitrust exemption by the U.S. Congress. Otherwise, their business model based on "kickbacks" would be a violation of law. These bureaucratic entities do not recognize or understand the overall cost of care as it relates to safety and effectiveness of devices, and they create a substantial administrative burden that is primarily related to collection of their administrative fees.

The Company's business strategy may not be successful in the future:
As the level of complexity and uncertainty in the medical device industry increases, evidenced, for example, by the unpredictable regulatory environment, the Company's views of the future and product/ market strategy may not yield financial results consistent with the past.

As the healthcare industry becomes increasingly bureaucratic it puts smaller companies like UTMD at a competitive disadvantage:
An aging population is placing greater burdens on healthcare systems, particularly hospitals. The length of time and number of administrative steps required in adopting new products for use in hospitals has grown substantially in recent years. Smaller companies like UTMD typically do not have the administrative resources to deal with broad new administrative requirements, resulting in either loss of revenue or increased costs. As UTMD introduces new products it believes are safer and more effective, it may find itself excluded from certain clinical users because of the existence of long term supply agreements for preexisting products, particularly from competitors which offer hospitals a broader range of products and services. Restrictions used by hospital administrators to limit clinician involvement in device purchasing decisions makes communicating UTMD's clinical advantages much more difficult.

A product liability lawsuit could result in significant legal expenses and a large award against the Company:
UTMD's devices are frequently used in inherently risky situations to help physicians achieve a more positive outcome than what might otherwise be the case. In any lawsuit where an individual plaintiff suffers permanent physical injury, the possibility of a large award for damages exists whether or not a causal relationship exists.

The Company's reliance on third party distributors in some markets may result in less predictable revenues:
UTMD's distributors have varying expertise in marketing and selling specialty medical devices. They also sell other devices that may result in less focus on the Company's products. In some countries, notably China, Pakistan and India not subject to similarly rigorous standards, a distributor of UTMD's products may eventually become a competitor with a cheaper but lower quality version of UTMD's devices.

The loss of one or more key employees could negatively affect UTMD performance:
In a small company with limited resources, the distraction or loss of key personnel at any point in time may be disruptive to performance. The Company's benefits programs are key to recruiting and retaining talented employees. An increase in UTMD's employee healthcare plan costs, for example, may cause the Company to have to reduce coverages which in turn represents a risk to retaining key employees.

Fluctuations in foreign currencies relative to the USD can result in significant differences in period to period financial results:
Since a significant portion of UTMD's sales are invoiced in foreign currencies and consolidated financial results are reported in USD terms, a stronger USD can have negative revenue effects. Conversely, a weaker USD would increase foreign subsidiary operating costs in USD terms. For the portion of sales to foreign entities made in fixed USD terms, a stronger USD makes the devices more expensive and weakens demand. For the portion invoiced in a foreign currency, not only USD-denominated sales are reduced, but also gross profits may be reduced because finished distributed products and/or U.S. made raw materials and components are likely being purchased in fixed USD.

ITEM 1B – UNRESOLVED STAFF COMMENTS

None

ITEM 2 PROPERTIES

Office and Manufacturing Facilities.

UTMD is a vertically integrated manufacturing company. Capabilities include silicone and plastics-forming operations including injection molding, insert and over-molding, thermoforming and extrusion; sensor production; manual and automated assembly of mechanical, electrical and electronic components; parts printing; various testing modalities; advanced packaging in clean room conditions; and a machine shop for mold making and fabrication of assembly tools and fixtures. Capabilities also include an R&D laboratory for both electronic and chemical processes, software development resources, communications and computer systems networked real time OUS, and administrative offices.

At the beginning of 2019, the Company's operations were located in 110,000 square feet of facilities in Midvale, Utah, a 77,000 square foot facility in Athlone, County Westmeath, Ireland, a 38,600 square foot facility in Romsey, Hampshire, England, a 3,200 square foot facility in Castle Hill NSW, Australia, and a 4,700 square foot facility in Mississauga, Ontario, Canada. Manufacturing is currently carried out primarily in the Utah and Ireland facilities, with some in the UK.

In late 2016 UTMD purchased a 38,600 square foot facility in Romsey and subsequently fitted-out the building in 2017. In November 2017, Femcare UK's operations moved into the refurbished building. The prior UK lease and all associated potential liabilities have been terminated. UTMD owns all of its property and facilities with the exception of a long term lease with 13 years remaining on one section of its Midvale parking lot.

ITEM 3 LEGAL PROCEEDINGS

The Company may be a party from time to time in litigation incidental to its business. Presently, there is no litigation or threatened litigation for which the Company believes the outcome may be material to its financial results.

ITEM 4 RESERVED

PART II

ITEM 5 MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information.
UTMD's common stock trades on the NASDAQ Global Market (symbol:UTMD). The following table sets forth the high and low sales price information as reported by NASDAQ for the periods indicated:

	2018		2017	
	High	Low	High	Low
1st Quarter	$101.45	$78.95	$73.00	$58.50
2nd Quarter	117.65	94.00	73.05	59.50
3rd Quarter	115.15	85.40	75.45	68.10
4th Quarter	99.95	73.98	85.00	73.05

Stockholders.
The number of beneficial stockholders of UTMD's common stock as of March 7, 2019 was at least 2,500.

Dividends.
The following sets forth cash dividends paid during the past two years:

Record Date	Payable Date	Per Share Amount
March 17, 2017	April 4, 2017	0.265
June 16, 2017	July 6, 2017	0.265
September 15, 2017	October 3, 2017	0.265

December 15, 2017	January 3, 2018	0.270	
March 16, 2018	April 3, 2018	0.270	
June 15, 2018	July 6, 2018	0.270	
September 14, 2018	October 2, 2018	0.270	
2017 total cash dividends paid per share		$ .795	*
2018 total cash dividends paid per share		$ 1.080	

*A dividend of $0.27 per share, with a record date of December 15, 2017, was paid on January 3, 2018.

Issuer Purchases of Equity Securities.
UTMD purchased 15,000 shares of its common stock for $1,205 including commissions and fees in December 2018. UTMD did not purchase any of its own securities in 2017.

ITEM 6 SELECTED FINANCIAL DATA

Dollar amounts are in thousands, except per share data.

The following selected consolidated financial data of UTMD and its subsidiaries for the five years ended December 31, 2018, are derived from the audited financial statements and notes of UTMD and its subsidiaries, certain of which are included in this report. The selected consolidated financial data should be read in conjunction with UTMD's Consolidated Financial Statements and the notes included elsewhere in this report.

	Year Ended December 31				
	2018	2017	2016	2015	2014
Net Sales	$41,998	$41,414	$39,298	$40,157	$41,278
Net Income	18,555	8,505	12,128	11,843	11,378
Earnings Per Common Share (Diluted)	4.95	2.28	3.22	3.14	3.02
Total Assets	99,768	92,745	76,191	79,175	81,076
Working Capital	55,643	43,909	31,451	28,807	20,704
Long-term Debt	0	0	0	0	973
Cash Dividends Per Common Share	1.085	1.065	1.045	1.025	1.005

ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Currency amounts are in thousands except per-share amounts and where noted. Currencies are abbreviated as follows: the U.S. Dollar (USD or $), the Great Britain Pound (GBP or £), the Euro (EUR or €), the Australian Dollar (AUD or A$) and the Canadian Dollar (CAD or C$).

The following comments should be read in conjunction with the accompanying financial statements.

Overview

Excluding a large favorable third quarter (3Q) 2018 adjustment correcting the U.S. repatriation (REPAT) tax on foreign subsidiary cash and cumulative earnings (E&P) recognized in 2017, Utah Medical Products, Inc. (Nasdaq: UTMD) concluded a solid year in 2018 in which it was able to exceed its beginning of year projections. An estimate of the REPAT tax impact of the U.S. "Tax Cuts and Jobs Act" (TCJA), which was enacted in December 2017, was included in 4Q 2017 results according to U.S. Generally Accepted Accounting Principles (GAAP). A correction according to GAAP was included in 3Q 2018 results. In addition, a new Global Intangible Low-Taxed Income (GILTI) tax became applicable for 2018 that resulted from the TCJA, an estimate for which was included in both the 3Q and 4Q 2018 tax provision. All income statement categories of UTMD's operating performance in 2018 and 2017 were unaffected by the REPAT tax except for provision for income taxes, Net Income (NI) and Earnings Per Share (EPS).

Income statement results in 2018 compared to 2017 were as follows:

	2018	2017	Change
Net Sales	$41,998	$41,414	+ 1.4 %
Gross Profit (GP)	26,306	26,395	(0.3 %)
Operating Income (OI)	18,697	19,011	(1.6 %)
Income Before Tax (EBT)	19,458	19,082	+ 2.0 %
NI Before REPAT and GILTI taxes	15,504	14,562	+ 6.5 %
Net Income (NI) per GAAP	18,555	8,505	+118.2%
EPS Before REPAT Tax and GILTI taxes	4.136	3.897	+ 6.1 %
Earnings per Share (EPS) per GAAP	4.950	2.276	+117.5%

The REPAT tax correction booked in 3Q 2018 was $3,230 (lower tax provision), and the estimated GILTI tax booked in 2H 2018 was $179. The estimated REPAT tax booked in the 2017 income statement tax provision according to GAAP was $6,288, offset by a $230 adjustment (lower tax provision) to UTMD's long term deferred tax liability (DTL) as a result of the new combined Federal and Utah State tax rate of 25.95% compared to the 39% rate prior to enactment of the TCJA. In UTMD management's view, comparing GAAP NI and EPS between 2018 and 2017 does not provide stockholders with meaningful insight about UTMD's financial performance.

The associated key 2018 profit margins (profits as a percentage of sales) compared to the 2017 calendar year follow:

	2018	2017
Gross Profit Margin (GPM)	62.6 %	63.7 %
Operating Income Margin (OIM)	44.5 %	45.9 %
Income Before Tax Margin (EBTM)	46.3 %	46.1 %
NIM (non-GAAP, before TCJA taxes)	36.9 %	35.2 %

The 2018 EBTM and non-GAAP NIM expansion was due to non-operating income from higher interest rates on higher cash balances, and a gain from a 3Q 2018 sale of an unneeded Utah storage facility. The lower GPM came from higher direct material costs, a portion of which was due to a change in sales mix toward devices with higher direct material content. Although loaded direct labor costs were higher, the labor productivity of UTMD's manufacturing plants remained consistent with the prior year. The lower OPM resulted from the effect of the lower GPM plus 3% (+$224) higher Operating Expenses (OE) with only 1% higher revenues for the year. Although OE as a whole were up $224, both general and administrative (G&A) expenses, excluding the expense from amortizing Femcare Identifiable Intangible Assets (IIA), and product development (R&D) expenses in USD terms were about the same as in the prior year. The G&A expense of amortizing Femcare IIA in USD terms was up $75 (+4%), even though in GBP terms the amortization expense was the same in both years, because of the strength of the GBP compared to the USD in the 1H 2018. Sales and marketing (S&M) expenses were up $164 (+11%) as UTMD added some people.

Excluding the noncash effects of depreciation, amortization of intangible assets, remeasured value of foreign currency bank balances and non-cash stock option expense, 2018 consolidated earnings before taxes and interest expense (EBITDA) were $22,464 compared to $21,979 in 2017. The REPAT tax accrual in 2017 and adjustment in 2018, 2017 DTL adjustment and GILTI tax accrual in 2018 had no effect on this EBITDA metric. All things considered, the primary difference that led to higher EBITDA in 2018 was the net non-operating income (NOI) from sale of an unneeded storage facility in Utah.

GAAP NI in 2018 was $18,555 compared to $8,505 in 2017. Because the REPAT tax and net DTL adjustment were one-time tax events not related to normal operations, and the GILTI tax is new in 2018, UTMD management believes that the presentation of NI and EPS results excluding the estimated REPAT tax in 2017, the 2018 REPAT tax correction, the 2017 favorable adjustment in DTL and the 2018 GILTI tax provision, provides meaningful supplemental information to both management and investors that is more clearly indicative of UTMD's operating results in 2018 compared to 2017.

The resulting non-GAAP NI and EPS follow:

	2018	2017	Change
NI (non-GAAP)	$15,504	$14,562	+ 6.5 %
EPS (non-GAAP)	$4.136	$3.897	+ 6.1 %

In summary, UTMD achieved $4.14 in "normal" 2018 EPS compared to $3.90 in 2017 with a 1% increase in sales.
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Measures of the Company's liquidity and overall financial condition improved as of the end of 2018 compared to the end of 2017 as the result of continued strong positive cash flow from normal operations. The Company's continued excellent positive cash flow in 2018 allowed it to increase cash dividends paid to stockholders, repurchase 15,000 UTMD shares in the open market and use $0.4 million in cash for maintaining Property, Plant and Equipment (PP&E) in good working order. In addition, UTMD used $447 in cash to pay 19% of its corrected REPAT tax by April 2018 instead of only the 8% due in the first year, based on the initial estimate that was substantially too high.

In spite of the above cash uses, UTMD increased its cash equivalent balances to $51 million at the end of 2018 compared to $40 million at the end of 2017. Current assets increased 24% and total assets increased 8%. Total liabilities decreased $3,847 primarily because of the change in REPAT tax payable. The Company remained without debt. As a result, UTMD's total debt ratio (total liabilities to total assets) was 11% at the end of 2018 compared to 16% at the end of 2017. Stockholders' Equity (SE) increased to $89.0 million from $78.1 million at the end of 2017, despite the 2018 payments of $4,026 in cash dividends to stockholders and use of $1,205 for share repurchases, both of which reduce SE. The return on average SE (ROE) prior to the payment of dividends was 22.2% in 2018 compared to 11.5% in 2017. Based on non-GAAP NI, ROE before dividends in 2018 was 18.6% compared to 19.8% in 2017.

Productivity of Assets and Working Capital Assets.
Assets.
Year-end 2018 total consolidated assets were $99,768 comprised of $60,903 in current assets, $10,359 in consolidated net PP&E and $28,506 in net intangible assets. This compares to $92,745 total assets at the end of 2017 comprised of $49,188 in current assets, $11,621 in consolidated net PP&E and $31,936 in net intangible assets. Total asset turns (total consolidated sales divided by average total assets for the year) in 2018 were 44%, compared to 49% in 2017. The 2018 increase in assets, primarily cash, was substantially greater than the increase in sales.

Current assets increased $11,715 due to a $11,157 increase in cash and investments, a $332 increase in accounts and other receivables and a $169 increase in year-end inventories. Year-end 2018 and 2017 cash and investment balances were $51,112 and $39,955, representing 51% and 43% of total assets, respectively. Net (after allowance for doubtful accounts) year-end trade accounts receivable (A/R) balances increased $333. This was due to average days in A/R from date of invoice on December 31, 2018 at 36 days based on 4Q 2018 shipments compared to 32 days at the end of 2017 based on 4Q 2017 shipments. The Company believes any older A/R will be collected or are within its reserve balances for uncollectible amounts. Average 2018 consolidated inventory turns were 2.9 compared to 3.1 in 2017 based on the applicable year's cost of goods sold. The Company's cash reserves allowed it to increase inventories to take advantage of quantity discounts from vendors.

Working capital (current assets minus current liabilities) at year-end 2018 was 27% higher at $55,643 compared to $43,909 at year-end 2017. Consistent with Federal and State rules, 2018 ending current liabilities included only $85 (8%) of the State REPAT tax liability because the 2019 Federal liability had been prepaid in 2018 due to the over-estimate of the total Federal REPAT tax liability. The REPAT tax current liability was $503 at the end of 2017. The end of 2018 working capital significantly exceeds UTMD's needs for normal operations, funding future growth and timely payment of accrued REPAT tax liabilities, in addition to funding the subsequent 1Q 2019 $23 million repurchase of inventory and FILSHIE Clip System distribution rights in the U.S. from CooperSurgical Inc (CSI).

PP&E includes Utah, Ireland and England manufacturing molds, production tooling and equipment, test equipment, and product development laboratory equipment. In addition, PP&E includes computers and software, warehouse equipment, furniture and fixtures, facilities and real estate for all five locations in Utah, Ireland, UK, Canada and Australia, the fungible market value of which increases UTMD's enterprise value relative to most of its industry peers. Manufacturing facilities in Utah, Ireland and the UK are standalone buildings, whereas the distribution facilities in Australia and Canada are part of larger industrial condominiums. Ending 2018 net consolidated PP&E (depreciated book value of all fixed assets) declined $1,262 as a result of the combination of capital expenditures of $402, depreciation of $765 and the effect of foreign currency exchange (FX) rates on year-end foreign subsidiary asset

balances.

The following end-of-year FX rates in USD applied to assets and liabilities of each applicable foreign subsidiary:

	12-31-18	12-31-17
EUR	1.1456	1.2021
GBP	1.2760	1.3523
AUD	0.7046	0.7815
CAD	0.7329	0.7988

The year-end 2018 net book value (after accumulated depreciation) of consolidated PP&E was 33% of purchase cost. End-of-year PP&E turns (Net Sales divided by Net PP&E) was 4.1 in 2018 compared to 3.6 in 2017 due to the higher 2018 sales, depreciation which exceeded new PP&E purchases and a stronger USD at 2018 year-end. The future leverage in productivity of fixed assets which will not have to be increased to support new business activity will be a source of future profitability. In 2019, PP&E purchases to support ongoing operations are not expected to exceed depreciation of fixed assets.

Net intangible assets (after accumulated amortization) are comprised of the capitalized costs of obtaining patents and other intellectual property, as well as the value of identifiable intangible assets (IIA) and goodwill resulting from acquisitions. Net intangible assets were $28,506 (29% of total assets) at the end of 2018 compared to $31,936 (34% of total assets) at the end of 2017. Per US GAAP, intangible assets are categorized as either 1) IIA, which are amortized over the estimated useful life of the assets, or 2) goodwill, which is not amortized or expensed until the associated economic value of the acquired asset becomes impaired. The two categories of Femcare intangibles at year-end 2018 were net IIA of $14,734 and goodwill of $6,511. The accumulated amortization of Femcare IIA as of December 31, 2018 since the March 18, 2011 acquisition was $15,992. UTMD's goodwill balance was $13,703 at the end of 2018, 48% of total net intangibles. The goodwill portion of intangible assets resulting from the Femcare acquisition which is not amortized declined $389 due to a weaker GBP at year-end. The GBP FX rate at December 31, 2018 declined 5.6% from December 31, 2017.

Because the products associated with UTMD's acquisitions of Columbia Medical in 1997, Gesco in 1998, Abcorp in 2004 and Femcare in 2011 continue to be viable parts of UTMD's overall business, UTMD does not expect the current goodwill value associated with the four acquisitions to become impaired in 2019. Amortization of IIA was $2,191 in 2018 compared to $2,113 in 2017. The 2018 non-cash amortization expense of Femcare IIA was $2,130 (£1,595) compared to $2,055 (£1,595) in 2017. The USD difference was again due to the change in USD/GBP FX rate. The 2019 non-cash amortization expense of Femcare IIA will again be £1,595, or $2,058 if the USD/GBP average FX rate is 1.29. Looking forward, the 2019 operating expense associated with the amortization of $21,000 IIA resulting from the acquisition of CSI remaining FILSHIE Clip System U.S. distribution rights will be $4,053.

Liabilities.
The remaining $2,526 balance of the corrected $3,058 total REPAT tax liability from the TCJA is 83% instead of 92% (after the allowed 8% in the first of eight years' pay out), because the initial Federal payment was based on an initial estimate which was too high. UTMD's only REPAT tax current liability at December 31, 2018 is the $85 due to the State in 2018. The initial $6,288 estimated REPAT tax liability resulting from the TCJA was divided into 8% in current liabilities and 92% in long term liabilities in UTMD's December 31, 2017 balance sheet. The Federal and State REPAT tax payment requirement is 8% of the respective REPAT tax liability per year for the first five years, 15% in the sixth year, 20% in the seventh year and 25% in the eighth year. However, current IRS policy requires that any estimated tax overpayment of regular income taxes during the year, beginning with the estimated payments made in 2017, be applied first to the REPAT tax obligation rather than the ensuing year's normal income taxes, based on some rationale only understood by IRS bureaucrats.

UTMD's $179 estimate of the new 2018 GILTI tax is included in December 31, 2018 current liabilities. A discussion of the GILTI tax was included in UTMD's Form SEC 10-Q dated September 30, 2018.

Year-end 2018 current liabilities were $20 lower than at the end of 2017. Total liabilities were $3,946 lower at the end of 2018 compared to the end of 2017. The resulting 2018 year-end total debt ratio was 11% compared to 16% at the end of 2017.

The year-end 2018 DTL balance created as a result of the fifteen year deferred tax consequence of the amortization of Femcare's IIA was $2,541, down from $3,102 at the end of 2017. The larger decline in this DTL in addition to $2,130 in 2018 amortization of IIA, was due to a 6% weaker GBP compared to the USD at the end of 2018 compared to the end of 2017. In addition to liabilities stated on the balance sheet, UTMD has operating lease and purchase

obligations described in Note 8 to the financial statements.

Results of Operations.

a) Revenues.

Under accounting standards applicable for 2018, the Company believed that revenue should be recognized at the time of shipment as title generally passes to the customer at the time of shipment, or completion of services performed under contract. Revenue recognized by UTMD is based upon documented arrangements and fixed contracts in which the selling price is fixed prior to acceptance and completion of an order. Revenue from product or service sales is generally recognized at the time the product is shipped or service completed and invoiced, and collectibility is reasonably assured. Over 99% of UTMD's revenue is recognized at the time UTMD ships a physical device to a customer's designated location, where the selling price for the item shipped was agreed prior to UTMD's acceptance and completion of the customer order. There are no post-shipment obligations which have been or are expected to be material to financial results.

There are circumstances under which revenue may be recognized when product is not shipped, which have met the criteria of SAB 104: the Company provides engineering services, for example, design and production of manufacturing tooling that may be used in subsequent UTMD manufacturing of custom components for other companies. This revenue is recognized when UTMD's service has been completed according to a fixed contractual agreement.

Beginning on January 1, 2018, the Company adopted ASU 2014-09, a new revenue recognition accounting standard. Management completed an extensive assessment and implementation of the standard, including UTMD's various contracts with customers and associated performance obligations and the Company's conclusions regarding its revenue recognition practices and procedures. Other items like commissions and rights of return were also evaluated by the Company. Management is confident that the Company has properly evaluated the standard's requirements and has arrived at appropriate conclusions in recognizing revenue in accordance with the new standard. Those practices and procedures the Company will use to recognize revenue under the new standard are not significantly different than the methods used previously since UTMD has traditionally recognized revenue upon shipping a physical device to a customer's designated location, which is also when the Company has met its performance obligations under contracts it has with its customers that represent over 99% of its revenue. While the Company's revenue not associated with shipping a physical product is immaterial, management believes the Company's practices in recognizing that revenue is also in accordance with ASU 2014-09.

Terms of sale are established in advance of UTMD's acceptance of customer orders. In the U.S., Ireland, UK, France and Australia since the beginning of 2017, UTMD has generally accepted orders directly from and shipped directly to end user clinical facilities, as well as third party medical/surgical distributors, under UTMD's Standard Terms and Conditions (T&C) of Sale. About 14% of UTMD's domestic end user sales, excluding Femcare's FILSHIE Clip System sales to its exclusive U.S. distributor, CooperSurgical Inc. (CSI), went through third party med/surg distributors which contract separately with clinical facilities to provide purchasing, storage and scheduled delivery functions for the applicable facility. UTMD's T&C of Sale to end user facilities are substantially the same in the U.S., Canada, Ireland, UK, France and Australia.

UTMD may have separate discounted pricing agreements with a specific clinical facility or group of affiliated facilities based on volume of purchases. Pricing agreements which are documented arrangements with clinical facilities, or groups of affiliated facilities, if applicable, are established in advance of orders accepted or shipments made. For existing customers, past actual shipment volumes typically determine the fixed price by part number for the next agreement period of one year. For new customers, the customer's best estimate of volume is usually accepted by UTMD for determining the ensuing fixed prices for the agreement period. Prices are not adjusted after an order is accepted. For the sake of clarity, the separate pricing agreements with clinical facilities based on volume of purchases disclosure is not inconsistent with UTMD's disclosure above that the selling price is fixed prior to the acceptance of a specific customer order.

UTMD's global consolidated trade sales are comprised of domestic and outside the U.S. (OUS) sales. Domestic sales in 2018 and 2017 included 1) direct domestic sales, sales of finished devices to end-user facilities and med/surg distributors in the U.S.; 2) domestic OEM sales, sales of components or finished products, which may not be medical devices, to other companies for inclusion in their products; and 3) sales of the FILSHIE Clip System by Femcare UK to CSI. OUS sales are export sales from UTMD in the U.S. to customers outside the U.S. invoiced in USD, and all sales from UTMD subsidiaries in Ireland, Canada, Australia and the UK (other than Femcare UK sales to CSI) which may be invoiced in EUR, GBP, CAD, AUD or USD. The term "trade" means sales to customers which are not part of UTMD. Each UTMD entity except Femcare Australia and Femcare Canada also had 2018 intercompany sales of components and/or finished devices to other UTMD entities.

Global consolidated trade sales in 2018 were $41,998 compared to $41,414 in 2017 and $39,298 in 2016. The $584 (+1.4%) higher sales in 2018 were the result of several offsetting factors described below. Total U.S. domestic sales were up $906 (+4.5%) in 2018, at $21,192 compared to $20,286 in 2017. OUS sales were down $322 (1.5%) compared to 2017.

Domestic Sales.
U.S. domestic sales in 2018 were $21,192 (50% of total sales) compared to $20,286 (49% of total sales) in 2017. The primary contributors to the 2018 total $906 (+4.5%) higher domestic sales were $968 (+31%) higher sales of

components and finished devices used in other companies' products (OEM customers) and $402 (+3.0%) higher direct sales of UTMD finished devices to domestic end-users. The OEM and Direct user sales increases were partially offset by $464 (12.3%) lower sales to CSI, Femcare's US distributor of the FILSHIE Clip System.

Domestic OEM sales in 2018 represented almost 10% of total sales compared to 8% in 2017. UTMD sold components and finished devices to 152 different U.S. companies in 2018 compared to 148 companies in 2017, for use in their product offerings. Sales to UTMD's largest OEM customer, which are expected to continue to grow at a rapid rate in 2019, were up 67%.

Domestic direct (end-user) sales of neonatal products were $4,185 (+3% higher), labor & delivery (L&D) products $3,749 (about the same), pressure monitoring (BPM) products $1,021 (+9% higher) and gynecology/electrosurgery/ urology products excluding the FILSHIE Clip System $4,849 (+4% higher).

On December 31, 2018 UTMD entered into a definitive agreement with CSI to purchase the remaining 4.75 year life of CSI's exclusive U.S. distribution rights for the FILSHIE Clip System in the U.S., with shipments beginning to customers on February 1, 2019. In addition to adding the distributor margin to sales looking forward, UTMD hopes to expand its direct domestic gynecology sales of the FILSHIE Clip System through a direct marketing focus with end users including a conversion to single use applicator kits, approved by the FDA for distribution in the U.S. in late 2016, which UTMD believes is in the best interest of patients.

Outside the U.S. (OUS) Sales.
Sales OUS in 2018 were $20,806 (1.5% lower) compared to $21,129 in 2017.

The variance in order pattern of UTMD's China distributor for BPM devices explains 55% of the difference. In 2017, this distributor purchased five shipments at an average $393 each, with two of the shipments in the 2Q 2017. In 2018, this distributor purchased three shipments at an average $416 each, with one in each of the first three quarters and none in 4Q 2018. The order received from this distributor in fixed USD for 2019 returns to four shipments during the year at an average of $419 per shipment, which will add $430 in 2019 sales compared to 2018.

Sixty-seven percent of (USD denominated) 2018 OUS sales were invoiced in foreign currencies compared to 64% in 2017. As a portion of total sales, 33% of UTMD's USD-equivalent sales were invoiced in foreign currencies in both 2018 and 2017. In 2018, the GBP, EUR, AUD and CAD converted sales represented 10%, 12%, 5% and 6% of total 2018 USD sales, respectively. This compares to 10% GBP, 10% EUR, 6% AUD and 7% CAD of total 2017 USD sales. Because a significant portion of UTMD's sales are invoiced in foreign currencies, changes in FX rates can potentially have a material effect on period-to-period USD-denominated sales. FX rates had a varied impact during 2018. UTMD's FX rates for income statement purposes are transaction-weighted averages. The average rates from the applicable foreign currency to USD during 2018 compared to 2017 follow:

	2018	2017	Change	
GBP	1.334	1.290	+3.4	%
EUR	1.180	1.133	+4.1	%
AUD	0.747	0.767	(2.5	)%
CAD	0.773	0.769	+0.5	%
Sales weighted average:			+2.2	%

FX rates added $306 to 2018 year (as a whole) sales using the same FX rates as in 2017 (constant currency). The USD strengthened considerably later in 2018 compared to the first half of the year.

USD-denominated trade (excludes intercompany) sales of devices to OUS customers by UTMD's Ireland facility (UTMD Ltd) were $5,008 in 2018 compared to $5,224 in 2017. The FX impact added $134 to 2018 sales compared to 2017. Ireland manufactures the BPM devices it sells to UTMD's China distributor, which were $716 lower in 2018 than in 2017 due to the previously described order pattern fluctuation. In constant EUR currency and eliminating sales of BPM devices to its China distributor in both years, 2018 Ireland trade sales experienced 11% growth compared to 2017. In EUR terms, UTMD Ltd 2018 sales including intercompany shipments and China trade sales were 6% higher for the year.

In 2018, UTMD formally renamed its UK subsidiary from Femcare-Nikomed Ltd to Femcare Ltd. USD-denominated 2018 trade sales of devices to domestic UK, domestic France and international distributor customers of Femcare Ltd, excluding intercompany sales and sales to CSI (which are classed domestic sales), were $5,849 (+9%) higher compared to $5,356 in 2017. The FX impact added $209 to 2018 sales compared to 2017. In constant currency, 2018 sales were up 5%. Sales of the FILSHIE Clip System in Europe (including the UK) remained strong. Separately, Femcare Ltd sales to CSI (included in U.S. domestic sales) were $464 (12%) lower in 2018 than in 2017. After depletion of CSI's inventory, the UK trade sales to CSI in 2018 will become intercompany sales to UTMD in Utah in 2019. In GBP terms, total UK subsidiary 2018 sales including intercompany shipments as well as sales to CSI were 6% lower for the year.

USD-denominated sales of devices to end-users in Australia by Femcare's Australia distribution subsidiary (Femcare Australia Pty Ltd) were 14% lower in 2018 compared to 2017. The FX rate impact subtracted $50 from 2018 sales in 2017. AUD denominated sales in 2018 were 12% lower than in 2017.

USD-denominated sales of devices to end-users in Canada by UTMD's Canada distribution subsidiary (Utah Medical Products Canada, Inc.) were 12% lower in 2018 compared to 2017. The FX impact added $13 to 2018 sales. CAD denominated sales in 2018 were 13% lower than in 2017.

Looking forward to 2019, there again seem to be several offsetting influences on projected sales which may not be minor. UTMD expects worldwide macroeconomic conditions to weaken, which may affect the demand for discretionary specialty medical devices. A continuing trade war with China could result in significant adverse effects on UTMD's distributors. On the matter of BREXIT, UTMD does not foresee a material impact on its financial results in 2019, despite the politically expressed doomsday concerns. As of this date in early March 2019, the FX rates of the above foreign currencies remain consistent with the 4Q 2018 average rates, i.e. substantially weaker relative to the USD than in 2018 as a whole year. If the current FX rates remain for the balance of 2019, a projected negative $500 impact on same foreign currency sales would wipe out the additional sales obtained from the China distributor. Although it remains uncertain as to whether or not the weaker FILSHIE Clip System sales experienced particularly in 4Q 2018 in Australia, Canada and the U.S. might represent a trend into 2019, or just a fluctuation in end-of-year order pattern, UTMD expects a substantial increase in FILSHIE Clip System sales in the U.S. due to direct sales to end-users beginning in February. Combining the above assumptions with another strong increase in U.S. OEM sales, management currently projects UTMD 2019 USD consolidated revenues may be in the range of 9-10% higher than in 2018.

UTMD groups its sales into four general product categories: 1) obstetrics, comprised of labor and delivery management tools for monitoring fetal and maternal well-being, for reducing risk in performing difficult delivery procedures and for improving clinician and patient safety; 2) gynecology/ electrosurgery/ urology, comprised of tools for gynecological procedures associated primarily with cervical/ uterine disease including LETZ, endometrial tissue sampling, transvaginal uterine sonography, diagnostic laparoscopy, surgical contraception and other MIS procedures; specialty excision and incision tools; conservative urinary incontinence therapy devices; and urology surgical procedure devices; 3) neonatal critical care, comprised of devices that provide developmentally-friendly care to the most critically ill babies, including providing vascular access, enteral feeding, administering vital fluids, oxygen therapy while maintaining a neutral thermal environment, providing protection and assisting in specialized applications; and 4) blood pressure monitoring/ accessories/ other, comprised of specialized components as well as molded parts and assemblies sold on an OEM basis to other companies. In these four categories, UTMD's primary revenue contributors enjoy significant brand awareness by clinical users.

Global revenues by product category:

	2018	%	2017	%	2016	%
Obstetrics	$4,447	11	$4,499	11	$4,532	12
Gynecology/ Electrosurgery/ Urology	23,167	55	23,175	56	20,683	53
Neonatal	6,436	15	6,154	15	6,007	15
Blood Pressure Monitoring and Accessories*	7,948	19	7,586	18	8,076	20
Total:	$41,998	100	$41,414	100	$39,298	100

OUS revenues by product category:

	2018	%	2017	%	2016	%
Obstetrics	$698	3	$732	3	$658	3
Gynecology/ Electrosurgery/ Urology	15,022	72	14,759	70	12,851	65
Neonatal	2,252	11	2,105	10	1,965	10
Blood Pressure Monitoring and Accessories*	2,834	14	3,533	17	4,335	22
Total:	$20,806	100	$21,129	100	$19,809	100

*includes molded components and finished medical and non-medical devices sold to OEM customers.

As a summary description of revenues in the above tables:

1. Obstetrics. Increases in sales of newer devices helped offset declines from competition with older devices.

2. The gynecology/ electrosurgery/ urology (ES/Gyn) product category includes FILSHIE Clip System sales, which were $464 lower to CSI (U.S. distributor) and $17 higher OUS (despite being $654 lower in Canada and Australia combined). Electrosurgery sales were $371 higher. Urology sales were $45 higher.
3. Neonatal intensive care unit (NICU) device sales are experiencing consistent growth OUS.
4. OUS blood pressure monitoring and accessories (BPM) sales in 2018 suffered a loss of $717 compared to 2017 sales of BPM kits to UTMD's China distributor due to a variation in order pattern.

In calendar year 2019, despite an expected negative FX rate impact on foreign currency sales, UTMD expects overall revenues to be in the range of 9–10% higher due to the acquisition of the right to sell FILSHIE Clip System devices directly to U.S. medical facilities and continued growth in domestic OEM product sales.

Gross Profit (GP).
UTMD's 2018 consolidated GP, the surplus after subtracting costs of manufacturing, which includes purchasing raw materials, forming components, assembling, inspecting, testing, packaging, sterilizing and shipping products, from net revenues, was $26,306 (62.6% of sales) compared to $26,395 (63.7% of sales) in 2017, and $23,690 (60.3% of sales) in 2016.

UTMD's 2018 GPM was squeezed by higher labor and direct materials costs, as well as a product mix difference. OEM sales, which grew faster than other sales categories, have inherently lower GPMs than direct end user device sales, because another entity incurs operating expenses (OE) including sales and marketing (S&M) expenses, as well as much of product development (R&D) and general and administrative (G&A) expenses. The combination of higher variable manufacturing costs and change in product mix resulted in a 2018 GPM of 62.6% compared to 63.7% in 2017, which remained above management's overall GPM target of 60%. Utah and Ireland manufacturing operations, despite higher loaded (by benefits and taxes) labor costs, maintained direct labor and manufacturing overhead productivity in 2018 consistent with the prior year. In addition to the product mix GPM dilution, actual raw material price increases and increased freight-in expense from raw material vendors helped dilute the GPM.

Because UTMD's medical devices are differentiated and not subject to GPO agreements or other significant commodity pricing pressures, the Company was able to avoid unit sales price reductions.

UTMD's Ireland subsidiary's (UTMD Ltd's) GP was EUR 3,606 in 2018 compared to EUR 3,234 in 2017 and EUR 3,988 in 2016. The associated GPMs were 49.8% in 2018, 47.5% in 2017 and 49.5% in 2016. The higher GP and GPM in 2018 were due to the 6% higher total sales, including intercompany sales, and a more favorable product mix as sales to UTMD's China distributor, which were substantially lower, are priced at a very low GPM.

Femcare UK GP was GBP 5,010 in 2018 compared to GBP 5,317 in 2017, and GBP 4,138 in 2016. The lower GP in 2018 was due to $464 (12.3%) lower sales of FILSHIE Clip System devices to CSI in the U.S. The 2018 GPM was 71.7% compared to 71.7% in 2017 as well, and 69.4% in 2016.

Femcare Australia and Femcare Canada are purely distribution facilities for UTMD finished devices in their respective countries. Australia GP was AUD 1,526 in 2018 compared to AUD 1,846 in 2017 and AUD 2,049 in 2016. In addition to 11.6% lower AUD sales, GP were further leveraged lower as a weaker AUD raises the AUD cost of finished devices purchased from other UTMD subsidiaries in their fixed currency terms. The respective Femcare Australia GPMs were 58.7% in 2018, 62.7% in 2017 and 65.1% in 2016. Canada GP was CAD 1,999 in 2018 (60.0% of sales) compared to 2,300 (60.2% of sales) in 2017, its first year of operation. The 13% lower GP was due to 13% lower CAD sales.

In the U.S., GP was $13,065 in 2018 compared to $12,497 in 2017 and $12,547 in 2016. GPMs were 54.1% in 2018, 55.0% in 2017 and 54.3% in 2016. The lower 2018 U.S. GPM was the result of higher direct materials costs and higher direct material content of high growth OEM product sales. Otherwise, U.S. direct labor and manufacturing overhead costs as a percentage of sales were consistent with the prior year, primarily because of UTMD's very experienced manufacturing personnel.

A summation of the above 2018 GP of each subsidiary will not yield consolidated total GP because of elimination of profit in inventory of intercompany goods. With a 9–10% projected increase in total consolidated 2019 sales, UTMD expects almost a two percentage point increase in its consolidated 2019 GPM, yielding a 12-13% increase in 2019 consolidated GP compared to 2018. This would be the result of gaining the previous CSI distributor margin on 2019 direct sales of the FILSHIE Clip System in the U.S., offset by projected marginally higher direct material costs and higher labor costs as a result of a Utah employee cost of living adjustment at the beginning of 2019. The increase in consolidated GP will be subdued until the $2,098, approximate 9 months' worth, of CSI repurchased inventory is consumed, as the price of the inventory is the same as the past Femcare sales price to CSI, previously realized in UK

GP.

c) Operating Income (OI). OI results from subtracting OE from GP. OI in 2018 was $18,697 (44.5% of sales) compared to $19,011 in 2017 (45.9% of sales), and $16,187 (41.2% of sales) in 2016. The lower 2018 OIM reflected the lower 2018 GPM, and higher OE as planned. The UTMD Ltd (Ireland) OIM in 2018 was 45.9% compared to 42.7% in 2017, and 45.9% in 2016. Femcare UK's 2018 OIM was 38.1% compared to 40.1% in 2017, and 30.3% in 2016. Femcare Australia's 2018 OIM was 45.4% compared to 50.0% in 2017, and 54.3% in 2016. Femcare Canada's 2018 OIM was 49.1% compared to 51.5% in 2017. UTMD U.S. OIM in 2018 was 39.1% compared to 39.8% in 2017, and 38.1% in 2016.

OE include sales and marketing (S&M) expenses, product development (R&D) expenses and general and administrative (G&A) expenses. Consolidated OE were $7,608 (18.1% of sales) in 2018 compared to $7,385 (17.8% of sales) in 2017, and $7,503 (19.1% of sales) in 2016. The following table provides a comparison of OE categories for the last three years.

		2018	2017	2016
S&M expenses excluding the MDET		$1,708	$1,544	$ 1,673
S&M expense – U.S. MDET				
R&D expenses		454	447	475
G&A expenses:				
a)	litigation expense provision	(8)	29	54
b)	corporate legal	32	32	15
c)	stock option compensation	64	129	92
d)	management bonus accrual	373	430	445
e)	outside accounting audit/tax	238	196	199
f)	intangible asset amortization	2,191	2,113	2,223
g)	property & liability insurance premiums	126	155	178
h)	all other G&A expenses	2,431	2,309	2,149
G&A expenses – total		5,447	5,393	5,355
Total Consolidated OE:		$7,608	$7,385	$7,503
	Consolidated OE % of sales:	18.1 %	17.8 %	19.1 %

Description of OE Categories

i) S&M expenses:

S&M expenses in 2018 were $1,708 (4.1% of 2018 sales) compared to $1,544 (3.7% of sales) in 2017, and $1,673 (4.3% of sales) in 2016. The higher USD S&M expenses were due primarily to UTMD hiring planned additional S&M personnel in the U.S. Although further expanded S&M resources are needed in 2019 to distribute and support the FILSHIE Clip System directly to end user facilities in the U.S., S&M expenses as a percentage of total revenues in 2019 are not expected to increase.

S&M expenses are the costs of communicating UTMD's differences and product advantages, providing training and other customer service in support of the use of UTMD's solutions, attending clinical meetings and medical trade shows, administering customer agreements, advertising, processing orders, shipping, paying commissions to outside independent representatives and, when applicable, paying the MDET in the U.S. In markets where UTMD sells

directly to end-users, which in 2018 included the U.S., Ireland, UK, Australia, France and Canada, the largest components of S&M expenses were the cost of employing direct sales representatives, including associated costs of attending trade shows, travel, subsistence and communications; the cost of customer service required to timely process orders; and the distribution costs associated with shipping products to many locations. The theoretical trade-off between higher gross profit margins for selling directly at end user prices is higher S&M expenses as a percent of sales. S&M expenses associated with direct France sales have been effectively absorbed by the UK subsidiary with a minimal increase in S&M resources.

S&M expenses include all customer support costs including training. In general, training is not required for UTMD's products since they are well-established and have been clinically widely used. Written "Instructions For Use" are packaged with all finished devices. Although UTMD does not have any explicit contracts with customers to provide training, it does provide hospital in-service and clinical training as required and reasonably requested.

UTMD promises prospective customers that it will provide, at no charge in reasonable quantities, electronic media and other instructional materials developed for the use of its products. UTMD provides customer support from offices in the U.S., Canada, Ireland, UK and Australia by telephone to answer user questions and help troubleshoot any user issues. Occasionally, on a case-by-case basis, UTMD may utilize the services of an independent practitioner to provide educational assistance to clinicians. All in-service and training expenses are routinely expensed as they occur. Except for the consulting services of independent practitioners and occasional use of marketing consultants, all of these services are allocated from fixed S&M overhead costs. Historically, additional consulting costs have been immaterial to financial results, which is also UTMD's expectation for the future.

The MDET, a component of the Patient Protection and Affordable Care Act, (known commonly as Obamacare) was effective between 2013 and 2015. In December 2015, U.S. legislators suspended the MDET for 2016 and 2017, and in January 2018, further suspended it for 2018 and 2019. The excise tax was 2.3% of domestic sales of medical devices listed with the FDA. Medical devices designed for human use were taxed, whether or not they were sold for human use, e.g. veterinarian uses or laboratory use were also taxed. The impact of the tax was felt beyond 2.3%, as costs associated with administering, tracking, collecting and paying the tax were significant.

ii) R&D expenses:
R&D expenses were $454 (1.1% of sales) in 2018 compared to $447 (1.1% of sales) in 2017, and $475 (1.2% of sales) in 2016. R&D expenses include the costs of investigating clinical needs, developing innovative concepts, testing concepts for viability, validating methods of manufacture, completing any necessary premarketing clinical trials, regulatory documentation and other activities required for design control, responding to customer requests for product enhancements, and assisting manufacturing engineering on an ongoing basis in developing new processes or improving existing processes. Although no new UTMD devices were launched in 2018, R&D played a significant and continuing role in manufacturing process improvements that were needed to support fast growing OEM product sales, in addition to continuing work on new product projects. UTMD does not pre-announce new devices that are being developed. R&D expenses in 2019 as a percentage of 2019 sales are not expected to increase.

iii) G&A expenses:
G&A expenses in 2018 were $5,447 (13.0% of sales) compared to $5,393 (13.0% of sales) in 2017, and $5,355 (13.6% of sales) in 2016. G&A expenses include the “front office” functional costs of executive management and outside directors, finance and accounting, corporate information systems, human resources, stockholder relations, corporate risk management, corporate governance, protection of intellectual property, amortization of identifiable intangibles and legal costs. The table above helps clarify certain specific categories of G&A expenses of interest to stockholders. Amortization of the 2011 acquired Femcare IIA is part of G&A expenses. Although the IIA GBP amortization expense in 2018 was the same as in 2017, because of the stronger GBP for the year as a whole, the USD 2018 IIA amortization expense was $75 higher than in 2017. The resulting G&A noncash amortization expense of Femcare IIA was 5.1% of total 2018 sales compared to 5.0% of total sales in 2017 and 5.5% of sales in 2016. The Femcare IIA amortization expense will continue until March 2026 (or until the value of any remaining IIA becomes impaired).

The early 2019 $21,000 purchase of CSI exclusive FILSHIE Clip System distribution rights becomes an IIA which will be amortized on a straight line basis over the remaining 4.75 year life of the Femcare distribution agreement with CSI. This new amortization expense included in G&A expenses will be $4,053 in 2019, by itself about 9% of projected 2019 total revenues. The new G&A amortization expense exceed UTMD’s increase in 2019 GP.

In 2019, not including unforeseen litigation expenses or possible acquisition costs, UTMD expects consolidated OE to be about 2.5% higher than in 2018 apart from the new CSI IIA amortization expense. In summary, management projects resulting 2019 consolidated OI to be 4-5% lower than in 2018.

d) Non-operating Income (NOI), Non-operating Expense (NOE) and EBT. NOI includes royalties from licensing UTMD’s technology, rent from leasing underutilized property to others, income earned from investing the Company’s excess cash and gains or losses from the sale of assets or remeasurement of foreign currency bank account balances into USD, offset by NOE which includes interest on bank loans, bank service fees and excise taxes. The period-to-period remeasured value of EUR cash balances held in the UK and GBP balances held in Ireland generates a gain or loss which is booked at reporting period end as NOI or NOE.

Net NOI (combination of NOE and NOI) was $761 in 2018 compared to $71 in 2017 and $235 in 2016. The primary causes of the $690 higher NOI in 2018 compared to 2017 were a one-time $450 gain from the sales of assets in 2Q 2018 and $201 higher interest received on higher U.S. cash balances. A description of NOE and NOI components

follows:
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1) Interest Expense. There was no interest expense in 2018, 2017 or 2016. Absent an acquisition or large repurchase of shares that requires new borrowing, UTMD does not expect any interest expense in 2019.
2) Investment of excess cash. Consolidated investment income (including gains and losses on sales of investments) was $248 in 2018 compared to $17 in 2017 and $12 in 2016. Prior to 2018, cash was generally held in non-interest bearing bank accounts because avoiding the bank operating fees which would result from lower balances offset the low interest that could be earned at then current interest rates. UTMD estimates investment income will be lower in 2019 because of the use of $21,000 cash to repurchase the CSI FILSHIE Clip System distribution rights.
3) Royalties. Femcare received a royalty from licensing the use of the FILSHIE Clip System intangibles to CSI as part of its U.S. exclusive distribution agreement. Royalties in 2018 were $76 compared to $86 in 2017 and $91 in 2016. UTMD will not receive a CSI royalty in 2019 because of the purchase of the distribution agreement. Presently, there are no other arrangements under which UTMD is receiving royalties from other parties.
4) Gains/ losses from remeasured currency in bank accounts. UTMD recognized 2018 NOI of $13, 2017 NOI of $4 and 2016 NOI of $129 from gains on remeasured foreign currency bank balances. EUR and AUD currency cash balances in the UK, and GBP currency cash bank balances in Ireland, are subject to remeasured currency translation gains/ losses as a result of period to period changes in FX rates. Because of UTMD's subsidiaries' profitability, the subsidiaries may continue to accumulate cash until uses of cash that increase stockholder value are identified. No remeasured currency gains or losses are included in UTMD's projections for 2019.
5) Other NOI/NOE. Income received from renting unused warehouse space in Ireland and parking lot space in Utah for a cell phone tower, offset by bank fees, miscellaneous non-operating expenses and non-MDET excise taxes resulted in a net NOE of $3 in 2018 compared to NOE of $36 in 2017 and NOI of $3 in 2016. UTMD estimates Other NOI/NOE will be nominal in 2019.

Income before Taxes (EBT) results from adding net NOI or subtracting net NOE from OI. Consolidated EBT was $19,458 (46.3% of sales) in 2018 compared to $19,082 (46.1% of sales) in 2017, and $16,422 (41.8% of sales) in 2016. The 2018 EBT of UTMD Ltd. (Ireland) was €3,144 (43.4% of sales), compared to €2,779 (40.8% of sales) in 2017, and €3,489 (43.3% of sales) in 2016. Femcare UK's 2018 EBT was £2,896 (41.5% of sales) compared to £3,155 (42.5% of sales) in 2017 and £2,141 (35.9% of sales) in 2016. Femcare AUS's 2018 EBT was AUD 1,183 (45.5% of sales) compared to AUD 1,473 (50.0% of sales) in 2017 and AUD 1,713 (54.4% of sales) in 2016. Femcare Canada's 2018 EBT was CAD 1,632 (49.0% of sales) compared to 1,906 (49.9% of sales) in 2017.

As a side note for clarity of financial results, UTMD's 2018, 2017 and 2016 EBT, as well as all other income statement measures above the EBT line in the Income Statements, were unaffected by the 2017 accrual of the REPAT tax, the reduction in the 2017 end DTL, the 2018 correction in the REPAT tax and the new GILTI tax accrued in 2018, all of which resulted from the TCJA enacted in late 2017. The year-to-year GAAP comparisons of GP, OI and EBT are good indicators of UTMD's operating performance.

Looking forward, based on the projected 4-5% lower OI plus lower NOI in 2019 because of one-time gains in 2018, management expects consolidated EBT to be 7-8% lower than in 2018.

e) Net Income (NI), EPS and ROE. NI is EBT minus income taxes, often called the "bottom line". There were tax law changes enacted in the U.S. in 2017 and in the UK in 2016. The lowering of a future income tax rate results in a reduction in DTL. According to US GAAP, the total effect of tax rate changes on DTL balances is recorded as a component of the income tax provision related to continuing operations in the period in which the law is enacted. The DTL adjustments which lowered the applicable year's consolidated income tax provision were $230 in 2017 and $123 in 2016. There was no DTL adjustment in 2018.

In addition, the U.S. TCJA enacted in December 2017 included a special levy on the cumulative income (E&P) of UTMD's foreign subsidiaries. Foreign cash balances of $29 million were taxed at a 15.5% rate, and the remaining E&P at an 8% rate for accrued Federal income tax purposes. The State of Utah followed the Federal government and also levied a REPAT tax on half the E&P at the State of Utah corporate income tax rate of 5%. UTMD's end of 2017 tax provision was increased by an estimated $6,288 to incorporate the total Federal and State REPAT tax according to

GAAP, reducing 2017 NI and EPS accordingly. In 3Q 2018, after more IRS information became available and when UTMD's independent tax advisors completed the 2017 income tax return, it became known to the Company that the actual REPAT tax liability was $3,058, resulting in a favorable $3,230 adjustment to UTMD's 3Q 2018 income tax provision. The favorable adjustment was due to the allowance of foreign tax credits by the IRS. Although the REPAT tax is clearly a tax on foreign income, the State of Utah did not follow the IRS and allow foreign tax credits. In addition, the Company became aware of a new and ongoing Global Intangible Low-Taxed Income (GILTI) tax applicable beginning in 2018 that resulted from the TCJA, an estimate for which is included in the 2018 tax provision for the first time. Perversely, because the State of Utah also does not presently allow foreign tax credits when calculating the GILTI tax, the State GILTI tax represents an ongoing substantial tax on foreign income which was conceptually meant to be alleviated by the State REPAT tax of over $1 million. Essentially no GILTI tax will be received by the Federal government due to the deductibility of State GILTI taxes.

Because of the estimated "one-time" REPAT tax in 2017, the DTL adjustment in 2017 resulting from the adoption of lower Federal and State corporate income tax rates, the REPAT tax correction in 2018 and the new GILTI tax in 2018, calculating and comparing period-to-period income tax provisions as a percentage of EBT does not provide meaningful information to stockholders, in UTMD's opinion. Therefore, NI and EPS are presented below both according to GAAP and also prior to recognition of the various tax provisions related to the TCJA.

US GAAP:

	2018	2017	2016
NI	$18,555	$8,505	$12,128
NIM	44.2 %	20.5 %	30.9 %
EPS	$4.950	$2.276	$3.220

Non-GAAP (excluding TCJA REPAT and GILTI taxes):

	2018	2017	2016
NI	$15,504	$14,562	$12,004
NIM	36.9 %	35.2 %	30.5 %
EPS	$4.136	$3.897	$3.188

Note: The tax provision adjustments only affected UTMD's income tax provision, NI and EPS, not consolidated revenues (sales), GP, OI or EBT.

The (non-US GAAP) consolidated combined income tax provision rate for 2018 was 20.3% of EBT compared to 23.7% in 2017, and 26.9% in 2016. The GAAP consolidated income tax provision rate for 2018 was 4.6% compared to 55.4% of EBT in 2017 and 26.2% in 2016. The non-US GAAP difference in rates was due primarily to the tax deduction allowed in the UK and Ireland on the remeasured value of their USD cash balances, as well as the mix of income generated and actual tax provisions in sovereignties with varying tax rates. Both UK and Ireland subsidiaries experienced native currency losses on the value of their large USD cash balances in 2017. These currency translation losses are tax deductions in the applicable foreign jurisdiction, but do not affect UTMD's EBT (USD are USD). But the actual tax (lower) provisions of the OUS subsidiaries do become part of UTMD's consolidated income tax provision.

In general, year to year fluctuations in the combined tax rate will result from variation in EBT contribution from subsidiaries in jurisdictions with different corporate income tax rates. The UK had an income tax rate of 20% in 1Q 2017 and a rate of 19% thereafter through March 2020, compared to a rate of 20% in 2016. The UK also allows a tax deduction for sales of UK patented products which varies from year-to-year based on somewhat complicated rules which are sorted out for UTMD by independent tax accountants. The current UK income tax rate of 19% is scheduled to decline to 17% beginning April 1, 2020. The income tax rate for AUS has been and is planned to remain at 30%. The income tax rate for Canada was and is expected to remain at about 26%. Profits of the Ireland subsidiary are taxed at a 12.5% rate on exported manufactured products, and a 25% rate on rental and other types of income including income from sales of medical devices in Ireland domestically.

The Company believes that investors benefit from referring to the non-GAAP financial measures above in assessing UTMD's performance. The non-GAAP financial measures also facilitate management's internal comparisons for purposes of planning future performance. The non-GAAP financial measures disclosed by UTMD should not be considered a substitute for or superior to financial measures calculated in accordance with GAAP, and the financial results calculated in accordance with GAAP and reconciliations to those financial statements should be carefully evaluated.

EPS are NI divided by the number of shares of stock outstanding (diluted to take into consideration stock option awards which are "in the money," i.e., have exercise prices below the applicable period's weighted average market value). Diluted EPS in 2018 per GAAP were $4.950 ($4.136 prior to the REPAT tax correction and GILTI tax provision), compared to $2.276 in 2017 ($3.897 prior to the REPAT tax and DTL adjustment) and $3.220 ($3.188 prior to the DTL adjustment) in 2016. The 2018 non-GAAP results exceeded management's expectations for the year.

The 2018-ending weighted average number of diluted common shares (the number used to calculate diluted EPS) was 3,749 (in thousands), compared to 3,737 shares in 2017 and 3,766 shares in 2016. Dilution for "in the money" unexercised options for the year 2018 was 18 (in thousands) shares compared to 19 shares in 2017 and 15 shares in 2016. Actual outstanding common shares as of December 31, 2018 were 3,720.

In summary, after an outstanding year of growth in 2017, UTMD achieved slightly better revenues in 2018, with GP and OI challenged by broadly higher costs. Nevertheless, helped by the gain on sales of assets and a lower combined income tax rate, non-GAAP NI and EPS were up 6%.

UTMD's calendar year 2019 operating plan for conservative reasons excludes additional share repurchases, acquisitions other than the repurchase of CSI distribution rights and potential sales growth from unannounced new products. Incorporating the model described above which projects 7-8% lower EBT, and adding the GILTI tax as it is currently administered by the State of Utah, management estimates 2019 EPS between $3.70 and $3.80.

Return on stockholders' equity (ROE) is the portion of NI retained by UTMD (after payment of dividends) to internally finance its growth, divided by the average accumulated stockholders' equity (ASE) during the applicable time period. ROE includes balance sheet measures as well as income statement measures. Maintaining a high ROE is a key management objective for UTMD in order to grow without diluting its stockholders' interest. ROE is the quotient of NI divided by ASE, but it is the product of NIM, productivity of assets and financial leverage. UTMD's high NIM is the primary factor that continues to drive its ROE. Repurchases of shares and dividends help ROE as the applicable value reduces ASE, the denominator. Because of its magnitude, the REPAT tax estimate in 2017 and correction in 2018 both had a significant impact on the overall ROE ratio, even though the REPAT tax amounts reduce both the numerator and denominator.

UTMD's 2018 ROE was 17% using 2018 GAAP NI and subtracting dividends. In comparison, 2017 ROE was 8% using GAAP NI and subtracting dividends, and 12% in 2016. Before dividends, UTMD's 2018 ROE was 22%, compared to 2017 ROE at 12% and 2016 at 17%. Because of the impact on NI from the over-estimate of the REPAT tax in 2017 and the correction in 2018, stockholders might consider that the average ROE of 17% is more indicative of results in both years.

ASE was $83,557 in 2018, $73,683 in 2017 and $69,445 in 2016. Maintaining a high ROE with the dilutive effect of rapidly growing ASE suggests an excellent increase in stockholder value.

Liquidity and Capital Resources

Cash Flows.

Net cash provided by operating activities, including adjustments for depreciation and other non-cash operating expenses, along with changes in working capital and the tax benefit attributable to exercise of employee incentive

stock options, totaled $16,834 in 2018 compared to $16,908 in 2017 and $14,528 in 2016. The largest changes in 2018 changes in cash from operating activities compared to 2017 changes (second order derivative) were related to the REPAT tax: a $10,505 increase in GAAP net income, and a $2,727 adjustment reduction to the long term REPAT tax payable instead of the establishment of a $5,785 liability in the prior year. Other contributors included a $426 greater reduction to cash from operating activities as a result of the gain on sale of assets, a $254 greater reduction from higher accounts receivable, a reduction of $558 from lower accrued expenses instead of a $1,027 increase in adjustment to cash from operating activities from higher accrued expenses in 2017, a $332 lower reduction as a result of a smaller change in deferred income taxes, and a $222 lower reduction as a result of a smaller increase in inventories. Other changes were generally consistent with prior year changes relative to effective working capital management and sales activity.

In investing activities, during 2018 UTMD used $402 to purchase new molds and manufacturing equipment to maintain and improve operating capabilities. In 2017, UTMD used $1,597 for capital expenditures including fitting-out the 38,600 square foot facility in the UK that it purchased in late 2016 to replace its leased facility.

In 2018, UTMD received $454 and issued 13,283 shares of stock upon the exercise of employee and director stock options. Employees and directors exercised a total of 15,722 option shares in 2018, with 2,439 shares immediately being retired as a result of optionees trading the shares in payment of the exercise price of the options. Option exercises in 2018 were at an average price of $43.22 per share. The Company received a $49 tax benefit from option exercises in 2018, which is reflected in net income as a result of adopting a new accounting standard in 2017. UTMD repurchased 15,000 shares of its stock in the open market during 2018 at an average cost of $80.35 per share.

In comparison, in 2017 UTMD received $302 and issued 8,302 shares of stock upon the exercise of employee and director stock options. Employees and directors exercised a total of 8,638 option shares in 2017, with 336 shares immediately being retired as a result of optionees trading the shares in payment of the exercise price of the options. Option exercises in 2017 were at an average price of $37.83 per share. The Company received a $38 tax benefit from option exercises in 2017, which is reflected in net income as a result of adopting a new accounting standard in 2017. UTMD did not repurchase any shares of its stock in the open market during 2017. In 2016, UTMD received $376 and issued 11,945 shares of stock upon the exercise of employee and director stock options. Employees and directors exercised a total of 12,806 option shares in 2016, with 861 shares immediately being retired as a result of optionees trading the shares in payment of the exercise price of the options. Option exercises in 2016 were at an average price of $33.68 per share. The Company received a $50 tax benefit from option exercises in 2016. UTMD repurchased 50,000 shares of stock in the open market during 2016 at an average cost of $57.00 per share.

UTMD did not borrow in any of the three years 2016-2018. Cash dividends paid to stockholders were $4,026 in 2018 compared to $2,955 in 2017 and $3,916 in 2016. The $1,005 cash dividend declared for 4Q 2017 was paid in early January 2018, a change from the dividend declared in 4Q 2016, which was paid in late December 2016.

Management believes that future income from operations and effective management of working capital will provide the liquidity needed to finance internal growth plans. In an uncertain economic environment, UTMD’s cash balances allow management to operate with the long-term best interest of stockholders in mind. Planned 2019 capital expenditures for ongoing operations are expected to be less than depreciation of current PP&E.

Management plans to utilize cash not needed to support normal operations in one or a combination of the following: 1) in general, to continue to invest at opportune times in ways that will enhance future profitability; 2) to make additional investments in new technology and/or processes; and/or 3) to acquire a product line or company that will augment revenue and EPS growth and better utilize UTMD’s existing infrastructure. If there are no better strategic uses for UTMD’s cash, the Company will continue to return cash to stockholders in the form of dividends and share repurchases when the stock appears undervalued.

Management's Outlook.
UTMD is small, but its employees are experienced and remain diligent in their work. UTMD’s passion is in providing differentiated clinical solutions that will help improve the effectiveness of medical procedures and reduce health risks, particularly for women and their babies.

The safety, reliability and performance of UTMD's medical devices are high and represent significant clinical benefits while providing minimum total cost of care. UTMD will continue to leverage its reputation as a device innovator which will responsively take on challenges to work with clinicians who use its specialty devices. In doing so, UTMD will continue to differentiate itself, especially from commodity-oriented competitors. In 2019, UTMD plans to

1) exploit distribution and manufacturing synergies by further integrating capabilities and resources in its multinational operations;
2) focus on effectively direct marketing of the benefits of the FILSHIE Clip System in the U.S.;
3) introduce additional products helpful to clinicians through internal new product development;
4) continue to achieve excellent overall financial operating performance;
5) utilize positive cash generation to continue providing cash dividends to stockholders and make open market share repurchases if/when the UTMD share price seems undervalued; and
6) be vigilant for accretive acquisition opportunities which may be brought about by difficult burdens on small, innovative companies.

The Company has a fundamental focus to do an excellent job in meeting clinicians' and patients' needs, while providing stockholders with excellent returns. In 2018, the value of UTMD's stock increased 2%, ending the year at $83.08/ share, while $1.085 in dividends/ share were paid. In comparison, the DJIA, S&P 500 and NASDAQ indices were down 4% or more in 2018.

Taking a longer term view, as of the end of 2018 from the end of 1998, UTMD's share price increased 1,166%, representing a 13.5% annually compounded share price increase over the twenty year time span. If additional returns to stockholders from cash dividends are added, stockholder value increased 1,385% over the twenty-year time span, representing 14.4% annually compounded growth in value. In comparison to UTMD's 1,166% increase in stock value over the same twenty years, the NASDAQ Composite Index was up 203%, the S&P 500 Index was up 104% and the DJIA was up 154%.

Combining share price appreciation as a result of a long term profitable financial performance and a capital allocation strategy that includes opportunistic share repurchases with steadily growing quarterly cash dividends paid to stockholders since 2004, longer term UTMD stockholders have experienced excellent returns. Management is committed to continue that performance.

Off Balance Sheet Arrangements
None

Contractual Obligations
The following is a summary of UTMD's significant contractual obligations and commitments as of December 31, 2018:

Contractual Obligations and Commitments	Total	2019	2020 - 2021	2022 - 2023	2024 and thereafter
Long-term debt obligations	$-	$-	$-	$-	$ -
Operating lease obligations	613	61	117	91	344
Purchase obligations	1,637	1,632	5	-	-
Total	$2,250	$1,693	$122	$91	$ 344

Critical Accounting Policies and Estimates
The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as well as the reported amounts of revenues and expenses during the

reporting period.

Management bases its estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms the basis for making judgments about the carrying values of assets and liabilities that are not readily available from other sources. Management has identified the following as the Company's most critical accounting policies which require significant judgment and estimates. Although management believes its estimates are reasonable, actual results may differ from these estimates under different assumptions or conditions.

Allowance for doubtful accounts: The majority of the Company's receivables are with healthcare facilities and medical device distributors. Although the Company has historically not had significant write-offs of bad debt, the possibility exists, particularly with foreign distributors where collection efforts can be difficult or in the event of widespread hospital bankruptcies.

Inventory valuation reserves: The Company strives to maintain inventory to 1) meet its customers' needs and 2) optimize manufacturing lot sizes while 3) not tying-up an unnecessary amount of the Company's capital increasing the possibility of, among other things, obsolescence. The Company believes its method of reviewing actual and projected demand for its existing inventory allows it to arrive at a fair inventory valuation reserve. While the Company has historically not had significant inventory write-offs, the possibility exists that one or more of its products may become unexpectedly obsolete for which a reserve has not previously been created. The Company's historical write-offs have not been materially different from its estimates.

Accounting Policy Changes

The Company's management has evaluated the recently issued accounting pronouncements through the filing date of these financial statements and has determined that the application of these pronouncements will not have a material impact on the Company's financial position and results of operations.

ITEM 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company had manufacturing operations, including related assets, in the U.S. denominated in the U.S. Dollar (USD), in Ireland denominated in the Euro (EUR), and in England denominated in the British Pound (GBP). UTMD also has trading activities in the U.S. and in subsidiaries in other countries denominated in the USD, EUR, GBP, the Australian Dollar (AUD) and the Canadian Dollar (CAD). The currencies are subject to exchange rate fluctuations that are beyond the control of UTMD. The exchange rates were .8729, .8319 and .9474 EUR per USD as of December 31, 2018, 2017 and 2016, respectively. Exchange rates were .7837, .7395 and .8105 GBP per USD as of December 31, 2018, 2017 and 2016, respectively. Exchange rates were 1.4193, 1.2796 and 1.3829 AUD per USD on December 31, 2018, 2017 and 2016, respectively. Exchange rates were 1.3644, 1.2519 and 1.3425 CAD per USD on December 31, 2018, 2017, and 2016, respectively. Please see note 1 in Item, 8, below under "Translation of Foreign Currencies" for more information. UTMD manages its foreign currency risk without separate hedging transactions by either invoicing customers in the local currency where costs of production were incurred, or by converting currencies as transactions occur.

ITEM 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Currency amounts are in thousands except per-share amounts and where noted.

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MANAGEMENT'S REPORT ON INTERNAL CONTROL
OVER FINANCIAL REPORTING

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The Company's internal control over financial reporting includes those policies and procedures that:

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

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

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

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on its assessment and those criteria, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2018.

The Company's independent registered public accounting firm, Haynie & Company, has audited the Company's internal control over financial reporting as of December 31, 2018, and its report is shown on the next page.

Nortons Assurance Limited audited the internal control over financial reporting of Femcare Group Limited as of December 31, 2018, and its report follows the report of Haynie & Company.

By: /s/ Kevin L. Cornwell
Kevin L. Cornwell
Chief Executive Officer

By: /s/ Brian L. Koopman
Brian L. Koopman
Principal Financial Officer

Certified Public Accountants (a professional corporation)
50 West Broadway, Suite 600 Salt Lake City, Utah 84101 (801)532-7800 Fax (801)328-4461

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Utah Medical Products, Inc.
Midvale, Utah

Opinion on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying balance sheet of Utah Medical Products, Inc. (the Company) as of December 31, 2018, and the related statements of income, comprehensive income, stockholders' equity, and cash flows for the year ended December 31, 2018, and the related notes (collectively referred to as the financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework (2013) issued by COSO.

Basis for Opinion

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

We did not audit portions of the consolidated financial statements and we did not examine the effectiveness of internal control over financial reporting for portions of Femcare Group Limited, a wholly owned subsidiary. The portions not audited by us include assets of $38,787,000 as of December 31, 2018 and total revenues of $11,286,000 for the year ended December 31, 2018. Those portions of the consolidated financial statements and the effectiveness of internal control over financial reporting were audited by other auditors whose reports have been furnished to us, and our opinions, insofar as they relate to the amounts included for Femcare Group Limited and the effectiveness of Femcare Group Limited's internal control over financial reporting, is based solely on the reports of the other auditors.

Independent Accounting Firms
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We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects. Our audit of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ Haynie & Company
Haynie & Company

We have served as the Company's auditor since 2018.
Salt Lake City, Utah
March 14, 2019
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
of Utah Medical Products, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Utah Medical Products, Inc. as of December 31, 2017 and 2016, and the related consolidated statements of income and comprehensive income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2017. We also have audited Utah Medical Products, Inc.'s internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, based on our audits and the report of the other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Utah Medical Products, Inc. as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2017 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, based on our audit and the report of the other auditors, Utah Medical Products, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework (1992) issued by COSO.

Basis for Opinion

Utah Medical Products, Inc.'s management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on Utah Medical Products, Inc.'s internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to Utah Medical Products, Inc. in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We did not audit portions of the consolidated financial statements and we did not examine the effectiveness of internal control over financial reporting for portions of Femcare Group Limited, a wholly owned subsidiary. The portions not audited by us include assets of $26,564,000, and $19,412,000 as of December 31, 2017 and 2016, respectively, and total revenues of $11,371,000, $10,214,000, and $12,548,000, respectively for each of the years in the three-year period ended December 31, 2017. Those portions of the consolidated financial statements and the effectiveness of internal control over financial reporting were audited by other auditors whose reports have been furnished to us, and our opinions, insofar as they relate to the amounts included for Femcare Group Limited and the effectiveness of Femcare Group Limited's internal control over financial reporting, is based solely on the reports of the other auditors.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and

disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall consolidated financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

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

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

JONES SIMKINS LLC

We have served as Utah Medical Products, Inc.'s auditor since 2003.

Logan, Utah
March 5, 2018
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
of Utah Medical Products, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the consolidated balance sheets of Femcare Group Limited (the Company), including its subsidiaries, as of December 31, 2018 and 2017, and the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2018. We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017 and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework (2013) issued by COSO.

Basis for Opinion

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

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

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

NORTONS ASSURANCE LIMITED
We have served as the Company's auditor since 2011.
Reading, United Kingdom
March 8, 2019
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UTAH MEDICAL PRODUCTS, INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2018 and 2017
(In thousands)

ASSETS	2018	2017
Current assets:		
Cash	$51,112	$39,875
Investments, available-for-sale (notes 3 and 4)	-	80
Accounts and other receivables, net (note 2)	3,956	3,623
Inventories (note 2)	5,412	5,244
Prepaid expenses and other current assets	423	366
Total current assets	60,903	49,188
Property and equipment, net (notes 5 and 11)	10,359	11,621
Goodwill	13,703	14,092
Other intangible assets (note 2)	32,979	34,805
Other intangible assets - accumulated amortization	(18,176)	(16,961)
Other intangible assets - net (note 2)	14,803	17,844
Total assets	$99,768	$92,745
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$975	$934
Accrued expenses (note 2)	4,285	4,346
Total current liabilities	5,260	5,280
Long Term income tax payable (note 8)	2,441	5,785
Deferred tax liability - intangible assets	2,540	3,102
Deferred income taxes (note 8)	535	456
Total liabilities	10,776	14,623
Commitments and contingencies (notes 7 and 13)	-	-
Stockholders' equity:		
Preferred stock, $.01 par value; 5,000 sharesauthorized, no shares issued and outstanding	-	-
Common stock, $.01 par value; 50,000 shares authorized, issued 3,720 shares in 2018 and 3,721 shares in 2017	37	37
Accumulated other comprehensive income (loss)	(11,290)	(8,341)
Additional paid-in capital	122	809
Retained earnings	100,123	85,617
Total stockholders' equity	88,992	78,122
Total liabilities and stockholders' equity	$99,768	$92,745

See accompanying notes to financial statements.
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UTAH MEDICAL PRODUCTS, INC.
CONSOLIDATED STATEMENTS OF INCOME
AND COMPREHENSIVE INCOME
Years ended December 31, 2018, 2017 and 2016
(In thousands, except per share amounts)

	2018	2017	2016
Sales, net (notes 1, 3, 11 and 13)	$41,998	$41,414	$39,298
Cost of goods sold	15,692	15,019	15,608
Gross profit	26,306	26,395	23,690
Operating expense:			
Sales and marketing	1,708	1,544	1,673
Research and development	454	447	475
General and administrative	5,447	5,393	5,355
Operating income	18,697	19,011	16,187
Other income (expense):			
Dividend and interest income	217	17	12
Gains and (losses) on investments	32	-	-
Royalty income (note 14)	76	86	91
Other, net	437	(32)	132
Income before provision for income taxes	19,459	19,082	16,422
Provision for income taxes (note 9)	904	10,577	4,294
Net income	$18,555	$8,505	$12,128
Earnings per common share (basic) (note 1):	$4.97	$2.29	$3.23
Earnings per common share (diluted) (note 1):	$4.95	$2.28	$3.22
Other comprehensive income (loss):			
Foreign currency translation net of taxes of $0 in all periods	$(2,949)	$3,893	$(6,289)
Unrealized gain (loss) on investments net of taxes of $0, $6 and $3	-	10	5
Total comprehensive income	$15,606	$12,408	$5,844

See accompanying notes to financial statements.

UTAH MEDICAL PRODUCTS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOW
Years Ended December 31, 2018, 2017 and 2016
(In thousands)

	2018	2017	2016
Cash flows from operating activities:			
Net income	$18,555	$8,505	$12,128
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	765	660	610
Amortization	2,191	2,113	2,223
Gain on investments	(32)	-	-
Provision for (recovery of) losses on accounts receivable	20	4	-
Loss/(Gain) on disposal of assets	(410)	17	5
Deferred income taxes	(326)	(658)	(484)
Stock-based compensation expense	64	129	92
Tax benefit attributable to exercise of stock options	49	-	-
(Increase) decrease in:			
Accounts receivable	(496)	(242)	295
Other receivables	0	2	897
Inventories	(244)	(467)	(360)
Prepaid expenses and other current assets	(68)	24	23
Increase (decrease) in:			
Accounts payable	52	9	286
Accrued expenses	(558)	1,027	(1,187)
Long-term repatriation tax payable	(2,728)	5,785	-
Net cash provided by operating activities	16,834	16,908	14,528
Cash flows from investing activities:			
Capital expenditures for:			
Property and equipment	(402)	(1,597)	(3,293)
Intangible assets	-	-	(9)
Proceeds from the sale of investments	74	-	-
Proceeds from the sale of property and equiment	862	-	-
Net cash provided by (used in) investing activities	534	(1,597)	(3,302)
Cash flows from financing activities:			
Proceeds from issuance of common stock - options	454	302	376
Common stock purchased and retired	(1,205)	-	(2,850)
Tax benefit attributable to exercise of stock options	-	-	50
Dividends paid	(4,026)	(2,955)	(3,916)
Net cash (used in) financing activities	(4,777)	(2,653)	(6,340)
Effect of exchange rate changes on cash	(1,354)	921	(1,868)
Net increase in cash and cash equivalents	11,237	13,579	3,018
Cash at beginning of year	39,875	26,296	23,278

Cash at end of year	$51,112	$39,875	$26,296
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the year for:			
Income taxes	$4,851	$5,151	$4,846
Interest	-	-	-

See accompanying notes to financial statements.

UTAH MEDICAL PRODUCTS, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
Years Ended December 31, 2018, 2017 and 2016
(In thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Retained Earnings	Total Stockholders' Equity
Balance at December 31, 2015	3,751	$ 38	$ 2,710	$(5,961)	$72,861	$ 69,648
Shares issued upon exercise of employee stock options for cash	13	0	431	-	-	431
Shares received and retired upon exercise of stock options	(1)	(0)	(56)	-	-	(56)
Tax benefit attributable to appreciation of stock options	-	-	50	-	-	50
Stock option compensation expense	-	-	92	-	-	92
Common stock purchased and retired	(50)	(1)	(2,849)	-	-	(2,850)
Foreign currency translation adjustment	-	-	-	(6,289)	-	(6,289)
Unrealized holding gain (loss) from investments, available-for-sale, net of taxes	-	-	-	5	-	5
Common stock dividends	-	-	-	-	(3,916)	(3,916)
Net income	-	-	-	-	12,128	12,128
Balance at December 31, 2016	3,713	$ 37	$ 378	$(12,243)	$81,072	$ 69,244
Shares issued upon exercise of employee stock options for cash	9	0	327	-	-	327
Shares received and retired upon exercise of stock options	(0)	(0)	(25)	-	-	(25)
Stock option compensation expense	-	-	129	-	-	129
Common stock purchased and retired	-	-	-	-	-	-
Foreign currency translation adjustment	-	-	-	3,893	-	3,893
Unrealized holding gain (loss) from investments, available-for-sale, net of taxes	-	-	-	10	-	10
Common stock dividends	-	-	-	-	(3,960)	(3,960)
Net income	-	-	-	-	8,505	8,505
Balance at December 31, 2017	3,721	$ 37	$ 809	$(8,341)	$85,617	$ 78,122
Shares issued upon exercise of employee stock options for cash	16	0	679	-	-	679
Shares received and retired upon exercise of stock options	(2)	(0)	(225)	-	-	(225)
Stock option compensation expense	-	-	64	-	-	64
Common stock purchased and retired	(15)	(0)	(1,205)	-	-	(1,205)
Foreign currency translation adjustment	-	-	-	(2,949)	-	(2,949)
Unrealized holding gain (loss) from investments, available-for-sale, net of taxes	-	-	-	-	-	-
Common stock dividends	-	-	-	-	(4,049)	(4,049)
Net income	-	-	-	-	18,555	18,555
Balance at December 31, 2018	3,720	$ 37	$ 122	$(11,290)	$100,123	$ 88,992

See accompanying notes to financial statements.
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Utah Medical Products, Inc.
Notes to Consolidated Financial Statements
Years Ended December 31, 2018, 2017 and 2016

Currency amounts are in thousands except per-share amounts and where noted.

Note 1 – Summary of Significant Accounting Policies

Organization
Utah Medical Products, Inc. with headquarters in Midvale, Utah and its wholly-owned operating subsidiaries, Femcare Limited located in Romsey, Hampshire, England, Femcare Australia Pty Ltd located in Castle Hill, NSW, Australia, Utah Medical Products Canada, Inc. (dba Femcare Canada) located in Mississauga, Ontario, Canada and Utah Medical Products Ltd., which operates a manufacturing facility in Athlone, Ireland, (in the aggregate, the Company) are in the primary business of developing, manufacturing and globally distributing specialized medical devices for the healthcare industry. The Company's broad range of products includes those used in critical care areas and the labor and delivery departments of hospitals, as well as outpatient clinics and physicians' offices. Products are sold directly to end user facilities in the U.S., Ireland, UK, Canada, France and Australia, and through third party distributors in other outside the U.S. (OUS) markets. Domestically, until February 1, 2019, Femcare had an exclusive U.S. distribution relationship with CooperSurgical, Inc. (CSI) for the FILSHIE Clip System. UTMD also sells subcontract manufactured components and finished products to over 150 companies in the U.S. for their medical and non-medical products.

Use of Estimates in the Preparation of Financial Statements
The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Although actual results could differ from those estimates, management believes it has considered and disclosed all relevant information in making its estimates that materially affect reported performance and current values.

Principles of Consolidation
The consolidated financial statements include those of the Company and its subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Cash and Cash Equivalents
For purposes of the consolidated statement of cash flows, the Company considers cash on deposit and short-term investments with original maturities of three months or less to be cash and cash equivalents.

Investments
The Company classifies its investments as "available-for-sale." Securities classified as "available-for-sale" are carried in the financial statements at fair value. Realized gains and losses, determined using the specific identification method, are included in operations; unrealized holding gains and losses are reported as a separate component of accumulated other comprehensive income. Declines in fair value below cost that are other than temporary are included in operations. As of December 31, 2018 the Company held no investments other than short maturity money market funds which are part of cash and cash equivalents.

Concentration of Credit Risk
The primary concentration of credit risk consists of trade receivables. In the normal course of business, the Company provides credit terms to its customers. Accordingly, the Company performs ongoing credit evaluations of its customers and maintains allowances for possible losses which, when realized, have been within the range of

management's expectations as reflected by its reserves.

The Company's customer base consists of hospitals, medical device distributors, physician practices and others directly related to healthcare providers, as well as other manufacturing companies. Although the Company is affected by the well-being of the global healthcare industry, management does not believe significant trade receivable credit risk exists at December 31, 2018 except under an extreme global financial crisis.

Utah Medical Products, Inc.
Notes to Consolidated Financial Statements
Years Ended December 31, 2018, 2017 and 2016

Note 1 – Summary of Significant Accounting Policies (continued)

The Company maintains its cash in bank deposit accounts in addition to Fidelity Investment money market accounts. The Company has not experienced any losses in such accounts and believes it is not exposed to a significant credit risk on cash and cash equivalent balances.

Accounts Receivable

Accounts receivable are amounts due on product sales and are unsecured. Accounts receivable are carried at their estimated collectible amounts. Credit is generally extended on a short-term basis; thus accounts receivable do not bear interest although a late charge may be applied to such receivables that are past the due date. Accounts receivable are periodically evaluated for collectibility based on past credit history of customers and current market conditions. Provisions for losses on accounts receivable are determined on the basis of loss experience, known and inherent risk in the account balance and current economic conditions (see note 2).

Inventories

In 2017, the Company adopted Accounting Standard Update (ASU) 2015-11, "Inventory-Simplifying the Measurement of Inventory," which changed how inventory is valued. Finished products, work-in-process, raw materials and supplies inventories are stated at the lower of cost and net realizable value (NRV) computed on a first-in, first-out method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The adoption of ASU 2015-11 did not have an impact on the Company's financial statements (see note 2).

Property and Equipment

Property and equipment are stated at cost. Depreciation and amortization are computed using the straight-line method over estimated useful lives as follows:

Building and improvements	15-40 years
Furniture, equipment and tooling	3-10 years

Long-Lived Assets

The Company evaluates its long-lived assets in accordance with Accounting Standards Codification (ASC) 360, "Accounting for the Impairment of Long-Lived Assets." Long-lived assets held and used by the Company are reviewed for impairment whenever events or changes in circumstances indicate that their net book value may not be recoverable. When such factors and circumstances exist, the Company compares the projected undiscounted future cash flows associated with the related asset or group of assets over their estimated useful lives against their respective carrying amounts. Impairment, if any, is based on the excess of the carrying amount over the fair value of those assets and is recorded in the period in which the determination was made.

Intangible Assets

Costs associated with the acquisition of patents, trademarks, trade names, customer relationships, regulatory approvals & product certifications, license rights and non-compete agreements are capitalized, and are being amortized using the straight-line method over periods ranging from 5 to 20 years. UTMD's goodwill is tested for impairment annually, in the fourth quarter of each year, in accordance with ASC 350. UTMD also performs impairment tests contemporaneously, if circumstances change that would more than likely reduce the fair value of goodwill below its net book value. If UTMD determines that its goodwill is impaired, a second step is completed to measure the amount of the impairment loss. UTMD does not expect its goodwill to become impaired in the foreseeable future. Estimated

future amortization expenses on intangible assets held as of December 31, 2018, using the 2018 year-end 1.2760 USD/GBP and .7046 USD/AUD currency exchange rates, is about $2,047 in 2019 and 2020, and $2,041 in 2021 and 2022 (see note 2).

As a subsequent event, $21,000 in intangible assets were acquired from CSI on February 1, 2019. The future amortization expenses on those assets are estimated to be $4,053 in 2019, and $4,421 per year in 2020-2022 (see note 8).

Utah Medical Products, Inc.
Notes to Consolidated Financial Statements
Years Ended December 31, 2018, 2017 and 2016

Note 1 – Summary of Significant Accounting Policies (continued)

Stock-Based Compensation
At December 31, 2018, the Company has stock-based employee compensation plans, which are described more fully in note 10. The Company accounts for stock compensation under ASC 718, Share-Based Payment. This statement requires the Company to recognize compensation cost based on the grant date fair value of options granted to employees and directors. In 2018, the Company recognized $64 in stock-based compensation cost compared to $129 in 2017 and $92 in 2016.

Revenue Recognition
The Company recognizes revenue at the time of product shipment as UTMD meets its contractual performance obligations to the customer at the time of shipment. Revenue recognized by UTMD is based upon the consideration to which UTMD is entitled from its customers as a result of shipping a physical product, in accordance with the documented arrangements and fixed contracts in which the selling price was fixed prior to the Company's acceptance of an order. Revenue from service sales, which are immaterial to UTMD, is generally recognized when the service is completed and invoiced. As demonstrated by decades of experience in successful and consistent collections, there is very minor and insignificant uncertainty regarding the collectability of invoiced amounts reasonably within the terms of the Company's contracts. There are circumstances under which insignificant revenue may be recognized when product is not shipped, which meet the criteria of ASU 2014-09: the Company provides engineering services, for example, design and production of manufacturing tooling that may be used in subsequent UTMD manufacturing of custom components for other companies. This revenue is recognized when UTMD's performance obligations have been completed according to a fixed contractual agreement. UTMD includes handling fees charged to customers in revenues.

Income Taxes
The Company accounts for income taxes under ASC 740, "Accounting for Income Taxes," whereby deferred taxes are computed under the asset and liability method.

In November 2015, the FASB released ASU 2015-17, Income Taxes (Topic 740): Balance Sheet classification of Deferred Taxes. ASU 2015-17 requires that all deferred income taxes are classified as noncurrent in a classified statement of financial position. The Company adopted ASU 2015-17 retrospectively effective January 1, 2017.

On December 22, 2017 the U.S. Tax Cuts and Jobs Act of 2017 (TCJA) was signed into law. As a result of the TCJA, the U.S. statutory tax rate was lowered from 35% to 21% effective January 1, 2018, among other changes. ASC 740 requires companies to recognize the effect of tax law changes in the period of enactment; therefore, UTMD was required to revalue its deferred tax assets and liabilities at December 31, 2017 at the new rate.

The TCJA contains a deemed repatriation transition tax (REPAT tax) on accumulated earnings and profits of the Company's non-U.S. subsidiaries that have not been subject to U.S. tax. The Company has elected to pay its net REPAT tax over eight years.

On December 22, 2017, the SEC issued SAB 118 which provided guidance on accounting for the impact of the TCJA. SAB 118 provides a measurement period of up to one year from enactment for a company to complete its tax accounting under ASC 740. Once a company was able to make a reasonable estimate and record a provisional amount for effects of the TCJA, it was required to do so.

During the fourth quarter of 2017, the Company recorded a provisional tax charge for the REPAT tax of $6,288 and a provisional tax credit of $230 for the re-measurement of its U.S. deferred tax balances. Both provisional tax amounts were the Company's reasonable estimate of the impact of the TCJA based on its understanding and available guidance. During the third quarter of 2018, after more IRS information became available and when UTMD's independent tax advisors completed the 2017 income tax return, the Company recognized a benefit of $3,230 from adjustments to the provisional amount recorded for the REPAT tax at December 31, 2017 and included this adjustment as a component of income tax expense from continuing operations.

Utah Medical Products, Inc.
Notes to Consolidated Financial Statements
Years Ended December 31, 2018, 2017 and 2016

Note 1 – Summary of Significant Accounting Policies (continued)
The Company or one of its subsidiaries files income tax returns in the U.S. federal jurisdiction, in Utah, in the United Kingdom, in Australia, in Ireland and in Canada.

The Company recognizes interest accrued related to unrecognized tax benefits in interest expenses and any related penalties in income taxes. The Company did not recognize any tax-related interest expense or have any tax penalties in any of the three years 2016 through 2018.

Legal Costs
The Company has been involved in lawsuits which are an expected consequence of its operations and in the ordinary course of business. The Company maintains a reserve for legal costs which are probable and estimated based on previous experience and known risk. The reserve for legal costs at December 31, 2018 and 2017 was $149 and $182, respectively (see note 2).

Earnings per Share
The computation of basic earnings per common share is based on the weighted average number of shares outstanding during each year.

The computation of earnings per common share assuming dilution is based on the weighted average number of shares outstanding during the year plus the weighted average common stock equivalents which would arise from the exercise of stock options outstanding using the treasury stock method and the average market price per share during the year.

The shares (in thousands) used in the computation of the Company's basic and diluted earnings per share are reconciled as follows:

	2018	2017	2016
Weighted average number of shares outstanding – basic	3,730	3,718	3,751
Dilutive effect of stock options	18	19	15
Weighted average number of shares outstanding, assuming dilution	3,748	3,737	3,766

Presentation of Sales and Similar Taxes
Sales tax on revenue-producing transactions is recorded as a liability when the sale occurs. UTMD is not required to withhold sales tax on OUS sales, and at least 90% of domestic 2018 sales were to customers who are tax exempt or who are in jurisdictions where UTMD is not required to withhold sales tax.

Translation of Foreign Currencies
Assets and liabilities of the Company's foreign subsidiaries are translated into U.S. dollars at the applicable exchange rates at year-end. Net gains or losses resulting from the translation of the Company's assets and liabilities are reflected as a separate component of stockholders' equity. A negative translation impact on stockholders' equity reflects a current relative U.S. Dollar value higher than at the point in time that assets were actually acquired in a foreign currency. A positive translation impact would result from a U.S. dollar weaker in value than at the point in time foreign assets were acquired. Year-end translation gains or losses of non-functional currency bank account balances, e.g. EUR and AUD balances held by the UK subsidiary, are recognized as non-operating income or expense, as applicable.

Income and expense items are translated at the weighted average rate of exchange (based on when transactions actually occurred) during the year.

Utah Medical Products, Inc.
Notes to Consolidated Financial Statements
Years Ended December 31, 2018, 2017 and 2016

Note 2 – Detail of Certain Balance Sheet Accounts

	December 31, 2018	2017
Accounts and other receivables:		
Accounts receivable	$4,064	$3,713
Income tax receivable	-	-
Accrued interest and other	13	14
Less allowance for doubtful accounts	(121)	(104)
Total accounts and other receivables	$3,956	$3,623
Inventories:		
Finished products	$1,615	$1,313
Work-in-process	1,103	1,270
Raw materials	2,694	2,661
Total inventories	$5,412	$5,244
Goodwill:		
Balance before effect of foreign exchange	$14,092	$13,487
Effect of foreign exchange	(389)	605
Additions as a result of acquisitions	-	-
Subtractions as a result of impairment	-	-
Total Goodwill	$13,703	$14,092
Other Identifiable Intangible Assets:		
Patents	$2,136	$2,183
Non-compete agreements	128	135
Trademarks & trade names	9,375	9,921
Customer relationships	9,123	9,669
Regulatory approvals & product certifications	12,217	12,897
Total Other Identifiable Intangible Assets	32,979	34,805
Accumulated amortization	(18,176)	(16,961)
Other Identifiable Intangible Assets, Net	$14,803	$17,844
Accrued expenses:		
Income taxes payable	$845	$1,259
Payroll and payroll taxes	1,099	1,199
Reserve for litigation costs	149	182
Other	2,192	1,706
Total accrued expenses	$4,285	$4,346

Note 3 – Quarterly Results of Operations (Unaudited)

Unaudited Quarterly Data for 2018

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net Sales	$10,887	$10,965	$10,390	$9,756
Gross Profit	6,922	6,984	6,294	6,106
Net Income (Loss)	4,092	4,308	6,762	3,393

Earnings (Loss) Per Common Share (Diluted)	1.09	1.15	1.80	.91

Unaudited Quarterly Data for 2017

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net Sales	$10,259	$10,829	$10,125	$10,201
Gross Profit	6,535	6,893	6,496	6,470
Net Income	3,536	3,870	3,622	(2,522)
Earnings Per Common Share (Diluted)	.95	1.04	.97	(.67)

Utah Medical Products, Inc.
Notes to Consolidated Financial Statements
Years Ended December 31, 2018, 2017 and 2016

Note 4 – Investments

The Company's investments, classified as available-for-sale consist of the following:

	December 31, 2018	2017
Investments, at cost	$ -	$ 42
Equity securities:		
-Unrealized holding gains	-	38
-Unrealized holding (losses)	-	-
Investments, at fair value	$ -	$ 80.

During 2017, UTMD did not have any proceeds from the sale of available-for-sale securities. In 2018, UTMD sold shares of Citigroup and received proceeds of $74 resulting in a realized gain of $32.

Note 5 – Fair Value Measurements and Financial Instruments

The Company follows a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.
The Company uses the following valuation techniques to measure fair value for its assets and liabilities:

Level 1 - Quoted market prices in active markets for identical assets or liabilities;

Level 2 - Significant other observable inputs (e.g. quoted prices for similar items in active markets, quoted prices for identical or similar items in markets that are not active, inputs other than quoted prices that are observable such as interest rate and yield curves, and market-corroborated inputs);

Level 3 - Unobservable inputs for the asset or liability, which are valued based on management's estimates of assumptions that market participants would use in pricing the asset or liability.

The following table provides financial assets carried at fair value measured as of December 31 for the past two years:

	Level 1		Levels 2 & 3		Total	
	2018	2017	2018	2017	2018	2017
Equities	$ -	$ 80	-	-	$ -	$ 80
Total	$ -	$ 80	-	-	$ -	$ 80

None of the Company's financial instruments, which are current assets and liabilities that could be readily traded, are held for trading purposes. Detail on investments is provided in note 4 above. The Company estimates that the fair value of all financial instruments at December 31, 2018 does not differ materially from the aggregate carrying value of

its financial instruments recorded in the accompanying consolidated balance sheets.

Note 6 – Property and Equipment

Property and equipment consists of the following:

	December 31,	
	2018	2017
Land	$1,653	$1,339
Buildings and improvements	13,752	15,350
Furniture, equipment and tooling	16,003	15,696
Construction-in-progress	141	