

**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, 2019**

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. **001-12575**

**UTAH MEDICAL PRODUCTS INC**

(Exact name of Registrant as specified in its charter)

**Utah**

(State or other jurisdiction of incorporation or organization)

**87-0342734**

(I.R.S. Employer Identification No.)

**7043 South 300 West**

**Midvale, Utah 84047**

(Address of principal executive offices) (Zip Code)

**(801) 566-1200**

(Registrant's telephone number, including area code)

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

Title of each class:

Trading Symbol:

Name of each exchange on which  
registered:

**Common stock, \$0.01 par value**

**UTMD**

**NASDAQ**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark 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 the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐  
Non-accelerated filer ☐

Accelerated filer ☒  
Smaller reporting company ☐  
Emerging growth company ☐

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

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

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, 2019, the aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was **\$326,703,722**.

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 12, 2020, common shares outstanding were 3,697,431.**

**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 and responding to needs of clinicians and patients, 2) rapidly designing or acquiring economical solutions that gain premarketing regulatory concurrence, 3) reliably producing devices 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 assembly and 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, UTMD's medical devices are sold directly to clinical end-user facilities or a designated stocking distributor for a medical facility. 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), devices 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 260 distributors, 120 of which purchased at least five thousand dollars in UTMD medical devices during 2019.

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 \$117,872 in the form of share repurchases, and an additional \$58,800 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 including Femcare Australia Pty Ltd as a sales and distribution operation to directly serve Australia medical facilities. 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 59% of UTMD's consolidated 2019 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 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 (1794) 525 100. 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](http://www.utahmed.com) and [www.femcare.co.uk](http://www.femcare.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-eight years the most widely accepted transducer-tipped system. In addition, adjunct toco belts are provided by UTMD. 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, but does not market electronic monitors, the capital equipment that processes the electrical signals. In addition to products currently offered, UTMD continues 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 prong designed 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 CO<sub>2</sub> (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 FIO<sub>2</sub> (fractional inspired oxygen) control, minimizes convective heat loss from the head, provides optimum flows for elimination of CO<sub>2</sub> 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 devices 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 generators 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 markets a unique conization electrode for deep endocervical disease called C-LETZ®, designed by UTMD to limit the removal of healthy tissue margins that might compromise adequate cervical function. In 2010, UTMD introduced a patented electrode attachment that prevents interference with the colposcope during LETZ. 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. 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 and bladeless designs, suction and irrigation tubing, insufflation tubing and connectors, pressure infusor bags and control valves. Also acquired were Femcare's hormone replacement therapy (HRT) trocar/obturator and HRT procedure tray for subdermal placement of hormone tablets, and a femoral sponge product used during joint replacement surgery.



### EPITOME® and OptiMicro™ Electrosurgical Devices

In 1996, after finding the general surgical market lacked a precision electrosurgical blade, UTMD developed EPITOME, 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 or fatty tissue is necessary, such as in mammaplasty or abdominoplasty, UTMD believes that EPITOME has no close substitute. Furthermore, an independent study concluded 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, or plastic surgeons creating or working in a breast pocket during augmentation or capsulectomy.

In 2002, UTMD introduced a product line of ultra-fine tipped microdissection needles, called OptiMicro™ Needles, to complement the Epite Scalpel. Whereas the Epite Scalpel has been particularly effective for large scale surgeries that entail a great amount of tissue cutting, the OptiMicro electrosurgical needles are particularly useful in small-scale plastic and reconstructive surgery applications where extreme precision and ideal cosmetic results are expected. In 2009, UTMD added extended length OptiMicro needle versions useful in certain head and neck procedures.

### Filshie® Clip System

UTMD acquired the Filshie Clip System as part of its acquisition of Femcare in March 2011. In 2019, sales of Filshie Clips, applicators and accessories represented 36% 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 2019 was sold OUS directly by UTMD to medical facilities in Canada, Ireland, France, the UK and Australia, and through specialty distributors in other countries. In February 2019, UTMD acquired exclusive U.S. distribution rights from CooperSurgical Inc. (CSI) and began to directly sell the Filshie Clip System 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 either post-partum (following childbirth) or at times unrelated to the post-partum period (interval sterilization), is at least as easy to use, has much less intraoperative risk to apply, has a reported failure rate an order of magnitude less than Bipolar Cautery and is more effective and much simpler to perform than 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 (which is no longer manufactured). 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 clarification 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 typically 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. Marcus Filshie, the inventor of the clip, expressed his opinion in 2002 that more than 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. 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. In 2019, UTMD 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 but often not sought by hospitals. 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 ten 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., recommending the adoption 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 particular 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.

## **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 transducers, 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 2019, UTMD sold components and finished devices to 147 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 2019, as a percentage of consolidated total USD sales, represented 41% compared to 50% in 2018. The lower OUS share of total sales in 2019 was the result of higher sales of Filshie Clip System devices in the U.S. and a stronger USD which diminished foreign currency sales translated into USD terms. 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 2019, 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 260 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 primarily 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 2019 comprised 9% of total domestic direct sales.

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 in 2019 sold to over 260 regional distributors and OEMs (other medical device manufacturers and/or distributors) in over a hundred countries. Ten percent of UTMD's independent OUS distributors comprised 78% of UTMD's indirect OUS sales in the years of 2017 - 2019.

## 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, 2019, the Company had 182 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 164 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 nine unexpired 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 2019, royalties included in cost of goods sold were \$171. 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. During 2019 the Company received \$6 in royalty income, compared to \$76 in 2018 and \$86 in 2017.

#### GOVERNMENT REGULATION

UTMD's products and manufacturing processes are subject to regulation by the U.S. Food & Drug Administration ("FDA"), as well as many other regulatory entities globally. The FDA has authority to regulate the marketing, manufacturing, labeling, packaging and distribution of medical devices in the U.S. Requirements exist under other federal laws and under state, local and foreign statutes that 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 Utah FDA QSR inspection was in July 2014, which did not result in the issuance of any FDA-483 observations. In 2019, UTMD's manufacturing facilities in Utah were audited and certified by a recognized authorized auditing organization under a new Medical Device Single Audit Program (MDSAP). In most circumstances, the new MDSAP eliminates the need for FDA QSR inspections. The Company's most recent UK FDA QSR inspection was in July 2019, which also 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 ISO13485:2016 standard. In 2019, UTMD's manufacturing facilities in Ireland and UK were audited and certified by a recognized authorized auditing organization under the MDSAP. The MDSAP offers an "all-in-one" inspection regime to accommodate the quality system requirements of Australia, Brazil, Canada, USA and Japan.

UTMD remains on a continuous periodic audit schedule by its independent notified body and authorized MDSAP auditing organization 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 all of its major products.

#### 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 in a number of locations worldwide. That notwithstanding, the Company maintains safety stocks that anticipate potential disruption to its supply chain from changes in government policies including tariffs, as well as a possible disruption from the coronavirus, including the time required to source and qualify new vendors. Fortunately, given availability of its significant cash reserves, UTMD has the financial ability to mitigate supply chain risk by carrying extra inventories during periods of increased uncertainty.

Alternative sourcing of various components is continually underway. Vendors are qualified by UTMD's 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 2019 trade revenues in USD terms from customers OUS were \$19,411 (41% of total sales), compared to \$20,806 (50% of total sales) in 2018 and \$21,129 (51% of total sales) in 2017. OUS trade sales (U.S. exports) from the U.S. to OUS customers were \$4,322 in 2019, \$5,427 in 2018 and \$5,357 in 2017. U.S. exports represented 22%, 26% and 25% of total OUS trade sales in 2019, 2018 and 2017, 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 9 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 with fluctuating order patterns. Backlog shippable in less than 90 days was \$1,627 as of January 1, 2020, compared to \$3,164 as of January 1, 2019 and \$3,140 as of January 1, 2018.

## 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 41-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-seven years, including the last nine years following the acquisition of the Filshie Clip System, was less than \$20 per year, well below the deductible level of product liability insurance policies. In its 41 year history of shipping over 50 million finished devices used in critical care and over 400 million components, there has never been a product liability judgment against UTMD. This experience validates that the most important aspect of product liability risk management is the safe design and reliable integrity of manufactured products.

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-seven years, UTMD has been named as a defendant in a total of nine 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 fifth lawsuit, 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 sixth, UTMD was brought into the 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. There have been three Filshie Clip System lawsuits since UTMD acquired Femcare in 2011, all of which were dismissed with prejudice prior to the conclusion of discovery. The average annual cost of Filshie Clip System lawsuits since 2011 was \$8 per year. Other than the Filshie Clip System claims, there have been no product liability lawsuits during the last eight years.

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 they 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 or executive order healthcare reform in the United States, particularly as suggested by leading candidates in a presidential election year, have the potential to render the U.S. medical device marketplace unpredictable. A fully government-run healthcare system would likely eliminate healthcare consumer choice as well as commercial incentives for innovation.

Increasing regulatory burdens, including premarketing approval delays, may result in significant loss of revenue, unpredictable costs and loss of management focus on developing and marketing products that improve the quality of healthcare:

Thousands of small focused medical device manufacturers including UTMD that do not have the overhead structure that the few large medical device companies can afford are increasingly burdened with bureaucratic and underqualified regulator demands that are not reasonably related to assuring the safety or effectiveness of the devices that they provide. Premarketing submission administrative burdens, and substantial “user fees” or notified body review fees, represent a significant non-clinical and/or non-scientific barrier to new product introduction, resulting in lack of investment or delays to revenues from new or improved devices. The risks associated with such circumstances relate not only to substantial out-of-pocket costs, including potential litigation in millions of dollars, but also loss of business and a diversion of attention of key employees for an extended period of time from managing their normal responsibilities, particularly in new product development and routine quality assurance activities.

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 driven by 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 and overly cumbersome 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 suffered 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 devices and/or U.S. made raw materials and components are likely being purchased in fixed USD.

Trade restrictions and /or tariffs resulting from changing government trade policies have the potential to disrupt UTMD's supply chain.

The corona virus outbreak could potentially disrupt UTMD's supply chain, or interfere with normal business operations due to the loss of employee availability.

#### **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 2020, the Company's operations were located in 105,000 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.

In late 2016 UTMD purchased a 38,600 square foot facility in Romsey and subsequently fitted-out the building in 2017 with the capability to manufacture medical devices. 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 12 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:

	2019		2018	
	High	Low	High	Low
1st Quarter	\$ 102.46	\$ 80.22	\$ 101.45	\$ 78.95
2nd Quarter	96.16	76.60	117.65	94.00
3rd Quarter	102.44	82.62	115.15	85.40
4th Quarter	112.26	100.23	99.95	73.98

#### Stockholders.

The number of beneficial stockholders of UTMD's common stock as of March 6, 2020 was at least 2,500.

#### Dividends.

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

<u>Record Date</u>	<u>Payable Date</u>	<u>Per Share Amount</u>
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
December 14, 2018	January 3, 2019	0.275
March 15, 2019	April 2, 2019	0.275
June 14, 2019	July 3, 2019	0.275
September 13, 2019	October 3, 2019	0.275
2018 total cash dividends paid per share		\$ 1.080
2019 total cash dividends paid per share		\$ 1.100

#### Issuer Purchases of Equity Securities.

UTMD purchased 5,000 shares of its common stock for \$398 including commissions and fees in May 2019. UTMD purchased 15,000 shares of its common stock for \$1,205 including commissions and fees in December 2018.

**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, 2019, 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				
	2019	2018	2017	2016	2015
Net Sales	\$ 46,904	\$ 41,998	\$ 41,414	\$ 39,298	\$ 40,157
Net Income	14,727	18,555	8,505	12,128	11,843
Earnings Per Common Share (Diluted)	3.939	4.95	2.28	3.22	3.14
Total Assets	109,787	99,768	92,745	76,191	79,175
Working Capital	51,438	55,643	43,909	31,451	28,807
Long-term Debt	0	0	0	0	0
Cash Dividends Per Common Share	1.100	1.085	1.065	1.045	1.025

## 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.

In the final calendar quarter (4Q) of 2019, Utah Medical Products, Inc. (Nasdaq: UTMD) began to realize accretive profits net of the quarterly amortization of the purchase price paid to CooperSurgical Inc. (CSI) for the acquisition of exclusive Filshie Clip System distribution rights in the U.S. The 4Q results allowed UTMD to meet its beginning of 2019 year projections to stockholders for the year as a whole.

Income statement results in 2019 compared to 2018 were as follows:

	2019	2018	Change
Net Sales	\$ 46,904	\$ 41,998	+11.7%
Gross Profit (GP)	29,466	26,306	+12.0%
Operating Income	17,633	18,697	(5.7%)
Income Before Tax (EBT)	17,884	19,458	(8.1%)
<i>Net Income before TCJA tax adjustments</i>	<i>14,145</i>	<i>15,504</i>	<i>(8.8%)</i>
Net Income per US GAAP	14,727	18,555	(20.6%)
<i>EPS before TCJA tax adjustments</i>	<i>3.784</i>	<i>4.136</i>	<i>(8.5%)</i>
Earnings per Share (EPS) per US GAAP	3.939	4.950	(20.4%)

The 2019 sales increase was the result of 30% higher U.S. domestic sales, led by a \$3,501 increase in domestic sales of the Filshie Clip System and \$2,222 higher U.S. pressure transducer kit sales to an OEM customer. Sales outside the U.S. (OUS) were 7% lower, about half of which (\$631) was the result of a lower foreign currency exchange (FX) rate when converting foreign currency sales to USD. Operating Income and EBT were lower due to a new \$4,053 noncash expense in 2019 resulting from amortizing the \$21,000 purchase price of acquiring the remaining life of the U.S. exclusive distribution rights for the Filshie Clip System in February 2019.

Net Income and EPS per U.S. Generally Accepted Accounting Principles (US GAAP) in both 2019 and 2018 were affected by a change in UTMD's estimate of the IRC 965 Transition (REPAT) Tax initially booked in 2017 resulting from the U.S. "Tax Cuts and Jobs Act" (TCJA) enacted by Congress in December 2017, and the concomitant ensuing Global Intangible Low-Taxed Income (GILTI) tax and Foreign-Derived Intangible Income (FDII) tax credit which liability began in 2018. US GAAP Net Sales, GP, Operating Income and EBT were not affected by the TCJA tax estimate-related adjustments in 2019 or 2018. The adjustments to UTMD's income tax estimates are more fully explained later in this report. Because of the TCJA-related tax estimate adjustments, in UTMD management's view, a comparison of US GAAP Net Income and EPS between 2019 and 2018 does not provide stockholders with meaningful insight about UTMD's financial performance. The non-GAAP results presented above eliminate the TCJA-related tax estimate adjustments from Net Income and EPS.

The associated key 2019 profit margins (profits as a percentage of sales) compared to the 2018 calendar year follow:

	2019	2018
Gross Profit Margin (GPM)	62.8%	62.6%
Operating Income Margin	37.6%	44.5%
Income Before Tax Margin	38.1%	46.3%
<i>Net Income Margin before TCJA tax adjusts</i>	<i>30.2%</i>	<i>36.9%</i>
Net Income Margin per US GAAP	31.4%	44.2%

Measures of the Company's liquidity and overall financial condition improved as of the end of 2019 compared to the end of 2018 as the result of continued strong positive cash flow from normal operations. The Company's continued excellent positive cash flow in 2019 allowed it to increase cash dividends paid to stockholders, repurchase 5,000 UTMD shares in the open market, use \$23,048 to repurchase Filshie Clip System exclusive distribution rights and inventory from CSI and use \$540 in cash for maintaining Property, Plant and Equipment (PP&E) in good working order.

In spite of the above uses of \$28,097 in cash, UTMD's cash equivalent balances at the end of 2019 declined just \$8,325 to \$42,787 compared to \$51,112 at the end of 2018. Working capital declined just \$4,206 to \$51,438 at the end of 2019 from \$55,643 at the end of 2018. Total liabilities decreased \$2,082. The Company remained without debt. UTMD's total debt ratio (total liabilities to total assets) was 8% at the end of 2019 compared to 11% at the end of 2018. Stockholders' Equity increased to \$101,092 from \$88,992 at the end of 2018, despite the 2019 payments of \$4,112 in cash dividends to stockholders and use of \$398 for share repurchases, both of which reduce Stockholders' Equity.

Productivity of Fixed Assets and Working Capital Assets.  
Assets.

Year-end 2019 total consolidated assets were \$109,787 comprised of \$54,885 in current assets, \$10,728 in consolidated net PP&E and \$44,173 in net intangible assets. This compares to \$99,768 total assets at the end of 2018 comprised of \$60,903 in current assets, \$10,359 in consolidated net PP&E and \$28,506 in net intangible assets. Total asset turns (total consolidated sales divided by average total assets for the year) in 2019 were 45%, compared to 44% in 2018, as the growth in sales outpaced the growth in average assets.

Current assets decreased \$6,018 due to a \$8,325 decrease in year-end cash and investments, a \$786 increase in accounts and other receivables and a \$1,501 increase in year-end inventories. Year-end 2019 and 2018 cash and investment balances were \$42,787 and \$51,112, representing 39% and 51% of total assets, respectively. Net (after allowance for doubtful accounts) year-end trade accounts receivable (A/R) balances increased \$756. This was due to the 30% higher domestic sales. Average days in A/R from date of invoice on December 31, 2019 and at December 31, 2018 were both 36 days based on 4Q 2019 and 4Q 2018 shipments respectively. The Company believes any older A/R will be collected or are within its reserve balances for uncollectible amounts. Average 2019 consolidated inventory turns were 2.8 compared to 2.9 in 2018 based on the applicable year's cost of goods sold. The increase in inventories was primarily the result of beginning to directly sell the Filshie Clip System to U.S. medical facilities in 2019.

Working capital (current assets minus current liabilities) at year-end 2019 was 8% lower at \$51,438 compared to \$55,643 at year-end 2018. Consistent with Federal and State rules, the REPAT tax current liability was only \$101 at the end of 2019. The end of 2019 working capital significantly exceeds UTMD's needs for normal operations, funding future organic growth and timely payment of accrued tax liabilities, in addition to allowing for substantial funding of any future acquisition without diluting stockholder interest.

December 31, 2019 net \$10.7 million total 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. Manufacturing facilities in Utah, Ireland and the UK are standalone buildings with a combined 220,000 square feet on 15 acres of land. The distribution facilities in Australia and Canada with a combined 8,000 square feet are part of larger industrial condominiums. Management estimates the fair market value of the five owned facilities to be at least \$21 million excluding the contents, the fungible value of which increases stockholder enterprise value relative to most of UTMD's industry peers which lease their facilities.

Ending 2019 net consolidated PP&E (depreciated book value of all fixed assets) increased \$369 as a result of the combination of capital expenditures of \$540, depreciation of \$700 and the effect of 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:

	12-31-19	12-31-18
EUR	1.1227	1.1456
GBP	1.3268	1.2760
AUD	0.7030	0.7046
CAD	0.7715	0.7329

The year-end 2019 net book value (after accumulated depreciation) of consolidated PP&E was 32% of purchase cost. End-of-year PP&E turns (Net Sales divided by Net PP&E) was 4.4 in 2019 compared to 4.1 in 2018 due primarily to the 12% higher 2019 sales. A future leverage in productivity of fixed assets which will not have to be increased to support new business activity will be a source of incremental profitability.



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 \$44,173 (40% of total assets) at the end of 2019 compared to \$28,506 (29% of total assets) at the end of 2018. 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 2019 were net IIA of \$13,202 and goodwill of \$6,770. The accumulated amortization of Femcare IIA as of December 31, 2019 since the March 18, 2011 acquisition was \$18,750. The remaining Femcare IIA will be fully amortized in 6 more years. The goodwill portion of intangible assets resulting from the Femcare acquisition, which is not amortized, increased \$259 due to a stronger GBP at year-end. The GBP FX rate at December 31, 2019 increased 4.0% from December 31, 2018. In 2019, UTMD acquired an additional \$21,000 IIA from the purchase of the remaining life of exclusive U.S. distribution rights for the Filshie Clip System from CSI, of which \$4,053 was amortized during the year. The remaining CSI IIA will be fully amortized in 4 more years. UTMD's goodwill balance including the Femcare goodwill was \$13,961 at the end of 2019, 32% of total net intangibles.

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 2020. Amortization of IIA was \$6,144 in 2019 compared to \$2,191 in 2018. The difference was essentially the amortization of \$21,000 new IIA resulting from the acquisition of CSI remaining Filshie Clip System exclusive U.S. distribution rights in 2019. The 2019 non-cash amortization expense of Femcare IIA was \$2,037 (£1,595) compared to \$2,130 (£1,595) in 2018. The Femcare IIA amortization USD difference was again due to the change in USD/GBP FX rate. The 2020 non-cash amortization expense (included as part of operating expenses) of Femcare IIA will again be £1,595, or \$2,074 if the USD/GBP average FX rate is 1.30. The 2019 non-cash amortization expense of CSI IIA was \$4,053 compared to zero in 2018. The 2020 operating expense resulting from amortization of CSI IIA will be \$4,421.

#### Liabilities.

The remaining \$2,212 balance of the corrected \$2,792 total REPAT tax liability from the TCJA is 79% instead of 84% (after the allowed 16% in the first two years of eight years' pay out), because the initial Federal and State payments were based on an initial estimate which was conservatively too high at \$6,288 compared to the current adjusted estimate of \$2,792. 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.

Year-end 2019 current liabilities were \$1,812 lower than at the end of 2018. Ending accrued liabilities were \$1,952 lower due to lower taxes payable and lower customer deposits. Total liabilities were \$2,082 lower at the end of 2019 compared to the end of 2018. The resulting 2019 year-end total debt ratio was 8% compared to 11% at the end of 2018.

The year-end 2019 DTL balance created as a result of the fifteen year deferred tax consequence of the amortization of Femcare's IIA was \$2,239, down from \$2,541 at the end of 2018. The relatively small decline in this DTL considering the \$2,037 in 2019 amortization of IIA (suggesting a 15% tax rate) was due to a 4% stronger GBP compared to the USD at the end of 2019 compared to the end of 2018. 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 2019, 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 ASC 606: 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, Australia and Canada 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 9% of UTMD's domestic end-user sales 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 OUS sales. Domestic sales in 2019 included 1) direct domestic sales, sales of finished devices to end-user facilities and med/surg distributors in the U.S., and 2) domestic OEM sales, sales of components or finished products, which may not be medical devices, to other companies for inclusion in their products. In 2018, domestic sales included the above two items (except that direct domestic sales did not include the Filshie Clip System) plus 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 in 2018) 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 had 2019 intercompany sales of components and/or finished devices to other UTMD entities.

Global consolidated trade sales in 2019 were \$46,904 compared to \$41,998 in 2018 and \$41,414 in 2017. The \$4,906 (+11.7%) higher sales in 2019 were the result of several offsetting factors described below. Total U.S. domestic sales were up \$6,302 (+29.7%) in 2019, at \$27,493 compared to \$21,192 in 2018. OUS sales were down \$1,395 (6.7%) at \$19,411 compared to \$20,806 in 2018.

#### Domestic Sales.

U.S. domestic sales in 2019 were \$27,493 (59% of total sales) compared to \$21,192 (50% of total sales) in 2018. The contributors to the 2019 total \$6,302 (+29.7%) higher domestic sales were \$3,501 (+106%) higher sales of Filshie Clip System devices in the U.S., \$2,452 (+60%) higher sales of components and finished devices used in other companies' products (OEM customers), and \$349 (+3%) higher direct sales of non-Filshie finished devices to domestic end-users. Domestic sales in 2017 were \$20,286.

Domestic Filshie Clip System sales in 2019 were 25% of total U.S. domestic sales compared to 16% in 2018. The higher domestic Filshie Clip System sales occurred as a result of converting from Femcare UK sales to a domestic distributor in 2018 to UTMD sales directly to end-users in 2019.

Domestic OEM sales in 2019 were 24% of total U.S. domestic sales compared to 19% in 2018. UTMD sold components and finished devices to 147 different U.S. companies in 2019 compared to 152 companies in 2018 for use in their product offerings. Sales to UTMD's largest OEM customer, representing 75% of total domestic OEM sales, were up \$2,222 (+82%). Although this customer has projected higher purchases from UTMD in 2020, UTMD is expecting lower 2020 sales due to recognizing the customer's inventory build-up.

Domestic direct (end-user) sales excluding the Filshie Clip System were 51% of total U.S. domestic sales in 2019 compared to 65% in 2018. Of UTMD's three main domestic direct categories, neonatal products were \$4,654 (+2% higher), labor & delivery (L&D) products were \$4,053 (+8% higher), and gynecology/ electrosurgery/ urology products excluding the Filshie Clip System were \$4,826 (about the same).

#### OUS Sales.

Sales OUS in 2019 were \$19,411 (6.7% lower) compared to \$20,806 in 2018. OUS sales were \$21,129 in 2017.

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. UTMD's FX rates for income statement purposes are transaction-weighted averages. The average rates from the applicable foreign currency to USD during 2019 compared to 2018 follow:

	2019	2018	Change
GBP	1.277	1.334	(4.3%)
EUR	1.119	1.180	(5.1%)
AUD	0.696	0.747	(6.9%)
CAD	0.754	0.773	(2.5%)
Sales weighted-average change:			(4.7%)

Forty-five percent (\$631) of the \$1,395 lower OUS sales were due to the changes in FX rates (stronger USD in 2019). EUR currency sales in 2019 were reduced \$277 compared to what the same EUR sales in 2018 would have been expressed in USD. GBP currency sales in 2019 were reduced \$174 compared to what the same GBP sales in 2018 would have been expressed in USD. AUD currency sales in 2019 were reduced \$126 compared to what the same AUD sales in 2018 would have been expressed in USD. CAD currency sales in 2019 were reduced \$54 compared to what the same CAD sales in 2018 would have been expressed in USD.

Sixty-six percent of (USD denominated) 2019 OUS sales were invoiced in foreign currencies compared to 67% in 2018. As a portion of total USD consolidated sales, 27% of UTMD's USD-equivalent sales were invoiced in foreign currencies in 2019 compared to 33% in 2018. The GBP, EUR, AUD and CAD converted sales represented 8%, 11%, 4% and 4% of total 2019 USD sales, respectively. This compares to 10% GBP, 12% EUR, 5% AUD and 6% CAD of total 2018 USD sales. The lower converted foreign currency sales percentages of total sales in 2019 were not only due to the stronger USD, but also much higher domestic sales.

Variations in order pattern of UTMD's China distributors, one for BPM devices and another for neonatal devices, continue to be significant from year-to-year. The China BPM distributor purchased \$662 more and the China neonatal device distributor \$519 less in 2019 compared to 2018, largely offsetting one another. UTMD expects that the reverse might be the case in 2020.

USD-denominated trade (excludes intercompany) sales of devices to OUS customers by UTMD's Ireland facility (UTMD Ltd) were \$5,894 (+18%) in 2019 compared to \$5,008 in 2018. As the EUR was down 5.1% relative to the USD in 2019, the FX impact subtracted \$277 from 2019 sales. In other words, constant currency sales were \$6,171 (+23%). UTMD Ltd produces the BPM devices sold to UTMD's China distributor. In constant EUR currency and eliminating sales of BPM devices to its China distributor in both years 2019 and 2018, 2019 Ireland trade sales experienced 13% growth compared to 2018.

In 2019, UTMD's UK subsidiary, Femcare Ltd., had \$5,382 trade sales of devices to domestic UK, domestic France and international distributor customers, down 8% compared to \$5,849 in 2018. The FX impact subtracted \$174 (4.3%) from 2019 sales, explaining about half of the lower sales in USD terms. The 2018 trade sales figure excludes sales to CSI, which in 2019 were intercompany sales.

USD-denominated sales of devices to end-users in Australia by Femcare's Australia distribution subsidiary (Femcare Australia Pty Ltd) were 12% lower in 2019 compared to 2018. The FX impact subtracted \$126 (6.9%) from 2019 sales, explaining 57% of the lower sales.

USD-denominated sales of devices to end-users in Canada by UTMD's Canada distribution subsidiary (Utah Medical Products Canada, Inc.) were 18% lower in 2019 compared to 2018. The FX impact subtracted \$54 (2.5%) from 2019 sales, explaining 14% of the lower sales.

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 transducers and 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:

	2019	%	2018	%	2017	%
Obstetrics	\$ 5,000	11	\$ 4,447	11	\$ 4,499	11
Gynecology/ Electrosurgery/						
Urology	25,354	54	23,167	55	23,175	56
Neonatal	6,066	13	6,436	15	6,154	15
Blood Pressure Monitoring						
and Accessories*	10,484	22	7,948	19	7,586	18
Total:	\$ 46,904	100	\$ 41,998	100	\$ 41,414	100

OUS revenues by product category:

	2019	%	2018	%	2017	%
Obstetrics	\$ 947	5	\$ 698	3	\$ 732	3
Gynecology/ Electrosurgery/						
Urology	13,731	71	15,022	72	14,759	70
Neonatal	1,412	7	2,252	11	2,105	10
Blood Pressure Monitoring						
and Accessories*	3,321	17	2,834	14	3,533	17
Total:	\$ 19,411	100	\$ 20,806	100	\$ 21,129	100

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

Looking forward to 2020, there again appear to be several offsetting influences on projected sales which may not be minor. Although FX rates over the course of the year are not predictable, the projected strength of the U.S. economy as well as geopolitical tensions suggest that the USD is unlikely to weaken relative to other currencies in 2020. A stronger USD reduced total sales 1.3% in 2019. UTMD's OUS distributor varying order patterns are likely to continue, but hopefully offsetting one another. UTMD's 2020 sales of BPM products to its China distributor, based on its initial annual fixed order, are projected to be \$220 lower than in 2019, a year in which sales to this distributor were \$662 higher than in 2018. On the other hand, based on recent activity, 2020 sales of neonatal products to international distributors are likely to be higher by about the same \$220 amount. In order to stay ahead of its rapid growth by building inventory, UTMD's largest OEM customer substantially increased 2019 purchases from UTMD in the U.S. and Ireland by \$2,407. It seems likely to UTMD that purchases from this customer in 2020 may be at least \$700 lower than in 2019 to more closely match its actual growth in demand. UTMD's sales of its niche L&D and gynecology devices excluding the Filshie Clip System are stable, but slow growing. Although the Company remains optimistic about increasing sales of its proven safe and very effective Filshie Clip System for tubal ligation, particularly in the U.S., growth may also be slow as an adjunct from the negative social media that has confused complications of Bayer's Essure tubal ligation device, which was removed from the market, with the Filshie Clip System. In summary, management currently believes overall UTMD year 2020 USD-denominated consolidated revenues are likely to not increase more than low single percentage digits.

b) Gross Profit (GP).

UTMD's 2019 consolidated GP, the surplus after subtracting costs of manufacturing, which includes purchasing raw materials, forming components, assembling, inspecting, testing, packaging and sterilizing products, from net revenues, was \$29,466 (62.8% of sales) compared to \$26,306 in 2018 (62.6% of sales) and \$26,395 (63.7% of sales) in 2017. GP in 2019 increased \$3,161, which was 64.4% of the \$4,906 increase in sales.

UTMD's expected 2019 GPM increase was damped by the need to sell the remaining Filshie Clip System inventory obtained from CSI as part of UTMD's acquisition of the remaining life of CSI's exclusive U.S. distribution agreement. The CSI inventory was purchased by UTMD at CSI's prior distributor price from Femcare. In other words, the margin received by UTMD from selling the CSI remaining inventory during most of 2019 was limited to the distributor margin, not the margin over the manufacturing cost.

In addition, there was a product mix change in 2019 which affected GPMs because OEM sales, which grew faster than other sales categories, have inherently lower GPMs than direct end-user device sales. With OEM sales, another entity incurs operating expenses including sales and marketing (S&M) expenses, as well as much of product development (R&D) and general and administrative (G&A) expenses. In addition to the product mix change, actual raw material price increases and increased freight-in expense from raw material vendors helped damp the GPM. However, fixed manufacturing overhead costs were diluted by higher sales and, despite higher loaded (by benefits and taxes) labor costs, the Company maintained direct labor productivity in 2019 consistent with the prior year.

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 2,908 in 2019 compared to EUR 3,606 in 2018 and EUR 3,234 in 2017. The associated GPMs were 43.1% in 2019, 49.8% in 2018, and 47.5% in 2017. Despite higher trade sales, the lower GP and GPM in 2019 were due to much lower intercompany sales of Sterishot (Filshie) kits manufactured by UTMD Ltd. due to lower sales in Canada and Australia, and the need to deplete the CSI inventory in the U.S. In addition, the \$662 higher China distributor BPM sales, priced at a very low GPM compared to other device sales, were from UTMD Ltd.

Femcare UK GP was GBP 3,884 in 2019 compared to GBP 5,010 in 2018 and GBP 5,317 in 2017. The lower GP in 2019 was due to the fact that the UK had no sales of Filshie Clip System devices to CSI in 2019 compared to \$3,296 in 2018, and had limited intercompany Filshie Clip System device sales to the U.S. because of the need to deplete the CSI inventory. The UK 2019 GPM was 70.2% compared to 71.7% in both 2018 and 2017.

Femcare Australia and Femcare Canada are purely distribution facilities for UTMD finished devices in their respective countries. Australia GP was AUD 1,415 in 2019, compared to AUD 1,526 in 2018 and AUD 1,846 in 2017. In addition to 5.8% lower AUD sales, Femcare Australia 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 57.7% in 2019, 58.7% in 2018, and 62.7% in 2017. Canada GP was CAD 1,670 in 2019 (54.5% of sales) compared to CAD 1,999 in 2018 (60.0% of sales) and 2,300 (60.2% of sales) in 2017, its first year of operation. The 16% lower GP was due to 16% lower CAD sales in 2019 compared to 2018, UTMD's weakest sales region.

In the U.S., GP was \$19,180 in 2019, compared to \$13,065 in 2018 and \$12,497 in 2017. UTMD U.S. GPMs were 57.1% in 2019, 54.1% in 2018, and 55.0% in 2017. Because UTMD in the U.S. grew its trade sales by 36% including direct sales of Filshie Clip System devices, and maintained its intercompany sales of components and finished devices, despite the high growth in lower margin OEM product sales, it was able to increase GP by 47%.

A summation of the above 2019 GP of each subsidiary will not yield consolidated total GP because of elimination of profit in inventory of intercompany goods. UTMD expects an increase in its consolidated 2020 GPM.

c) Operating Income.

Operating Income results from subtracting operating expenses from GP. Operating Income in 2019 was \$17,632 (37.6% of sales) compared to \$18,697 in 2018 (44.5% of sales), and \$19,011 (45.9% of sales) in 2017. The lower 2019 Operating Income margin reflected the new CSI IIA amortization expense (8.6% of sales) included in General and Administrative (G&A) operating expenses. Excluding non-cash Femcare and CSI IIA amortization expenses, UTMD consolidated operating expenses were 12.2% of sales in 2019, compared to 13.0% in 2018 and 12.9% in 2017.

The UTMD Ltd (Ireland) Operating Income margin in 2019 was 38.5% compared to 45.9% in 2018, and 42.7% in 2017. Femcare UK's 2019 Operating Income margin was 27.8% compared to 38.1% in 2018, and 40.1% in 2017. Femcare Australia's 2019 Operating Income margin was 38.6% compared to 45.4% in 2018, and 50.0% in 2017. Femcare Canada's 2019 Operating Income margin was 41.9% compared to 49.1% in 2018, and 51.5% in 2017. UTMD's 2019 Operating Income margin in the U.S. was 33.7% compared to 39.1% in 2018, and 39.8% in 2017. The new CSI IIA amortization expense hit the 2019 U.S. Operating Income margin, and the Femcare IIA amortization expense hit the Femcare UK Operating Income margin in years 2017-2019.

Operating expenses include sales and marketing (S&M) expenses, product development (R&D) expenses and G&A expenses. Consolidated operating expenses were \$11,834 (25.2% of sales) in 2019, \$7,608 (18.1% of sales) in 2018 and \$7,385 (17.8% of sales) in 2017. The following table provides a comparison of operating expense categories, as well as further segmentation of G&A expenses, for the last three years.

	2019	2018	2017
S&M expenses	\$ 1,738	\$ 1,708	\$ 1,544
R&D expenses	483	454	448
G&A expenses:			
a) litigation expense provision	16	(8)	29
b) corporate legal	32	32	32
c) stock option compensation	113	64	129
d) management bonus accrual	403	373	430
e) outside accounting audit/tax	216	238	196
f) Femcare IIA amortization	2,037	2,131	2,055
g) CSI IIA amortization	4,053	-	-
property & liability insurance			
h) premiums	91	126	155
i) all other G&A expenses	2,652	2,491	2,367
G&A expenses – total	9,613	5,447	5,393
Total Consolidated Operating Expense:	\$ 11,834	\$ 7,608	\$ 7,385
Percent of sales:	25.2%	18.1%	17.8%

Description of Operating Expense Categories

i) S&M expenses:

S&M expenses in 2019 were \$1,738 (3.7% of 2019 sales) compared to \$1,708 (4.1% of 2018 sales), and \$1,544 (3.7% of sales) in 2017.

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, and paying commissions to outside independent representatives. In markets where UTMD sells directly to end-users, which in 2017-2019 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. A trade-off for the higher GP obtained from selling directly at end-user prices is higher S&M expenses.

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.

ii) R&D expenses:

R&D expenses were \$483 (1.0% of sales) in 2019 compared to \$454 (1.1% of sales) in 2018, and \$447 (1.1% of sales) in 2017. 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 2019, 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.

iii) G&A expenses:

G&A expenses in 2019 were \$9,613 (20.5% of sales) compared to \$5,447 (13.0% of sales) in 2018 and \$5,393 (13.0% of sales) in 2017. 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 2019 was the same as in 2018, because of the weaker GBP for the year as a whole, the USD 2019 IIA amortization expense was \$94 lower than in 2018. The resulting G&A noncash amortization expense of Femcare IIA was 4.3% of total consolidated 2019 sales compared to 5.1% of total 2018 sales, and 5.0% of total sales in 2017. 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 U.S. distribution rights became an IIA which will be amortized on a straight line basis over the remaining life of the Femcare distribution agreement with CSI which was through 3Q 2023. This new IIA amortization expense included in G&A expenses, which began in February 2019, was \$4,053 in 2019 (8.6% of total sales). The 2019 new CSI IIA amortization expense exceeded UTMD's increase in GP by \$892. In 2020, a full year's CSI IIA amortization expense will be \$4,421. In contrast to 2019, as a result of management's projected 2020 increase in GPM, the GP benefit of acquiring the CSI distribution agreement should exceed the IIA amortization expense.

d) Non-operating income/Non-operating expense, and Earnings Before Taxes (EBT).

Non-operating income 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 from the sale of assets. Non-operating expense includes interest on bank loans, bank service fees, excise taxes and losses from the sale of assets. Also, 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 non-operating income or expense, as applicable.

Net non-operating income (combination of non-operating income and non-operating expense) was \$252 in 2019 compared to \$761 in 2018, and \$71 in 2017. The non-operating income in 2018 included a \$450 gain from the sales of assets which did not recur in 2019. A description of components of UTMD's non-operating income or expense follows:



- 1) Interest Expense. There was no interest expense in 2017-2019. Absent an acquisition or large repurchase of shares that requires new borrowing, UTMD does not expect any interest expense in 2020.
- 2) Investment of excess cash. Consolidated investment income (including gains and losses on sales of investments) was \$255 in 2019 compared to \$248 in 2018, and \$17 in 2017. 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.
- 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 2019 were \$5 compared to \$76 in 2018, and \$86 in 2017. UTMD did not receive a CSI royalty in 2019 after January 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 a non-operating expense of \$76 in 2019 compared to non-operating income of \$13 in 2018, and non-operating income of \$4 in 2017 from losses or 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.
- 5) Other non-operating income or expense. Income received from renting unused warehouse space in Ireland and parking lot space in Utah for a cell phone tower, offset by bank fees, and other miscellaneous non-operating expenses resulted in a net non-operating expense of \$85 in 2019 compared to \$3 in 2018 and \$36 in 2017.

EBT results from adding net non-operating income or subtracting net non-operating expense from Operating Income. Consolidated EBT was \$17,884 (38.1% of sales) in 2019 compared to \$19,458 (46.3% of sales) in 2018, and \$19,082 (46.1% of sales) in 2017. The 2019 EBT of UTMD Ltd. (Ireland) was €2,577 (38.2% of sales) compared to €3,144 (43.4% of sales) in 2018, and €2,779 (40.8% of sales) in 2017. Femcare UK's 2019 EBT was £1,566 (28.3% of sales) compared to £2,896 (41.5% of sales) in 2018, and £3,155 (42.5% of sales) in 2017. Femcare AUS's 2019 EBT was AUD 952 (38.8% of sales) compared to AUD 1,183 (45.5% of sales) in 2018, and AUD 1,473 (50.0% of sales) in 2017. Femcare Canada's 2019 EBT was CAD 1,280 (41.8% of sales) compared to CAD 1,632 (49.0% of sales) in 2018, and 1,906 (49.9% of sales) in 2017.

As a side note for clarity of financial results, UTMD's 2019, 2018 and 2017 EBT, as well as all other income statement measures above the EBT line in the Income Statements, were unaffected by estimates of the REPAT tax and associated GILTI tax and FDII tax credit, all of which resulted from the TCJA enacted in late 2017.

EBITDA is a non-US GAAP metric that UTMD management believes is of interest to investors because it provides meaningful supplemental information to both management and investors that represents profitability performance without factoring in effects of financing, accounting decisions regarding non-cash expenses, capital expenditures or tax environments. If the Company were to need to borrow to pay for a major asset or acquisition, the projected EBITDA metric would be of primary interest to a lending institution to determine UTMD's credit worthiness. Although the U.S. Securities and Exchange Commission advises that EBITDA is a non-GAAP metric, UTMD's non-US GAAP EBITDA is the sum of the following elements in the table below, each of which is a US GAAP number:

	2019	2018	2017
EBT	\$ 17,884	\$ 19,458	\$ 19,082
Depreciation Expense	700	765	660
Femcare IIA Amortization Expense	2,037	2,130	2,055
CSI IIA Amortization Expense	4,053	0	0
Other Non-Cash Amortization Expense	54	60	57
Stock Option Compensation Expense	113	64	129
Remeasured Foreign Currency Balances	76	(13)	(4)
UTMD non-US GAAP EBITDA:	<u>\$ 24,917</u>	<u>\$ 22,464</u>	<u>\$ 21,979</u>

In summary, UTMD's 2019 non-US GAAP EBITDA grew 10.9% compared to 2018, despite lower EBT. This is indicative of the benefit of UTMD's acquisition of the CSI distribution agreement.

e) Net Income, Earnings Per Share (EPS) and Return on Equity (ROE).

Net Income

Net Income results after subtracting a provision for estimated income taxes from EBT. UTMD's US GAAP Net Income in 2019 was \$14,727 (31.4% of sales) compared to \$18,555 (44.2% of sales) in 2018, and \$8,505 (20.5% of sales) in 2017. Because of changes in tax estimates for the years 2017-2019 due to the TCJA enacted in December 2017, management does not believe either that the estimated tax provisions have a direct relationship to sales in the same periods, or that the year-to-year changes in US GAAP Net Income is indicative of UTMD's financial performance. Ignoring the REPAT and associated TCJA tax adjustments in



2017-2019, 2019 non-US GAAP Net Income was \$14,145 (30.2% of sales) compared to 2018 non-US GAAP Net Income of \$15,504 (36.9% of sales), and non-US GAAP Net Income of \$14,562 (35.2% of sales) in 2017.

Adding to the difference in 2019 Operating Income compared to 2018, US GAAP Net Income and EPS in 2019 were affected by another change in UTMD's estimate of its State tax liability under the TCJA. Stockholders may recall that UTMD recorded a 3Q 2018 favorable \$3,230 adjustment to its initial estimate of the combined Federal and Utah State IRC 965 transition (REPAT) tax recorded in 4Q 2017 financial results, and an unfavorable \$129 adjustment in 4Q 2018 for the new Global Intangible Low-Taxed Income (GILTI) tax. The 2018 tax estimate adjustments made to UTMD's income tax provision had a substantial positive impact on U.S. GAAP 2018 Net Income and EPS with which 2019 results are compared. As additional IRS guidance has become available, and the State of Utah's policy for the calculation of its REPAT tax and GILTI tax has become more clear despite lack of published guidance, UTMD's independent tax advisors have recently recommended a further \$582 favorable estimate adjustment, which has been recorded in UTMD's 4Q 2019 income tax provision. The adjustment emanates from an updated estimate of the 2017 Utah REPAT tax, application of Utah rules for income apportionment and further clarification of the new Foreign-Derived Intangible Income (FDII) regime associated with the GILTI regime as part of the TCJA. In summary, UTMD's initial \$6,288 conservative estimate of the combined Federal and State REPAT tax has ended up, after two subsequent adjustments, to only be \$2,792. In addition, the new GILTI tax on foreign subsidiary income is more than offset by the FDII tax credit for UTMD's exports of devices manufactured in the U.S. Despite management's initial comments after the TCJA was enacted, the resulting lower income taxes looking forward should be of substantial benefit to stockholders.

The US GAAP consolidated income tax provision rate for 2019 was 17.7% of EBT compared to 4.6% of EBT in 2018, and 55.4% of EBT in 2017. The non-US GAAP consolidated combined income tax provision rate for 2019 was 20.9% of EBT compared to 20.3% of EBT in 2018 and 23.7% in 2017. In general, year-to-year fluctuations in the combined tax provision rate will result from variation in EBT contribution from subsidiaries in jurisdictions with different corporate income tax rates. Taxes in foreign subsidiaries are based on taxable EBT in those sovereignties, which can be different from the contribution to consolidated EBT per US GAAP.

The UK had an income tax rate of 20% in 1Q 2017 and a rate of 19% thereafter. 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 UK tax specialists. The 2019 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. As UTMD stockholders likely know, in the U.S. the current Federal income tax rate is 21%, down from 34% prior to the TCJA. Federal taxes are not 21% of U.S. EBT, however, as income taxes paid to the State are a deductible expense for Federal tax purposes, other expenses are not deductible and there remains an R&D tax credit along with other credits, not to mention the new GILTI tax and FDII tax credit. The State income tax rate declined to 4.95% from 5% prior to the TCJA, but the State has enacted new income apportionment rules that provide for additional tax relief, and has its own (not formally published yet) rules for calculating the State REPAT, GILTI and FDII provisions of the TCJA.

#### EPS

EPS are Net Income 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 2019 per US GAAP were \$3.939 (\$3.784 prior to the State REPAT tax correction) compared to \$4.950 (\$4.136 prior to the REPAT tax correction and GILTI tax provision) in 2018, and \$2.276 in 2017 (\$3.897 prior to the REPAT tax and DTL adjustment). The 2019 non-US GAAP EPS result met management's projection at the beginning of the year.

The 2019-ending weighted average number of diluted common shares (the number used to calculate diluted EPS) was 3,739 (in thousands) compared to 3,749 in 2018, and 3,737 shares in 2017. Dilution for "in the money" unexercised options for the year 2019 was 18 (in thousands) compared to 18 shares in 2018, and 19 shares in 2017. Actual outstanding common shares as of December 31, 2019 were 3,722.

UTMD management believes that the presentation of Net Income and EPS results excluding the REPAT tax liability estimate in 2017 and adjustments in 2018 and 2019 provides meaningful supplemental information to both management and investors that is more clearly indicative of UTMD's bottom line results in comparing 2019 to the prior years 2018 and 2017. Net Income and EPS are presented below both according to GAAP and also prior to recognition of various tax estimates related to the TCJA.

#### US GAAP:

	2019	2018	2017
Net Income	\$ 14,727	\$ 18,555	\$ 8,505
Net Income Margin	31.4%	44.2%	20.5%
EPS	\$ 3.939	\$ 4.950	\$ 2.276

#### Non-US GAAP (excluding TCJA REPAT tax in 2017 and adjustments in 2018 and 2019):

	2019	2018	2017
Net Income	\$ 14,145	\$ 15,504	\$ 14,562
Net Income Margin	30.2%	36.9%	35.2%
EPS	\$ 3.784	\$ 4.136	\$ 3.897

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

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

To summarize 2019 financial results, UTMD achieved substantial growth in domestic revenues, but due to the strength of the USD, realized lower USD-denominated sales and demand OUS. Although GP grew consistent with sales, UTMD's GPM did not expand as much as expected to cover the new IIA amortization expense associated with the acquisition of the exclusive U.S. distribution rights for the Filshie Clip System from CSI. As a result, Operating Income was 5.7% lower than in 2018 despite continued excellent management of operating expenses. Without the same non-operating income benefit of asset sales in 2018, UTMD's 2019 non-US GAAP Net Income (ignoring tax estimate changes in both 2019 and 2018) declined 8.8% and non-US GAAP EPS declined 8.5% because of slightly lower diluted shares outstanding. Net Income and EPS met management's projections provided to stockholders at the beginning of the year (excluding the favorable income tax provision estimate adjustments).

Looking forward, because of the lack of predictability of UTMD's largest OEM customer's demand, the variability of FX rates affecting UTMD's foreign currency sales not to mention OUS distributor demand patterns, and expected slower growth in Filshie Clip System demand, management conservatively projects 2020 consolidated sales about the same as in 2019. An expected higher GPM, however, should fuel UTMD's continued growth in its non-US GAAP EBITDA metric. In a U.S. presidential election year, considering the rhetoric of leading candidates, that's about as specific as the Company can be in projecting the future.

#### ROE

Maintaining a high ROE is a key management objective for UTMD in order to grow without diluting stockholder interest. ROE is the quotient of Net Income divided by average Stockholders' Equity, but more specifically it is the product of the Net Income margin, productivity of assets and financial leverage. Although UTMD's high Net Income margin is the primary factor that continues to drive its ROE, cash dividends to stockholders and repurchase of shares help in lowering average Stockholders' Equity, reducing the denominator in calculating ROE. Before dividends, UTMD's 2019 ROE was 14.9% compared to 18.6% in 2018, and 19.8% in 2017 excluding the effect of the tax adjustments on Net Income associated with the TCJA. The lower 2019 ROE was the result of 8.8% lower non-US GAAP NI and 13.7% higher average Stockholders' Equity.

Because of its magnitude, the REPAT tax estimate in 2017, and estimate adjustments in both 2018 and 2019, had a significant impact on the overall ROE ratios, even though the REPAT tax amounts reduce both the numerator and denominator. UTMD's 2019 ROE before stockholder dividends (with US GAAP Net Income) was 15.5%. In comparison, 2018 ROE was 22.2%, and 2017 ROE was 4.6% with US GAAP Net Income. Because of the impact on Net Income from the over-estimate of the REPAT tax in 2017 and the corrections in 2018 and 2019, stockholders might consider that the average ROE of 14% is more indicative of results in all three years. Average Stockholders' Equity was \$95,042 in 2019 compared to \$83,557 in 2018, and \$73,683 in 2017. Maintaining a high ROE with the dilutive effect of rapidly growing Average Stockholders' Equity (despite reductions from dividends and stock repurchases) 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 \$17,056 in 2019 compared to \$16,834 in 2018, and \$16,908 in 2017. Changes in 2019 changes in cash from operating activities compared to 2018 changes (second order derivative) were largely related to the REPAT tax and acquisition of the CSI distribution rights: 1) largely with regard to the REPAT tax, \$3,827 smaller US GAAP net income, a \$2,397 smaller adjustment reduction to the long term REPAT tax payable, and a \$1,093 larger decrease in accrued liabilities (taxes payable); and 2) largely with regard to the CSI acquisition, a \$3,953 increase in non-cash amortization expense, a \$1,442 larger increase in inventories and a \$242 larger increase in accounts receivable. In addition, in 2019 UTMD realized a \$457 smaller gain on disposal of assets including investments compared to 2018. Other changes were generally consistent with prior year changes relative to effective working capital management and sales activity.

In investing activities, during 2019 UTMD used \$540 to purchase new molds and manufacturing equipment to maintain and improve operating capabilities, compared to using \$402 for that purpose in 2018. Also in 2019, UTMD used \$21,000 to purchase the remaining life of CSI's exclusive U.S. distribution rights for the Filshie Clip System.

In 2019 UTMD received \$283 and issued 7,042 shares of stock upon the exercise of employee and director stock options. Employees and directors exercised a total of 7,110 option shares in 2019, with 68 shares immediately being retired as a result of optionees trading the shares in payment of the exercise price of the options. Option exercises in 2019 were at an average price of \$40.80 per share. The Company received a \$23 tax benefit from option exercises in 2019, which is reflected in net income as a result of adopting a new accounting standard in 2017. UTMD repurchased 5,000 shares of its stock in the open market during 2019 at an average cost of \$79.52 per share.

In comparison, 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 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.

UTMD did not borrow in any of the three years 2017-2019. Cash dividends paid to stockholders were \$4,112 in 2019 compared to \$4,026 in 2018, and \$2,955 in 2017. 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 2020 capital expenditures for ongoing operations are expected to be more than depreciation of PP&E, primarily because the Midvale facility will receive a new roof costing about \$300 with an expected 15-year useful life.

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 2020, UTMD again plans to

- 1) exploit distribution and manufacturing synergies by further integrating capabilities and resources in its multinational operations;
- 2) focus on effectively direct marketing 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 2019, the value of UTMD's stock increased 30%, ending the year at \$107.90/ share, while \$1.10 in cash dividends/ share were paid. In comparison, the DJIA, S&P 500 and NASDAQ indices were up 22%, 29% and 35% respectively in 2019.

Taking a longer term view, as of the end of 2019 from the end of 1998, UTMD's share price increased 1,544%, representing a 14.3% annually compounded share price increase over the twenty-one year time span. If additional returns to stockholders from cash dividends are added, stockholder value increased 1,780% over the twenty-one year time span, representing 15.0% annually compounded growth in value. In comparison to UTMD's 1,544% increase in stock value over the past twenty-one years, the NASDAQ Composite Index was up 309%, the S&P 500 Index was up 163% and the DJIA was up 211%.

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, 2019:

<u>Contractual Obligations and Commitments</u>	<u>Total</u>	<u>2020</u>	<u>2021-2022</u>	<u>2023-2024</u>	<u>2025 and thereafter</u>
Long-term debt obligations	\$ -	\$ -	\$ -	\$ -	\$ -
Operating lease obligations	554	60	104	90	300
Purchase obligations	2,504	2,405	99	-	-
Total	<u>\$ 3,058</u>	<u>\$ 2,465</u>	<u>\$ 203</u>	<u>\$ 90</u>	<u>\$ 300</u>

#### 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 .8907, .8729 and .8319 EUR per USD as of December 31, 2019, 2018 and 2017, respectively. Exchange rates were .7537, .7837 and .7395 GBP per USD as of December 31, 2019, 2018 and 2017, respectively. Exchange rates were 1.4226, 1.4193 and 1.2796 AUD per USD on December 31, 2019, 2018 and 2017, respectively. Exchange rates were 1.2962, 1.3644 and 1.2519 CAD per USD on December 31, 2019, 2018, and 2017, 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, 2019. 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, 2019.

The Company's independent registered public accounting firm, Haynie & Company, has audited the Company's internal control over financial reporting as of December 31, 2019, 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, 2019, 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



## 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 balance sheets of Utah Medical Products, Inc. (the Company) as of December 31, 2019 and 2018, and the related statements of income, comprehensive income, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2019, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, 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, 2019, 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 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 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 \$40,845,000 and \$38,787,000 as of December 31, 2019 and 2018, respectively and total revenues of \$8,768,000 and \$11,286,000 for the years ended December 31, 2019 and 2018, respectively. 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 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 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 audits 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 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.

Haynie & Company  
Salt Lake City, Utah  
March 16, 2020

We have served as the Company's auditor since 2018

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 statements of income and comprehensive income of Utah Medical Products, Inc. December 31, 2017, and the related consolidated statements of stockholders' equity, and cash flows for the year 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 audit and the report of the other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the results of Utah Medical Products, Inc.'s operations and cash flows for the 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 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 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 total revenues of \$11,371,000 for the year 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audit 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 audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### **Definition and Limitations of Internal Control over Financial Reporting**

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

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



JONES SIMKINS LLC

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

Logan, Utah

March 5, 2018

## 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, 2019 and 2018, 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, 2019. We also have audited the Company's internal control over financial reporting as of December 31, 2019, 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, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018 and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, 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, 2019, based on criteria established in *Internal Control—Integrated Framework (1992)* 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.

We have served as the Company's auditor since 2011.

Reading, United Kingdom

March 10, 2020

UTAH MEDICAL PRODUCTS, INC.  
CONSOLIDATED BALANCE SHEETS  
December 31, 2019 and 2018  
(In thousands)

<u>ASSETS</u>	<u>2019</u>	<u>2018</u>
Current assets:		
Cash	\$ 42,787	\$ 51,112
Accounts and other receivables, net (note 2)	4,742	3,956
Inventories (note 2)	6,913	5,412
Prepaid expenses and other current assets	444	423
Total current assets	54,886	60,903
Property and equipment, net (notes 4 and 10)	10,728	10,359
Goodwill	13,961	13,703
Other intangible assets (note 2)	55,205	32,979
Other intangible assets - accumulated amortization	(24,993)	(18,176)
Other intangible assets - net (note 2)	30,212	14,803
Total assets	<u>\$ 109,787</u>	<u>\$ 99,768</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current liabilities:		
Accounts payable	\$ 1,098	\$ 975
Accrued expenses (note 2)	2,350	4,285
Total current liabilities	3,448	5,260
Long term lease liability	376	-
Long term income tax payable (REPAT tax) (note 7)	2,110	2,441
Deferred tax liability - intangible assets	2,239	2,540
Deferred income taxes (note 7)	521	535
Total liabilities	8,694	10,776
Commitments and contingencies (notes 6 and 12)	-	-
Stockholders' equity:		
Preferred stock, \$.01 par value; 5,000 shares authorized, no shares issued and outstanding	-	-
Common stock, \$.01 par value; 50,000 shares authorized, issued 3,722 shares in 2019 and 3,720 shares in 2018	37	37
Accumulated other comprehensive loss	(9,782)	(11,290)
Additional paid-in capital	18	122
Retained earnings	110,820	100,123
Total stockholders' equity	101,093	88,992
Total liabilities and stockholders' equity	<u>\$ 109,787</u>	<u>\$ 99,768</u>

See accompanying notes to financial statements.

UTAH MEDICAL PRODUCTS, INC.  
CONSOLIDATED STATEMENTS OF INCOME  
AND COMPREHENSIVE INCOME  
Years ended December 31, 2019, 2018 and 2017  
(In thousands, except per share amounts)

	2019	2018	2017
Sales, net (notes 1, 3, 9 and 11)	\$ 46,904	\$ 41,998	\$ 41,414
Cost of goods sold	17,438	15,692	15,019
Gross profit	29,466	26,306	26,395
Operating expense:			
Sales and marketing	1,738	1,708	1,544
Research and development	483	454	447
General and administrative	9,613	5,447	5,393
Operating income	17,632	18,697	19,011
Other income (expense):			
Dividend and interest income	254	217	17
Gains and (losses) on investments	-	32	-
Royalty income (note 12)	6	76	86
Other, net	(8)	437	(32)
Income before provision for income taxes	17,884	19,459	19,082
Provision for income taxes (note 7)	3,157	904	10,577
Net income	\$ 14,727	\$ 18,555	\$ 8,505
Earnings per common share (basic) (note 1):	\$ 3.96	\$ 4.97	\$ 2.29
Earnings per common share (diluted) (note 1):	\$ 3.94	\$ 4.95	\$ 2.28
Other comprehensive income (loss):			
Foreign currency translation net of taxes of \$0 in all periods	\$ 1,507	\$ (2,949)	\$ 3,893
Unrealized gain on investments net of taxes of \$0, \$0 and \$6	-	-	10
Total comprehensive income	\$ 16,234	\$ 15,606	\$ 12,408

See accompanying notes to financial statements.



UTAH MEDICAL PRODUCTS, INC.  
CONSOLIDATED STATEMENTS OF CASH FLOW  
Years Ended December 31, 2019, 2018 and 2017  
(In thousands)

	2019	2018	2017
<b>Cash flows from operating activities:</b>			
Net income	\$ 14,727	\$ 18,555	\$ 8,505
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	700	765	660
Amortization	6,144	2,191	2,113
Gain on investments	-	(32)	-
Provision for losses on accounts receivable	14	20	4
Amortization of operating lease assets	38	-	-
Loss/(Gain) on disposal of assets	16	(410)	17
Deferred income taxes	(396)	(326)	(658)
Stock-based compensation expense	113	64	129
Tax benefit attributable to exercise of stock options	23	49	-
(Increase) decrease in:			
Accounts receivable	(738)	(496)	(242)
Other receivables	(16)	-	2
Inventories	(1,686)	(244)	(467)
Prepaid expenses and other current assets	(16)	(68)	24
Increase (decrease) in:			
Accounts payable	114	52	9
Accrued expenses	(1,651)	(558)	1,027
Long-term repatriation tax payable	(330)	(2,728)	5,785
Net cash provided by operating activities	<u>17,056</u>	<u>16,834</u>	<u>16,908</u>
<b>Cash flows from investing activities:</b>			
Capital expenditures for:			
Property and equipment	(540)	(402)	(1,597)
Intangible assets	(21,000)	-	-
Proceeds from the sale of investments	-	74	-
Proceeds from the sale of property and equipment	-	862	-
Net cash provided by (used in) investing activities	<u>(21,540)</u>	<u>534</u>	<u>(1,597)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock - options	283	454	302
Common stock purchased and retired	(398)	(1,205)	-
Dividends paid	(4,112)	(4,026)	(2,955)
Net cash (used in) financing activities	<u>(4,227)</u>	<u>(4,777)</u>	<u>(2,653)</u>
Effect of exchange rate changes on cash	<u>386</u>	<u>(1,354)</u>	<u>921</u>
Net increase in cash and cash equivalents	(8,325)	11,237	13,579
Cash at beginning of year	<u>51,112</u>	<u>39,875</u>	<u>26,296</u>
Cash at end of year	<u>\$ 42,787</u>	<u>\$ 51,112</u>	<u>\$ 39,875</u>
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:</b>			
Cash paid during the year for:			
Income taxes	\$ 5,304	\$ 4,851	\$ 5,151
Interest	-	-	-

See accompanying notes to financial statements.

UTAH MEDICAL PRODUCTS, INC.  
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY  
Years Ended December 31, 2019, 2018 and 2017  
(In thousands)

	Common Stock		Additional	Accumulated		Total
	Shares	Amount	Paid-in	Other	Retained	Stockholders'
			Capital	Comprehensive	Earnings	Equity
				Income		
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	-	327	-	-	327
Shares received and retired upon exercise of stock options	-	-	(25)	-	-	(25)
Stock option compensation expense	-	-	129	-	-	129
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	3,722	\$ 37	\$ 809	\$ (8,341)	\$ 85,617	\$ 78,122
Shares issued upon exercise of employee stock options for cash	16	-	679	-	-	679
Shares received and retired upon exercise of stock options	(2)	-	(225)	-	-	(225)
Stock option compensation expense	-	-	64	-	-	64
Common stock purchased and retired	(15)	-	(1,205)	-	-	(1,205)
Foreign currency translation adjustment	-	-	-	(2,949)	-	(2,949)
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
Shares issued upon exercise of employee stock options for cash	7	-	290	-	-	290
Shares received and retired upon exercise of stock options	-	-	(7)	-	-	(7)
Stock option compensation expense	-	-	113	-	-	113
Common stock purchased and retired	(5)	-	(499)	-	101	(398)
Foreign currency translation adjustment	-	-	-	1,507	-	1,507
Common stock dividends	-	-	-	-	(4,132)	(4,132)
Net income	-	-	-	-	14,727	14,727
Balance at December 31, 2019	3,722	\$ 37	\$ 18	\$ (9,782)	\$ 110,820	\$ 101,093

See accompanying notes to financial statements.

Utah Medical Products, Inc.  
Notes to Consolidated Financial Statements  
Years Ended December 31, 2019, 2018 and 2017

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, 2019 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, 2019 except under an extreme global financial crisis.

Utah Medical Products, Inc.  
Notes to Consolidated Financial Statements  
Years Ended December 31, 2019, 2018 and 2017

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

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 (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, 2019, using the 2019 year-end 1.3268 USD/GBP and .7030 USD/AUD currency exchange rates, is about \$6,550 in 2020, \$6,543 in 2021, \$6,542 in 2022, \$5,805 in 2023, and \$2,121 in 2024 (see note 2).

In 2019, \$21,000 in intangible assets were acquired from CSI. The future amortization expenses on those assets are estimated to be \$4,421 per year in 2020-2022, and \$3,684 in 2023 (see note 15).

Utah Medical Products, Inc.  
Notes to Consolidated Financial Statements  
Years Ended December 31, 2019, 2018 and 2017

Note 1 – Summary of Significant Accounting Policies (continued)

Stock-Based Compensation

At December 31, 2019, the Company has stock-based employee compensation plans, which are described more fully in note 8. 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 2019, the Company recognized \$113 in stock-based compensation cost compared to \$64 in 2018 and \$129 in 2017.

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.

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. During the fourth quarter of 2019, after consultation with specialists in Utah most knowledgeable of Utah State Tax Commission rules, UTMD's estimate of the State portion of the REPAT tax was reduced by \$403. The Company recognized a net benefit of \$266 from its adjustment to the provisional amount recorded for the REPAT tax at December 31, 2017 because the reduced deductibility of the State REPAT tax increased the Federal REPAT tax estimate by \$137. The net \$266 benefit was included in 4Q 2019 as a component of income tax expense from continuing operations.

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 expense 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 2017 through 2019.

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, 2019 and 2018 was \$113 and \$149, 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:

	2019	2018	2017
Weighted average number of shares outstanding – basic	3,721	3,730	3,718
Dilutive effect of stock options	18	18	19
Weighted average number of shares outstanding, assuming dilution	<u>3,739</u>	<u>3,748</u>	<u>3,737</u>

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 2019 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, 2019, 2018 and 2017

Note 2 – Detail of Certain Balance Sheet Accounts

	2019	2018
Accounts and other receivables:		
Accounts receivable	\$ 4,835	\$ 4,064
Accrued interest and other	43	13
Less allowance for doubtful accounts	(136)	(121)
Total accounts and other receivables	<u>\$ 4,742</u>	<u>\$ 3,956</u>
Inventories:		
Finished products	\$ 1,708	\$ 1,615
Work-in-process	1,022	1,103
Raw materials	4,183	2,694
Total inventories	<u>\$ 6,913</u>	<u>\$ 5,412</u>
Goodwill:		
Balance before effect of foreign exchange	\$ 13,703	\$ 14,092
Effect of foreign exchange	258	(389)
Subtractions as a result of impairment	-	-
Total Goodwill	<u>\$ 13,961</u>	<u>\$ 13,703</u>
Other Identifiable Intangible Assets:		
Patents	\$ 2,194	\$ 2,136
Non-compete agreements	133	128
Trademarks & trade names	9,738	9,375
Customer relationships	9,486	9,123
Distribution agreements	21,000	-
Regulatory approvals & product certifications	12,654	12,217
Total Other Identifiable Intangible Assets	55,205	32,979
Accumulated amortization	(24,993)	(18,176)
Other Identifiable Intangible Assets, Net	<u>\$ 30,212</u>	<u>\$ 14,803</u>
Accrued expenses:		
Income taxes payable (receivable)	\$ (513)	\$ 845
Payroll and payroll taxes	1,032	1,099
Reserve for litigation costs	113	149
Other	1,718	2,192
Total accrued expenses	<u>\$ 2,350</u>	<u>\$ 4,285</u>

Note 3 – Quarterly Results of Operations (Unaudited)

	Unaudited Quarterly Data for 2019			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net Sales	\$ 10,732	\$ 11,846	\$ 12,494	\$ 11,831
Gross Profit	6,773	7,500	7,379	7,814
Net Income	3,139	3,525	3,705	4,359
Earnings Per Common Share (Diluted)	.84	.94	.99	1.17

	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	4,092	4,308	6,762	3,393
Earnings Per Common Share (Diluted)	1.09	1.15	1.80	.91

Utah Medical Products, Inc.  
Notes to Consolidated Financial Statements  
Years Ended December 31, 2019, 2018 and 2017

Note 3 – Quarterly Results of Operations (Unaudited) (continued)

	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)

Note 4 – Property and Equipment

Property and equipment consists of the following:

	December 31,	
	2019	2018
Land	\$ 1,671	\$ 1,653
Buildings and improvements	13,887	13,752
Furniture, equipment and tooling	16,254	16,003
Right of Use Asset	414	-
Construction-in-progress	372	141
Total	32,598	31,549
Accumulated depreciation	(21,870)	(21,190)
Property and equipment, net	<u>\$ 10,728</u>	<u>\$ 10,359</u>

Included in the Company's consolidated balance sheet are the assets of its manufacturing and administrative facilities in Utah, Canada, England, Australia and Ireland. Property and equipment, by geographic area, are as follows:

	December 31, 2019			
	U.S. & Canada	England & Australia	Ireland	Total
Land	\$ 621	\$ 664	\$ 386	\$ 1,671
Buildings and improvements	6,385	3,311	4,191	13,887
Furniture, equipment and tooling	14,316	793	1,145	16,254
Right of Use Asset	385	-	29	414
Construction-in-progress	205	-	167	372
Total	21,912	4,768	5,918	32,598
Accumulated depreciation	(17,808)	(784)	(3,278)	(21,870)
Property and equipment, net	<u>\$ 4,104</u>	<u>\$ 3,984</u>	<u>\$ 2,640</u>	<u>\$ 10,728</u>

	December 31, 2018			
	U.S. & Canada	England & Australia	Ireland	Total
Land	\$ 621	\$ 639	\$ 393	\$ 1,653
Buildings and improvements	6,348	3,205	4,199	13,752
Furniture, equipment and tooling	14,104	765	1,134	16,003
Construction-in-progress	141	-	-	141
Total	21,214	4,609	5,726	31,549
Accumulated depreciation	(17,475)	(531)	(3,184)	(21,190)
Property and equipment, net	<u>\$ 3,739</u>	<u>\$ 4,078</u>	<u>\$ 2,542</u>	<u>\$ 10,359</u>



Note 5 – Long-term Debt

None in 2018 and 2019.

Note 6 – Commitments and Contingencies

Purchase Obligations

The Company has obligations to purchase raw materials for use in its manufacturing operations. The Company has the right to make changes in, among other things, purchase quantities, delivery schedules and order acceptance.

Product Liability

The Company is self-insured for product liability risk. “Product liability” is an insurance industry term for the cost of legal defense and possible damages awarded as a result of use of a company’s product during a procedure which results in an injury of a patient. The Company maintains a reserve for product liability litigation and damages consistent with its previous long-term experience. Actual product liability litigation costs and damages during the last three reporting years have been immaterial, which is consistent with the Company’s overall history.

The Company absorbs the costs of clinical training and trouble-shooting in its on-going operating expenses.

Warranty Reserve

The Company’s published warranty is: “UTMD warrants its products to conform in all material respects to all published product specifications in effect on the date of shipment, and to be free from defects in material and workmanship for a period of thirty (30) days for supplies, or twenty-four (24) months for equipment, from date of shipment. During the warranty period UTMD shall, at its option, replace any products shown to UTMD's reasonable satisfaction to be defective at no expense to the Purchaser or refund the purchase price.”

UTMD maintains a warranty reserve to provide for estimated costs which are likely to occur. The amount of this reserve is adjusted, as required, to reflect its actual experience. Based on its analysis of historical warranty claims and its estimate that existing warranty obligations are immaterial, no warranty reserve was made at December 31, 2019 or December 31, 2018.

Litigation

The Company has been involved in lawsuits which are an expected consequence of its operations and in the ordinary course of business. Presently, there is no litigation or threatened litigation for which the Company believes the outcome may be material to its financial results. The Company applies its accounting policy to accrue legal costs that can be reasonably estimated.

Utah Medical Products, Inc.  
Notes to Consolidated Financial Statements  
Years Ended December 31, 2019, 2018 and 2017

Note 7 – Income Taxes

Deferred tax assets (liabilities) consist of the following temporary differences:

	December 31,		
	2019	2018	2017
Inventory write-downs and differences due to UNICAP	\$ 84	\$ 60	\$ 56
Allowance for doubtful accounts	33	18	16
Accrued liabilities and reserves	55	62	89
Other - foreign	-	-	4
Depreciation and amortization	(2,933)	(3,216)	(3,789)
Unrealized investment gains	-	-	66
Deferred income taxes, net	<u>\$ (2,761)</u>	<u>\$ (3,076)</u>	<u>\$ (3,558)</u>

The components of income tax expense are as follows:

	Years ended December 31,		
	2019	2018	2017
Current	\$ 3,467	\$ 1,386	\$ 10,944
Deferred	(310)	(482)	(367)
Total	<u>\$ 3,157</u>	<u>\$ 904</u>	<u>\$ 10,577</u>

Income tax expense differed from amounts computed by applying the statutory federal rate to pretax income as follows:

	Years ended December 31,		
	2019	2018	2017
			\$
Federal income tax expense at the statutory rate	\$ 2,512	\$ 2,127	\$ 3,086
State income taxes	(124)	365	299
Foreign income taxes (blended rate)	985	1,607	1,444
R&D tax credits and manufacturing profit deduction	(9)	(146)	(303)
Deemed repatriation transition tax	(266)	(3,230)	6,288
Effective federal rate change	-	-	(230)
US Taxes on foreign income	59	179	-
Other	-	2	(7)
Total	<u>\$ 3,157</u>	<u>\$ 904</u>	<u>\$ 10,577</u>

The domestic and foreign components of income before income tax expense were as follows:

	Years ended December 31,		
	2019	2018	2017
Domestic	\$ 11,549	\$ 10,130	\$ 9,124
Foreign	6,335	9,329	9,958
Total	<u>\$ 17,884</u>	<u>\$ 19,459</u>	<u>\$ 19,082</u>

Utah Medical Products, Inc.  
Notes to Consolidated Financial Statements  
Years Ended December 31, 2019, 2018 and 2017

**Note 8 – Options**

The Company has stock option plans which authorize the grant of stock options to eligible employees, directors and other individuals to purchase up to an aggregate of 307 thousand shares of common stock, of which 52 thousand are outstanding as of December 31, 2019. All options granted under the plans are granted at current market value at the date of grant, and may be exercised between six months and ten years following the date of grant. The plans are intended to advance the interest of the Company by attracting and ensuring retention of competent directors, employees and executive personnel, and to provide incentives to those individuals to devote their utmost efforts to the advancement of stockholder value. Changes in stock options were as follows:

	Shares (000's)	Price Range Per Share
<b>2019</b>		
Granted	-	\$ - \$ -
Expired or canceled	2	58.50 74.64
Exercised	7	24.00 58.50
Total outstanding at December 31	52	26.52 74.64
Total exercisable at December 31	33	26.52 74.64
<b>2018</b>		
Granted	22	\$ 74.76 \$ 74.76
Expired or canceled	-	- -
Exercised	16	24.00 58.50
Total outstanding at December 31	61	24.00 74.64
Total exercisable at December 31	31	24.00 58.50
<b>2017</b>		
Granted	-	\$ - \$ -
Expired or canceled	12	49.18 58.50
Exercised	9	24.00 49.18
Total outstanding at December 31	54	24.00 58.50
Total exercisable at December 31	39	24.00 58.50

For the years ended December 31, 2019, 2018 and 2017, the Company reduced current income taxes payable by \$23, \$49 and \$38, respectively, for the income tax benefit attributable to sale by optionees of common stock received upon the exercise of stock options.

**Stock-Based Compensation**

In 2019, the Company recognized \$113 in equity compensation cost, compared to \$64 in 2018 and \$129 in 2017.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	Years ended December 31,		
	2019	2018	2017
Expected dividend amount per quarter	\$ -	\$ .2875	\$ -
Expected stock price volatility	-	27.5%	-
Risk-free interest rate	-	2.57%	-
Expected life of options	-	4.9 years	-

The per share weighted average fair value of options granted during 2018 is \$15.77. No options were granted in 2017 or 2019.

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Note 8 – Options (continued)

All UTMD options vest over a four-year service period. At December 31, 2019 there was \$241 total unrecognized compensation expense related to non-vested stock options under the plans. A \$33 portion of the cost is expected to be recognized over the next nine months, and the remaining \$208 recognized over the next 3 years. Expected dividend amounts were estimated based on the actual cash dividend rate at the time the options were granted and an estimate of future dividends based on past dividend rate changes as well as management's expectations of future dividend rates over the expected holding period of the options. Expected volatility is based on UTMD's historical volatility over recent periods of time and trends in that volatility, giving weight to more recent periods. Risk free interest rates were estimated based on actual U.S. Treasury Securities Interest rates as reported by the Federal Reserve Bank for periods of time equivalent to the holding periods estimated for the options on the dates the options were granted. Expected term of options were estimated based on historical holding periods for similar options previously granted by UTMD to employees and directors.

The following table summarizes information about stock options outstanding at December 31, 2019:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Actual Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$ 26.52 - 49.18	18,560	3.25	\$ 40.18	18,560	\$ 40.18	
50.72 - 74.64	33,129	8.21	68.77	13,554	64.75	
<u>\$ 26.52 - 74.64</u>	<u>51,689</u>	<u>6.42</u>	<u>\$ 58.50</u>	<u>32,114</u>	<u>\$ 50.55</u>	
			2019	2018	2017	
Intrinsic Value of Stock Options Exercised			\$ 354	\$ 812	\$ 270	
Intrinsic Value of Stock Options Outstanding			2,553	1,605	1,951	

Note 9 – Geographic Information

The Company had sales in the following geographic areas based on the customer's country of domicile:

	2019	2018	2017
United States	\$ 27,493	\$ 21,192	\$ 20,286
Europe	8,906	9,160	8,519
Other	10,505	11,646	12,609

Note 10 – Long-lived Assets by Geographic Area

The Company's long-lived assets by geographic area were as follows:

	2019	2018	2017
United States	\$ 27,605	\$ 10,309	\$ 10,866
England	23,548	24,892	28,604
Ireland	2,639	2,543	2,803
Australia	423	447	525
Canada	686	676	759

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Note 11 – Revenues by Product Category and Geographic Region

Global revenues by product category:

	2019	2018	2017
Obstetrics	\$ 5,000	\$ 4,447	\$ 4,499
Gynecology/ Electrosurgery/ Urology	25,354	23,167	23,175
Neonatal	6,066	6,436	6,154
Blood Pressure Monitoring and Accessories	10,484	7,948	7,586
Total:	<u>\$ 46,904</u>	<u>\$ 41,998</u>	<u>\$ 41,414</u>

Included in the Global revenues (above) were OUS revenues by product category:

	2019	2018	2017
Obstetrics	\$ 947	\$ 698	\$ 732
Gynecology/ Electrosurgery/ Urology	13,731	15,022	14,759
Neonatal	1,412	2,252	2,105
Blood Pressure Monitoring and Accessories	3,321	2,834	3,533
Total:	<u>\$ 19,411</u>	<u>\$ 20,806</u>	<u>\$ 21,129</u>

Note 12 - Product Sale and Purchase Commitments

The Company has had license agreements for the rights to develop and market certain products or technologies owned by unrelated parties. The confidential terms of such agreements are unique and varied, depending on many factors relating to the value and stage of development of the technology licensed. Royalties on future product sales are a normal component of such agreements and are included in the Company's cost of goods sold on an ongoing basis.

In 2019, 2018 and 2017, UTMD received royalties of \$6, \$76 and \$86, respectively, for the use of intellectual property of Filshie Clip System as part of Femcare's exclusive U.S. distribution agreement with CSI.

UTMD had \$3,058 in operating lease and purchase commitments as of December 31, 2019.

Note 13 – Employee Benefit Plans

The Company sponsors a contributory 401(k) savings plan for U.S. employees, and contributory retirement plans for Ireland, UK, Australia and Canada employees. The Company's matching contribution is determined annually by the board of directors. Company contributions were approximately \$171, \$160 and \$153 for the years ended December 31, 2019, 2018 and 2017, respectively.

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Note 14 – Leases

UTMD has operating leases for a portion of its parking lot at its Midvale facility and an automobile at its Ireland facility. The remaining lease term on the parking lot is 12 years and on the automobile is 24 months. There are no options to extend or terminate the leases. UTMD has no other leases yet to commence. As neither lease contains implicit rates, UTMD's incremental borrowing rate, based on information available at adoption date, was used to determine the present value of the leases.

The components of lease cost were as follows:

	As of December 31, 2019
Operating Lease Cost ( <i>in thousands</i> )	\$ 60
Right of Use Assets obtained in exchange for new operating lease obligations	\$ 42

Other information

	As of December 31, 2019
Weighted Average Remaining Lease Term - Operating Leases	12 years
Weighted Average Discount Rate – Operating Leases	5.4%

Operating lease liabilities/ payments (*in thousands*)

Operating lease payments, 2020	\$ 60
Operating lease payments, 2021	\$ 60
Operating lease payments, 2022	\$ 45
Operating lease payments, 2023	\$ 45
Operating lease payments, 2024	\$ 45
Thereafter	\$ 299

Reconciliation of operating lease liabilities/ payments to operating lease liabilities (*in thousands*)

Total operating lease liabilities/ payments	\$ 554
Operating lease liabilities – current (included in Accrued Expenses)	38
Operating lease liabilities – long term	376
Present value adjustment	\$ 140

Maturities of lease liabilities were as follows (*in thousands*):

Year ending December 31,	
2020	\$ 38
2021	\$ 40
2022	\$ 27
2023	\$ 29
2024	\$ 29
Thereafter	\$ 251

Note 15 - Distribution Agreement Purchase

UTMD completed the purchase of exclusive U.S. distribution rights for the FILSHIE Clip System from CooperSurgical, Inc. (CSI) on February 1, 2019, after which CSI will no longer sell the FILSHIE Clip System and UTMD will distribute the FILSHIE Clip System directly to clinical facilities in the U.S. The \$21,000 purchase price represents an identifiable intangible asset which will be straight-line amortized and recognized as part of G&A expenses over the 4.75 year remaining life of the prior CSI distribution agreement with Femcare. As part of the agreement, UTMD also purchased the remaining CSI inventory for approximately \$2,100.

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Note 16 - Earnings Per Share

Basic earnings per share is calculated by dividing net income attributable to the common stockholders of the company by the weighted average number of common shares outstanding during the period. Diluted earnings per share is calculated by assuming the exercise of stock options at the closing price of stock at the end of 2019.

The following table reconciles the numerator and the denominator used to calculate basic and diluted earnings per share:

	2019	2018	2017
<b>Numerator</b> <i>(in thousands)</i>			
Net income	14,727	18,555	8,505
<b>Denominator</b>			
Weighted average shares, basic	3,721	3,730	3,718
Dilutive effect of stock options	18	18	19
Diluted shares	3,739	3,748	3,737
Earnings per share, basic	3.96	4.97	2.29
Earnings per share, diluted	3.94	4.95	2.28

Note 17 – Recent Accounting Pronouncements

In March 2016, new accounting guidance was issued to simplify several aspects of accounting for employee share-based payment (including stock option) transactions, including the accounting for income taxes, forfeitures and statutory tax withholding requirements, as well as classification in the statement of cash flows. Under the guidance, entities recognize all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement. UTMD adopted this standard on January 1, 2017, which had an insignificant impact on its consolidated financial statements. UTMD made a determination to continue to account for forfeitures by estimating the number of awards that are expected to vest. Because UTMD primarily issues incentive stock options, excess tax benefits and tax deficiencies have historically been minimal.

In May 2014, new accounting guidance (ASU 2014-09) was issued that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to fulfill a contract. UTMD adopted this new standard on January 1, 2018, using a modified retrospective approach. In accordance with ASU 2014-09, UTMD's revenue recognition is based on its contracts and the performance obligations identified in them. With very insignificant and limited exceptions, the Company's performance obligation is met when it ships a physical product to a customer's designated location. The basis on which UTMD recognizes revenue was updated on January 1, 2018, but it did not result in a change to the process and timing of revenue recognition, because the previous revenue recognition method complies with ASU 2014-09. Therefore, the adoption of ASU 2014-09 did not have an impact on UTMD's financial statements. In accordance with this adoption disaggregated revenue is presented in Note 11.

Note 17 – Recent Accounting Pronouncements (continued)

In February 2016, new accounting guidance (ASU 2016-02, Leases (Topic 842)) was issued which requires recording most leases on the balance sheet. The new lease standard requires disclosure of key information about lease arrangements and aligns many of the underlying principles of this new model with those in the new revenue recognition standard. This guidance is effective for annual reporting periods beginning after December 15, 2018, with early adoption permitted. The new guidance became effective for UTMD on January 1, 2019. UTMD applied the requirements using the modified retrospective method and so will not restate comparative financial statements. Implementation of the standard resulted in addition of right of use assets and lease liabilities of \$452 to the consolidated condensed balance sheet and will require additional disclosures but will have no effect on the income statement. UTMD's only leases are for a portion of the parking lot at the Midvale facility and an automobile in Ireland (see Note 14).

Note 18 – Subsequent Events

The Company evaluated its December 31, 2019 financial statements for subsequent events through the date the financial statements were issued. The Company is not aware of any subsequent events which would require recognition or disclosure in the financial statements.

**ITEM 9 – CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A – CONTROLS AND PROCEDURES**

Evaluation of Disclosure Controls and Procedures.

UTMD Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in the Securities Exchange Act of 1934 Rule 13a-15(e). UTMD's Board of Directors, operating through its Audit Committee, provides oversight to its financial reporting process.

During 2019, UTMD evaluated the effectiveness of the design and operation of its disclosure controls and procedures. Based on that evaluation, UTMD's Chief Executive Officer and Principal Financial Officer concluded that, as of December 31, 2019, its disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, the Company has included, as part of this Form 10-K, a report of management's assessment of the effectiveness of its internal controls as of December 31, 2019. Haynie & Company, the independent registered public accounting firm of the Company, has audited the effectiveness of the Company's internal control over financial reporting. Nortons Assurance Limited, the independent registered public accounting firm of Femcare Group Limited (Femcare Group) has audited the effectiveness of Femcare Group's internal control over financial reporting. Management's report, and the reports of Haynie & Company and Nortons Assurance Limited appear on pages 37 through 42 of this Form 10-K under the captions "Management's Report on Internal Control Over Financial Reporting" and "Report of Independent Registered Public Accounting Firm" and are incorporated herein by reference.

Changes in Internal Control Over Financial Reporting.

There have been no changes in UTMD's internal control over financial reporting that materially affected, or were reasonably likely to materially affect, the Company's internal control over financial reporting during the fourth quarter of the fiscal year ended December 31, 2019, and there were no material weaknesses.

**ITEM 9B – OTHER INFORMATION**

None.



### **PART III**

#### **ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information from the definitive proxy statement of the registrant for the 2020 annual meeting of stockholders under the captions,

- “PROPOSAL NO. 1. ELECTION OF DIRECTORS: General,” and “Directors and Nominees,”
- “SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN PERSONS,” and
- “EXECUTIVE OFFICER COMPENSATION: 2019 Director Compensation,”

is incorporated herein by reference.

UTMD adopted a Code of Ethics for its executive officers, including the Chief Executive Officer and outside directors, in October 2003. The Code of Ethics, along with UTMD’s Code of Conduct, which covers all exempt employees (including all officers and outside directors) and certain non-exempt employees, is posted on UTMD’s web site at [www.utahmed.com](http://www.utahmed.com). UTMD intends to post on its website any waivers of or amendments to its Code of Ethics.

#### **ITEM 11 - EXECUTIVE COMPENSATION**

The information from the definitive proxy statement of the registrant for the 2020 annual meeting of stockholders under the captions,

- “EXECUTIVE OFFICER COMPENSATION,”
- COMPENSATION DISCUSSION AND ANALYSIS,” and
- BOARD OF DIRECTORS AND OTHER BOARD COMMITTEE REPORTS: Compensation and Option Committee Interlocks and Insider Participation,” specifically excluding the “Report of the Compensation Committee”

is incorporated herein by reference.

#### **ITEM 12 - SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information from the definitive proxy statement of the registrant for the 2020 annual meeting of stockholders under the captions,

- “SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN PERSONS” and
- “DISCLOSURE RESPECTING THE COMPANY’S EQUITY COMPENSATION PLANS”

is incorporated herein by reference.

#### **ITEM 13 - CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information from the definitive proxy statement of the registrant for the 2020 annual meeting of stockholders under the captions,

- “CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS”
- “BOARD OF DIRECTORS AND OTHER BOARD COMMITTEE REPORTS: Director Independence”

is incorporated herein by reference.

The information from the definitive proxy statement of the registrant for the 2020 annual meeting of stockholders in the first paragraph under the caption, “Report of the Audit Committee” is incorporated herein by reference.

#### **ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information from the definitive proxy statement of the registrant for the 2020 annual meeting of stockholders under the caption “PROPOSAL NO 2. RATIFICATION OF THE APPOINTMENT OF INDEPENDENT REGISTERED PUBLIC

ACCOUNTING FIRM: Fees billed by Haynie & Company,” “Audit Committee Policy and Approval,” and “Auditor Independence” are incorporated herein by reference.

## PART IV

### ITEM 15 – EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report or incorporated herein by reference.

1. Financial Statements.

(See Table of Contents to Item 8, above.)

2. Supplemental Schedule.

Financial Statement Schedules are omitted because they are inapplicable or the required information is otherwise included in the accompanying Financial Statements and the notes thereto.

3. Exhibits.

Exhibit #	SEC Reference #	Title of Document	Location
1	3	<a href="#">Articles of Restatement of the Articles of Incorporation</a>	Incorporated by Reference (1)
2	3	<a href="#">Articles of Correction to the Restated Articles of Incorporation</a>	Incorporated by Reference (1)
3	3	<a href="#">Bylaws</a>	Incorporated by Reference (2)
4	4	<a href="#">Rights Agreement dated as of July 30, 2004, between Utah Medical Products, Inc., and Registrar and Transfer Company</a>	Incorporated by Reference (4)
5	4	<a href="#">Extension of Shareholder Rights Agreement</a>	Incorporated by Reference (5)
6	4	Designation of Rights, Privileges, and Preferences of Series “A” Preferred Stock	Incorporated by Reference (3)
7	10	<a href="#">Employment Agreement dated December 21, 1992 with Kevin L. Cornwell*</a>	Incorporated by Reference (6)
8	10	<a href="#">Amendment, effective May 15, 1998, to Employment Agreement dated December 21, 1992 with Kevin L. Cornwell*</a>	Incorporated by Reference (6)
9	10	<a href="#">Utah Medical Products, Inc., 2003 Employees’ and Directors’ Incentive Plan*</a>	Incorporated by Reference (7)
10	10	<a href="#">Utah Medical Products, Inc., 2013 Employees’ and Directors’ Incentive Plan*</a>	Incorporated by Reference (8)
11	10	<a href="#">Summary of Officer and Director Compensation</a>	This filing
12	21	<a href="#">Subsidiaries of Utah Medical Products, Inc.</a>	This filing
13	23	<a href="#">Consent of Haynie &amp; Company, UTMD’s independent auditors for the year ended December 31, 2019</a>	This filing
14	23	<a href="#">Consent of Jones Simkins LLC, UTMD’s independent auditors for the year ended December 31, 2017.</a>	This filing
15	23	<a href="#">Consent of Nortons Assurance Limited, Femcare Group Limited’s independent auditors for the years ended December 31, 2019, December 31, 2018 and December 31, 2017</a>	This filing
16	31	<a href="#">Certification of CEO pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>	This Filing



Exhibit #	Reference #	Title of Document	Location
17	31	<a href="#"><u>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>	This Filing
18	32	<a href="#"><u>Certification of CEO pursuant to 18 U.S.C. §1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>	This Filing
19	32	<a href="#"><u>Certification of Principal Financial Officer pursuant to 18 U.S.C. §1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>	This Filing
101.ins		XBRL Instance Document	This Filing
101.xsd		XBRL Taxonomy Extension Schema Document	This Filing
101.cal		XBRL Taxonomy Extension Calculation Linkbase Document	This Filing
101.def		XBRL Taxonomy Extension Definition Linkbase Document	This Filing
101.tab		XBRL Taxonomy Extension Label Linkbase Document	This Filing
101.pre		XBRL Taxonomy Extension Presentation Linkbase Document	This Filing

\* Management contract of compensatory plan or arrangement required to be filed pursuant to Item 14(c).

- (1) Incorporated by reference from the Company's annual report on form 10-K filed with the Commission for the year ended December 31, 2004.
- (2) Incorporated by reference from the Company's report on form 8-K filed with the Commission on February 13, 2014.
- (3) Incorporated by reference from the Company's registration statement on form S-8 filed with the Commission effective February 10, 1995.
- (4) Incorporated by reference from the Company's report on form 8-K filed with the Commission on October 1, 2004.
- (5) Incorporated by reference from the Company's report on form 8-K filed with the Commission on October 24, 2014.
- (6) Incorporated by reference from the Company's annual report on form 10-K filed with the Commission for the year ended December 31, 2003.
- (7) Incorporated by reference from the Company's 2003 definitive proxy statement on form DEF 14A filed with the Commission on March 27, 2003.
- (8) Incorporated by reference from the Company's 2013 definitive proxy statement on form DEF 14A filed with the Commission on March 7, 2013.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned this 13th day of March, 2020.

UTAH MEDICAL PRODUCTS, INC.

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on this 13th day of March, 2020.

By: /s/ James H. Beeson  
James H. Beeson, Director

By: /s/ Kevin L. Cornwell  
Kevin L. Cornwell, Director

By: /s/ Ernst G. Hoyer  
Ernst G. Hoyer, Director

By: /s/ Barbara A. Payne  
Barbara A. Payne, Director

By: /s/ Paul O. Richins  
Paul O. Richins, Director